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## Information and Notices

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### Contents

#### EUROPEAN PARLIAMENT

2013-2014 SESSION

Sittings of 21 to 24 October 2013

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TEXTS ADOPTED

#### I Resolutions, recommendations and opinions

##### RESOLUTIONS

##### European Parliament

##### Tuesday 22 October 2013

2016/C 208/01	European Parliament resolution of 22 October 2013 on the situation of human rights in the Sahel region (2013/2020(INI)) . . . . .	2
2016/C 208/02	European Parliament resolution of 22 October 2013 on local authorities and civil society: Europe's engagement in support of sustainable development (2012/2288(INI)) . . . . .	25
2016/C 208/03	European Parliament resolution of 22 October 2013 on Rethinking Education (2013/2041(INI)) . . .	32
2016/C 208/04	European Parliament resolution of 22 October 2013 on budgetary management of European Union pre-accession funds in the areas of judicial systems and the fight against corruption in the candidate and potential candidate countries (2011/2033(INI)) . . . . .	43
2016/C 208/05	European Parliament resolution of 22 October 2013 on the report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare- associated infections (2013/2022(INI)) . . . . .	55
2016/C 208/06	European Parliament resolution of 22 October 2013 on misleading advertisement practices (2013/2122 (INI)) . . . . .	67

EN

### **Wednesday 23 October 2013**

2016/C 208/07	European Parliament resolution of 23 October 2013 on marine knowledge 2020: 'Seabed mapping for promoting sustainable fisheries' (2013/2101(INI)) . . . . .	71
2016/C 208/08	European Parliament resolution of 23 October 2013 on the climate change conference in Warsaw, Poland (COP 19) (2013/2666(RSP)) . . . . .	78
2016/C 208/09	European Parliament resolution of 23 October 2013 on organised crime, corruption and money laundering: recommendations on action and initiatives to be taken (final report) (2013/2107(INI)) . .	89
2016/C 208/10	European Parliament resolution of 23 October 2013 on the e-Justice Action Plan 2014-2018 (2013/2852(RSP)) . . . . .	117
2016/C 208/11	European Parliament resolution of 23 October 2013 on the European Neighbourhood Policy: towards a strengthening of the partnership. Position of the European Parliament on the 2012 reports (2013/2621(RSP)) . . . . .	119
2016/C 208/12	European Parliament resolution of 23 October 2013 on the European Semester for economic policy coordination: implementation of 2013 priorities (2013/2134(INI)) . . . . .	137
2016/C 208/13	European Parliament resolution of 23 October 2013 on migratory flows in the Mediterranean, with particular attention to the tragic events off Lampedusa (2013/2827(RSP)) . . . . .	148
2016/C 208/14	European Parliament resolution of 23 October 2013 on the suspension of the TFTP agreement as a result of US National Security Agency surveillance (2013/2831(RSP)) . . . . .	153

### **Thursday 24 October 2013**

2016/C 208/15	European Parliament resolution of 24 October 2013 on the Annual Report from the Council to the European Parliament on the Common Foreign and Security Policy (2013/2081(INI)) . . . . .	157
2016/C 208/16	European Parliament resolution of 24 October 2013 on Implementation report on the regulatory framework for electronic communications (2013/2080(INI)) . . . . .	170

---

## **III Preparatory acts**

### **EUROPEAN PARLIAMENT**

#### **Tuesday 22 October 2013**

2016/C 208/17	P7_TA(2013)0425 Tariff quotas for wine ***I  European Parliament legislative resolution of 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on amending Council Regulation (EC) No 1215/2009 in relation to tariff quotas for wine (COM(2013)0187 — C7-0090/2013 — 2013/0099(COD))  P7_TC1-COD(2013)0099  Position of the European Parliament adopted at first reading on 22 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council amending Council Regulation (EC) No 1215/2009 in relation to tariff quotas for wine . . . . .	176
2016/C 208/18	European Parliament legislative resolution of 22 October 2013 on the Council position at first reading with a view to the adoption of a decision of the European Parliament and of the Council providing macro-financial assistance to the Kyrgyz Republic (11703/1/2013 — C7-0314/2013 — 2011/0458(COD)) . . . . .	177

2016/C 208/19	Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012)0541 — C7-0317/2012 — 2012/0267(COD)) . . . . .	178
2016/C 208/20	Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 — C7-0318/2012 — 2012/0266(COD)) . . . . .	310
2016/C 208/21	P7_TA(2013)0429  Ship recycling ***I  European Parliament legislative resolution of 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on ship recycling (COM(2012)0118 — C7-0082/2012 — 2012/0055(COD))  P7_TC1-COD(2012)0055  Position of the European Parliament adopted at first reading on 22 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC . . . . .	474
2016/C 208/22	P7_TA(2013)0430  European statistics on demography ***I  European Parliament legislative resolution of 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on European statistics on demography (COM(2011)0903 — C7-0518/2011 — 2011/0440(COD))  P7_TC1-COD(2011)0440  Position of the European Parliament adopted at first reading on 22 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council on European demographic statistics . . . . .	475
<b>Wednesday 23 October 2013</b>		
2016/C 208/23	European Parliament resolution of 23 October 2013 on the Council position on the draft general budget of the European Union for the financial year 2014 (13176/2013 — C7-0260/2013 — 2013/2145 (BUD)) . . . . .	476
2016/C 208/24	Amendments adopted by the European Parliament on 23 October 2013 on the proposal for a regulation of the European Parliament and of the Council concerning the exercise of the Union's rights for the application and enforcement of international trade rules (COM(2012)0773 — C7-0415/2012 — 2012/0359(COD)) . . . . .	493
2016/C 208/25	P7_TA(2013)0440  Trade between the Community and third countries in drug precursors ***I  European Parliament legislative resolution of 23 October 2013 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (COM(2012)0521 — C7-0316/2012 — 2012/0250(COD))  P7_TC1-COD(2012)0250  Position of the European Parliament adopted at first reading on 23 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors . . . . .	505

2016/C 208/26	Amendments adopted by the European Parliament on 23 October 2013 on the amended proposal for a regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund repealing Council Regulation (EC) No 1198/2006 and Council Regulation (EC) No 861/2006 and Council Regulation No XXX/2011 on integrated maritime policy (COM(2013)0245 — C7-0108/2013 — 2011/0380(COD)) . . . . .	506
2016/C 208/27	P7_TA(2013)0442  Drug precursors ***I  European Parliament legislative resolution of 23 October 2013 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors (COM(2012)0548 — C7-0319/2012 — 2012/0261(COD))  P7_TC1-COD(2012)0261  Position of the European Parliament adopted at first reading on 23 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors . . . . .	693
<b>Thursday 24 October 2013</b>		
2016/C 208/28	European Parliament resolution of 24 October 2013 on the Council position on Draft amending budget No 6/2013 of the European Union for the financial year 2013, Section III — Commission (14870/2013 — C7-0378/2013 — 2013/2151(BUD)) . . . . .	694
2016/C 208/29	P7_TA(2013)0451  General Union Environment Action Programme to 2020 ***I  European Parliament legislative resolution of 24 October 2013 on the proposal for a decision of the European Parliament and of the Council on a General Union Environment Action Programme to 2020: 'Living well, within the limits of our planet' (COM(2012)0710 — C7-0392/2012 — 2012/0337(COD))  P7_TC1-COD(2012)0337  Position of the European Parliament adopted at first reading on 24 October 2013 with a view to the adoption of Decision No .../2013/EU of the European Parliament and of the Council on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' . . . . .	696
2016/C 208/30	FP7_TA(2013)0452  Dangers arising from exposure to ionising radiation ***I  European Parliament legislative resolution of 24 October 2013 on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (COM(2012)0242 — C7-0151/2012 — 2011/0254(COD))  P7_TC1-COD(2011)0254  Position of the European Parliament adopted at first reading on 24 October 2013 with a view to the adoption of Directive 2013/.../EU of the European Parliament and of the Council laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation . . . . .	697

*Key to symbols used*

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure: first reading
- \*\*\*II Ordinary legislative procedure: second reading
- \*\*\*III Ordinary legislative procedure: third reading

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments by Parliament:

New text is highlighted in ***bold italics***. Deletions are indicated using either the ■ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.



**EUROPEAN PARLIAMENT**

2013-2014 SESSION

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TEXTS ADOPTED

Tuesday 22 October 2013

I

*(Resolutions, recommendations and opinions)*

RESOLUTIONS

EUROPEAN PARLIAMENT

P7\_TA(2013)0431

**Human rights in the Sahel region**

**European Parliament resolution of 22 October 2013 on the situation of human rights in the Sahel region (2013/2020(INI))**

(2016/C 208/01)

*The European Parliament,*

- having regard to the key UN and African human rights conventions and treaties, including the African Charter on Human and Peoples' Rights,
- having regard to the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and the Optional Protocol thereto,
- having regard to the Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa,
- having regard to the Rome Statute, adopted on 17 July 1998, which entered into force on 1 July 2002,
- having regard to the Cotonou Agreement of 23 June 2000, revised on 22 June 2010,
- having regard to the Council Conclusions of 25 June 2012 on the EU Strategic Framework on Human Rights and Democracy and the EU Action Plan on Human Rights and Democracy, and the Council Decisions of 25 July 2012 appointing the EU Special Representative (EUSR) for Human Rights <sup>(1)</sup> and of 18 March 2013 appointing the EUSR for the Sahel <sup>(2)</sup>, in particular the human rights articles in his mandate,
- having regard to Council conclusions on the Sahel, in particular Mali, including the Conclusions of 21 March 2011 on the EU Strategy for Security and Development in the Sahel, and more recent conclusions, including those of 17 and 31 January, 18 February, 22 April, 27 May and 24 June 2013,
- having regard to the UN Declaration on the Protection of Women and Children in Emergency and Armed Conflict, and to UN Security Council Resolutions 1325(2000) and 1820(2008) on Women, Peace and Security,
- having regard to the Council Conclusions of 14 June 2011 on the EU indicators for the Comprehensive Approach to the EU implementation of UN Security Council Resolutions 1325(2000) and 1820(2008) on Women, Peace and Security,

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<sup>(1)</sup> OJ L 200, 27.7.2012, p. 21.

<sup>(2)</sup> OJ L 75, 19.3.2013, p. 29.

Tuesday 22 October 2013

- having regard to the EU Guidelines on Human Rights,
- having regard to the EU guidelines on violence against women and girls and combating all forms of discrimination against them,
- having regard to the UN Security Council resolutions and the reports of the UN Secretary-General and the UN High Commissioner for Human Rights regarding the Sahel, in particular Mali,
- having regard to the UN Secretary-General's report to the UN Security Council on the situation in the Sahel region, dated 14 June 2013, and the attached UN integrated strategy for the Sahel,
- having regard to the UN Human Development Report 2013,
- having regard to the European Commission's Humanitarian Implementation Plans for the Sahel,
- having regard to the Joint Chairs' Conclusions of the International Donor Conference 'Together for a New Mali', held in Brussels on 15 May 2013,
- having regard to the high-level Conference on Women's Leadership in the Sahel held in Brussels on 9 April 2013, at the initiative of the European Union, the Office of the UN Secretary-General's Special Envoy for the Sahel and UN Women,
- having regard to the EU Plan of Action on Gender Equality and Women's Empowerment in Development Cooperation (2010-2015),
- having regard to the UN Secretary-General's report to the UN Security Council on Western Sahara, dated 8 April 2013, in particular its reference to the inter-connectedness between Western Sahara and the situation in the Sahel, and having regard to the Strategy for Security and Development in the Sahel drawn up by the European External Action Service (EEAS), in particular its statement that the problems in the Sahel are cross-border in nature and closely intertwined, and that only a regional focus and a holistic strategy which also includes neighbouring Maghreb countries will enable progress to be made in the region,
- having regard to the report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, dated 28 February 2013, regarding his mission to Morocco, including Western Sahara,
- having regard to its resolution of 25 November 2010 on the situation in Western Sahara <sup>(1)</sup>,
- having regard to its resolution of 13 December 2012 on the annual report on human rights and democracy in the world 2011 and the European Union's policy on the matter <sup>(2)</sup>,
- having regard to its resolution of 7 February 2013 on the 22nd session of the United Nations Human Rights Council <sup>(3)</sup>,
- having regard to its resolution of 16 February 2012 on Parliament's position on the 19th Session of the UN Human Rights Council <sup>(4)</sup>,
- having regard to the annual report on the Common Foreign and Security Policy from the High Representative of the European Union for Foreign Affairs and Security Policy to the European Parliament, endorsed by the Council on 4 October 2012,
- having regard to Rule 48 of its Rules of Procedure,

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<sup>(1)</sup> OJ C 99 E, 3.4.2012, p. 87.

<sup>(2)</sup> Texts adopted, P7\_TA(2012)0503.

<sup>(3)</sup> Texts adopted, P7\_TA(2013)0055.

<sup>(4)</sup> OJ C 249 E, 30.8.2013, p. 41.

**Tuesday 22 October 2013**

- having regard to the report of the Committee on Foreign Affairs and the opinions of the Committee on Development and the Committee on Women's Rights and Gender Equality (A7-0325/2013),
- A. whereas the Sahel is one of the poorest regions of the world, which confronts grave problems regarding human rights, the rule of law, security and armed conflict, as well as economic and social development; whereas the extreme poverty in the region is reflected in the UN Human Development Index for 2012, ranking Niger (186<sup>th</sup>), Chad (184<sup>th</sup>), Burkina Faso (183<sup>rd</sup>) and Mali (182<sup>nd</sup>) among the six least-developed countries in the world;
- B. whereas one of the defining characteristics of the region, mostly generated by political instability, poverty and unsecured borders, is the spill-over effect, which inherently causes shared human rights challenges throughout the entire Sahel; whereas this characteristic outlines the need for a well-coordinated and holistic approach towards the entire eco-geographic region of the Sahel;
- C. whereas establishing democracy, peace and good governance is a crucial challenge for the Sahel states; whereas these states must embark on the process of promoting human rights and fundamental freedoms, eradicating discrimination against women and minorities and promoting education and ethnic reconciliation;
- D. whereas the scope of this resolution encompasses the countries identified by the EU Sahel Strategy, specifically Mauritania, Mali, Niger and relevant parts of Burkina Faso and Chad; whereas the broader geographic and ecological definition of the Sahel also remains crucial with regard to the region's shared human rights challenges deriving from conflict and various human security failures, including state fragility; whereas this report will also discuss the human rights situation in the non-self-governing territory of Western Sahara and the Tindouf camps;
- E. whereas the maternal mortality rate in Mali, estimated at 1 100 deaths per 100 000 live births, is the highest in the world according to UN data; whereas the UN Human Development Report 2013 singles out Niger and Mali as having particularly high mortality rates among children under the age of five, with the rate rising above 200 deaths per 1 000 live births where mothers are lacking any education; whereas the World Bank estimate of primary school enrolment rates for Niger and Mali are among the worst in the world, standing at 62 % and 63 % respectively; whereas the UN estimates that some 18 million people were affected by the severe food and nutrition crisis of 2012 in the Sahel and West Africa; whereas the Commission estimates that in 2013, 10,3 million people in the region are still facing food insecurity, of whom 4,2 million are Malians, with 1,4 million children under the age of five at risk of severe acute malnutrition and another 3,1 million at risk of moderate acute malnutrition; whereas the Commission has been instrumental in the establishment of the Global Alliance for Resilience Initiative in the Sahel (AGIR-Sahel) and pledged EUR 517 million in humanitarian and development aid for 2012-2013;
- F. whereas sections of these countries' populations do not have access to care and suffer from numerous endemic diseases such as cholera, meningitis, measles and HIV/AIDS; whereas the death toll arising from HIV/AIDS is high, with 11 000 people afflicted with the diseases dying every year in Chad, 7 100 in Burkina Faso, 4 400 in Mali and 4 300 in Niger;
- G. whereas the Sahel states are rich in natural resources, particularly oil, gold and uranium, but whereas the income from the extraction of these resources is not fed back into the local economy in a sufficient manner so as to enable these states to develop;
- H. whereas civil wars and ethnic conflicts are leading to population movements and the establishment of refugee camps, such as those in Mopti (Burkina Faso), Mangaize (Niger), M'Bera (Mauritania) and Breijing (Chad); whereas living conditions and hygiene in these camps are deplorable;
- I. whereas in the last 20 years elections have been held on a regular basis in Mali; whereas prior to the coup d'état, the country was considered a relative success story for democracy in Africa;

Tuesday 22 October 2013

- J. whereas the Malian crisis is manifold and cannot be reduced to an ethnic conflict; whereas, however, Tuareg resentments and aspirations for independence or greater autonomy for northern Mali were exploited by armed jihadist groups, who in early 2012 allied with, and subsequently displaced, the secular National Movement for the Liberation of Azawad (MNLA) in their rebellion; whereas these groups, in particular Ansar Dine, Al-Qaeda in the Islamic Maghreb (AQIM) and the Movement for Oneness and Jihad in West Africa (MUJAO), further benefited from the instability arising from the subsequent coup in Bamako, as well as from the wider regional instability, and fuelled by the uncontrolled arsenals in Libya; whereas the impending existential threat to the Malian state itself, combined with the systematic violations of human rights in the north, precipitated the armed interventions by French, African and UN forces to halt the atrocities and human rights violations committed by the extremist groups, to restore democracy, the rule of law and the authority of the Malian state, and to re-establish respect for human rights; whereas a preliminary peace agreement was signed on 18 June 2013 between the Malian Government and rebel forces; whereas the situation in Mali requires a response that goes beyond addressing security threats, including long-term commitment and decisive action on the part of the international community to tackle deep-rooted political, developmental and humanitarian challenges;
- K. whereas the presence of terrorist groups in the Sahel causes serious instability and insecurity in the region, with hostage-taking and violent attacks; whereas the Sahel is a transit zone for drug-trafficking by criminal gangs from Latin America; whereas drug-traffickers are often linked to terrorist groups which provide security for them while in transit; whereas the presence of these traffickers is a source of instability both for the Sahel and for the European Union, which is often the final destination of this trade;
- L. whereas the governments of the Sahel region need to involve the populations concerned in order to reach a durable solution to the crisis; whereas the participation of women, in particular, in the resolution of the Sahel crisis is a necessary condition for reaching long-term stability; whereas the fight against impunity, including impunity for gender-based violence during conflict, is fundamental to the stability of the region and the building of lasting peace;
- M. whereas the EU has paid increased attention to the Sahel, as evidenced by the adoption of the EU Strategy for Security and Development in the Sahel in 2011, the launch of the EU Common Security and Defence Policy (CSDP) Capacity Building Mission (EUCAP Sahel Niger) in July 2012 and the EU CSDP Training Mission (EUTM) in Mali in February 2013, and the nomination of an EUSR for the Sahel; whereas the mandate of the new EUSR, adopted on 18 March 2013, includes a strong human rights component;
- N. whereas complex and interdependent problems require a comprehensive, coordinated approach making use of the full range of EU instruments and policies, linking EU objectives on crisis management, the security sector, development co-operation and ecological sustainability to EU efforts in the areas of human rights, democracy support and the rule of law; whereas a comprehensive strategy for the region should encompass effective coordination via the VP/HR among relevant Commissioners, such as the Commissioner for Development and Humanitarian Aid, the EEAS, EUSRs, including the Special Representatives for Human Rights and the Sahel, and the EU Counter-terrorism Coordinator, as well as Member States; whereas an effective solution to the current crisis must encompass economic and social policies that aim to improve the living standards of the population;
- O. whereas EU policies should focus in particular on rural development and agriculture, in order to ensure food security as a contribution to durable socio-economic development in sub-Saharan Africa; whereas the Commission, in partnership with the United Nations Office for the Coordination of Humanitarian Affairs (UNOCHA), the United Nations Children's Emergency Fund (UNICEF), the United Nations, the United Nations High Commissioner for Refugees (UNHCR) and the World Food Programme (WFP), among others, launched the AGIR-Sahel initiative, aspiring to increase inter-organisational cooperation, as part of the EU's Comprehensive Approach, in addressing the food crisis in the Sahel; whereas the partners identified a minimum investment of EUR 750 million to provide a social safety net to protect the most vulnerable if and when drought hits again in the future;

**Tuesday 22 October 2013**

- P. whereas infringements of human rights and the political, environmental, developmental and humanitarian crisis in the Sahel region affect women in particular, who are often victims of discrimination, exceptional physical and human insecurity, chronic poverty and marginalisation; whereas gender equality, the political and economic empowerment of women, the promotion of gender equality and the defence of women's rights are crucial to reducing poverty and encouraging sustainable development; whereas an increasingly restrictive social environment is limiting women's mobility and productivity, and ultimately their capacity to function as effective leaders and defenders of women's rights; whereas women in the Sahel region make up the majority of small-scale farmers and yet they are penalised in terms of land rights; whereas this lack of ownership over land contributes to poverty among women; whereas studies show that if women are educated and can earn and control income, a number of positive results follow, for example: maternal and infant mortality declines, the health and nutrition of women and children improve, agricultural productivity rises, climate change can be mitigated, population growth slows, economies expand and cycles of poverty are broken;
- Q. whereas at the July 2012 London Summit on Family Planning more than one hundred governments, international agencies and NGOs set themselves the objective of investing an additional USD 4 billion by 2020 so as to increase the number of women using contraception in the world's 69 poorest countries, which include the Sahel countries, by 120 million; whereas this funding is in addition to the current figure of USD 10 billion;
- R. whereas the Sahel countries are signatories of the Cotonou Agreement; whereas partnership with the European Union is based on mutually agreed provisions on human rights and good governance and involves development aid, good governance, the promotion of human rights and humanitarian aid;
- S. whereas EU co-operation with the African Union (AU), the Economic Community of West African States (ECOWAS), the Arab Maghreb Union, regional human rights institutions and UN human rights bodies and civil society organisations remains a pre-requisite for productively advocating the protection and advancement of human rights in the Sahel;
- T. whereas on 14 June 2013 the UN Secretary General proposed, in its report to the UN Security Council, the adoption of an integrated strategy for the Sahel built around three strategic goals, namely enhancing inclusive and effective governance throughout the region, building national and regional security mechanisms capable of addressing cross-border threats and integrating humanitarian and development plans and interventions in order to build long-term resilience;
- U. whereas a ceasefire in Western Sahara between the Moroccan Government and the Polisario Front has been in place since 1991; whereas the UN considers Western Sahara a non-self-governing territory; whereas the Sahrawi Arab Democratic Republic is a full member of the AU and currently recognised by over 35 UN states, but not by the UN collectively or by any EU Member State; whereas Morocco has legal obligations to account for its exercise of de facto administering power over the territory and people of Western Sahara; whereas the UN, under the auspices of the Security Council, is acting as a mediator to find a solution to the conflict; whereas according to the UN Secretary-General, however, no progress has been made on the fundamental issues of the future status of the territory; whereas a referendum on the status of Western Sahara, first agreed on principle in 1988, has still not taken place;
- V. whereas Morocco has signed and ratified several international and human rights treaties such as the International Convention for the Protection of All Persons from Enforced Disappearance, the International Covenant on Civil and Political Rights (ICCPR), the Convention Against Torture (CAT), the Convention on the Elimination of all Forms of Discrimination Against Women, and the United Nations Declaration on the Protection of Human Rights Defenders (UNPHRD);
- W. whereas UN Security Council Resolutions 1754(2007), 1783(2007), 1871(2009), 1920(2010), 1979(2011), 2044(2012) and 2099(2013) call on the neighbouring states to cooperate fully with the United Nations and with each other, and to strengthen their involvement to end the current impasse and to achieve progress towards a political solution;
- X. whereas the refugee camps near Tindouf in Algeria, having first been established thirty-seven years ago, remain the second longest-operating in the world; whereas a political stalemate precludes any realistic prospect of their dissolution, or the resettlement or repatriation of their inhabitants, in the near future;

Tuesday 22 October 2013

- Y. whereas both the Moroccan Government and the Polisario Front have been accused of human rights violations; whereas the UN Mission for the Referendum in Western Sahara (MINURSO) does not include a human rights dimension in its mandate, and offers no mechanism for alleged human rights violations to be reported; whereas UN Security Council Resolution 2099 of 25 April 2013 extended the mandate of MINURSO; whereas the Secretary General's report of 8 April 2013 devotes three pages to the issue of human rights; whereas the UN Security Council and EU Member States in the UN Security Council failed to support a US proposal to give MINURSO a human rights mandate, which led to popular demonstrations in Western Sahara;

### ***General considerations***

1. Expresses its deep concern over the human rights situation in the Sahel region, which has been aggravated by multiple crises in the political, social, economic and ecological spheres; stresses that deeply enmeshed challenges require an integrated and comprehensive policy response and a political solution involving the various parties to the conflict;
2. Notes that the situation of human rights in the Sahel has acquired greater international prominence as a result of the armed conflict in Mali and the intervention by the French, African and UN forces; acknowledges that this conflict has created specific problems in that country, as well as exacerbating structural challenges already present in Mali and elsewhere in the region, such as in Libya; stresses, however, that the immediate concerns in Mali should not deflect attention from the chronic and pervasive problems that seriously impact on human rights in the rest of the Sahel, in particular, organised crime, slavery and human trafficking, arms and drug trafficking, jihadi extremism and radicalisation, fragile governance and institutional corruption, systemic and debilitating poverty, child soldiers and discrimination against women;
3. Points out that the permeability of borders is a characteristic feature of the countries in the region; stresses that the worsening of the situation in the Sahel is closely linked to the massive influx of weapons into Northern Mali following the war in Libya, whereas in other countries in the region Libyan rebels were routinely disarmed at the borders; renews its call for regulation and strict checks on arms sales so as to ensure that Member States do not become involved in the proliferation of conflicts;
4. Welcomes the increased attention to human rights in EU policy; notes that the UN has developed a comprehensive strategy on the Sahel with a strong human rights dimension; recalls that the EU and the countries of the Sahel, as signatories to the Cotonou Agreement, have assumed mutual obligations to protect human rights and democratic principles, based on the rule of law and transparent and accountable governance; points out that the Sahel states are parties to most international treaties for the protection of human rights, women's rights and the rights of the child;
5. Emphasises the important role played by the EU, as the world's largest aid donor, in addressing the development challenges faced by the Sahel region; stresses the importance of engaging other international actors in efforts such as eradicating poverty and hunger, promoting gender equality and reducing child mortality rates, according to the Millennium Development Goals;

### ***Human rights in armed conflict situations***

6. Attaches particular urgency to the human rights situation in Mali, with reports of serious human rights violations in northern Mali by armed Tuareg rebels as well as jihadi groups; notes that alleged crimes include mass rape, torture, mutilation and cruel treatment, including amputation and public floggings, public stoning for perceived adultery, ethnic-based violence, attempted ethnic cleansing, extrajudicial and summary executions of prisoners, the massacre of Malian soldiers, illegal arrests and detention, the passing of sentences without due process, forced marriages and sexual slavery, intentionally directing attacks against cultural objects, and the destruction and looting of property; is deeply concerned about the new trends in terrorist and criminal techniques, including suicide bombings, kidnapping and hostage-taking, and the use of children as human shield; notes that, since January 2013, there have also been numerous reports of human rights violations by elements of the Malian security forces and, to a lesser extent, vigilante groups, against suspected jihadists or those perceived to have cooperated with rebel groups; notes that those targeted have largely come from the Tuareg, Arab and Peuhl communities, and that the army has been frequently accused of ethnic-based reprisals; expresses grave concern that alleged offences have included torture and inhuman treatment, forced disappearances, and extrajudicial and summary executions both of prisoners and civilians; expresses further concern at reports in southern Mali of killings, torture and

**Tuesday 22 October 2013**

disappearances by the military of members of the security forces who were loyal to the pre-coup Touré regime; notes, moreover, with grave alarm the reports of landmines killing and maiming Malian civilians, including children; calls on all combatants to desist from using landmines, and to work swiftly and effectively with regional and international actors to ensure the full removal of these armaments;

7. Welcomes the fact that a peace accord was signed in Mali on 18 June 2013 in order to pave the way for the successfully held presidential election and for peace negotiations between the Malian authorities and armed insurgent groups in northern Mali, and that the signatories have all promised to end human rights violations in every form; embraces their commitment to unity, dialogue and the restoration of constitutional order; recognises, nevertheless, that this is a preliminary agreement which must be followed by action on both sides to bring the conflict to a definitive end; urges the Malian authorities and their international partners, to this end, to pay close attention to the new patterns of human rights violations, particularly reprisals based on ethnicity, that have emerged since the recovery of certain parts of northern Mali, and which could constitute a grave obstacle to peace-building and reconciliation if not properly addressed; welcomes the fact that the Malian Government has set up units to monitor military operations in northern Mali and has opened investigations into the human rights violations allegedly committed by certain elements of the Malian armed forces; calls upon the armed forces to show professionalism as they consolidate themselves in formerly rebel-held areas; calls, moreover, upon the Malian Government to redouble its efforts to facilitate the reporting of abuses both in their current operations and in any future offensives, including through support to the National Human Rights Commission, and to respect due process when interrogating suspected militants; reiterates its condemnation of the reported atrocities committed against the civilian population, prisoners and soldiers; recalls the International Criminal Court (ICC) Prosecutor's determination of a reasonable basis to believe that atrocities committed in the Mali conflict may constitute war crimes; believes, moreover, that some atrocities could constitute crimes against humanity;

8. Notes with grave concern that a further reason for the escalating destabilisation in Mali is the growing level of corruption, leaving the population of the north, including Tuareg, Songhai, Arabs and others out of the range of international aid; emphasises that one of the most dangerous effects of corruption is the creation of cultural and ethnic separation between northern and southern Mali;

9. Notes with grave concern the UNHCR's estimate of almost 300 000 internally displaced persons (IDPs) in Mali, in addition to over 175 000 refugees in neighbouring Burkina Faso, Niger, Mauritania, and to a lesser extent Algeria; calls for immediate action in those refugee camps and those parts of northern Mali which are reportedly suffering from cholera, extreme food insecurity and alarming levels of child mortality, far exceeding the figures for the region as a whole, as a result of malnutrition and lack of access to safe water and healthcare; appeals to international donors to honour their financial commitments as a matter of urgency and, without delay, to raise the USD 290 million needed to enable the UNHCR to halt the severe food crisis now affecting 3,4 million Malians; stresses the importance of securing the refugees' and IDPs' safety, and facilitating their orderly return to their home communities as a key element of national reconciliation;

10. Draws attention to the suffering of women in the recent Mali conflict; specifically condemns as a war crime the use of abduction and rape as weapons of war; expects the EU and other international partners of Mali to cooperate closely with the Malian authorities to implement the commitments inherent in UN Security Council Resolutions 1325 and 1820 and in the EU Comprehensive Approach; draws attention to the importance of establishing transitional justice mechanisms to end impunity for perpetrators of gender-based violence;

11. Urges the EU and the Sahel countries to implement fully the following UN Security Council resolutions: Resolution 1325 on women, peace and security, which calls for women's participation in all aspects and at all levels of conflict resolution, Resolution 1820 on sexual violence in conflict and post-conflict situations, and the subsequent Resolutions 1888, 1889 and 1960, which build on the aforementioned resolutions; asks, therefore, for women's participation in peace processes to be emphasised and guaranteed and for the need to include gender mainstreaming in conflict prevention, peace-keeping operations, humanitarian aid and post-conflict reconstruction to be recognised; deplores the extreme suffering inflicted on women, simply because they are women, in conflict zones; maintains that action of this kind, including the rape of girls by soldiers, forced prostitution, forced impregnation of women, sexual slavery, rape, sexual harassment and consensual abduction (by means of seduction) are crimes which must not be ignored; affirms that the EU must treat these as fundamental problems to be taken into account; emphasises that it is essential to ensure access to abortion for women and girls who have been raped in situations of armed conflict;

Tuesday 22 October 2013

12. Points out that women are frequently discriminated against when it comes to recognising their work in campaigning for peace; recalls that where more women are regularly engaged in conflict resolution and peace-building processes, they play a key role in peace negotiations, broadening the scope of reconstruction, rehabilitation and peace building; encourages, therefore, the participation of women in all national, regional and international reconciliation efforts for Mali, and especially the north of the country; calls for national action plans under UN Security Council Resolution 1325 to be subject to regular reviews and for their priority points to be updated regularly;

13. Abhors the grave violations and brutal acts of violence perpetrated against children in Mali, including the well-documented recruitment and use of child soldiers by nearly all of the armed groups active in the north, including government forces; emphasises the importance of allocating sufficient resources to the tasks of demobilisation and rehabilitation of child soldiers; welcomes, to this end, the draft agreement being drawn up between the Malian Government and the UN enabling child soldiers involved in the armed groups to be handed over to UN representatives, and applauds the actions of UNICEF to reintegrate these children; expresses deep concern at the findings of the latest UN report on children and armed conflict, which underlines how the character and tactics of the conflict in Mali have created unprecedented threats to children; condemns in the strongest terms the killing and maiming of children, rape and sexual violence, forced marriages, abductions, attacks on schools and hospitals, and restrictions on girls' access to education, that have occurred during the Mali conflict; notes that a majority of schools in the north have not yet reopened, and urges for immediate action to enable them to do so; draws attention to the cases of abandonment of children born as a result of rape crimes in northern Mali as a worrying trend for which a solution needs to be found urgently; expresses deep concern, furthermore, at reports of children being detained along with adults and undergoing interrogation without due protection; welcomes, in this connection, the UN Security Council's aim to provide specific protection for women and children affected by armed conflict;

14. Calls on all the Sahel countries to embark on a policy of prevention and protection aimed at ensuring that children will not be recruited by force by armed groups; calls on the Sahel countries to refrain from recruiting children to their regular armies and to condemn any person guilty of this war crime;

15. Deplores the attempted obliteration of northern Mali's precious cultural heritage, with armed groups destroying ancient Sufi shrines and other cherished monuments in Timbuktu and Gao, along with approximately 4 200 ancient manuscripts, ethnic Dogon ceremonial masks and cultural houses (togunas) in Douentza, as well as libraries in Kidal and elsewhere; considers that the cultural desecration witnessed in northern Mali constitutes a war crime; welcomes and calls for EU support to the UNESCO Action Plan for the Rehabilitation of Cultural Heritage and the Safeguarding of Ancient Manuscripts in Mali;

16. Welcomes the French military operation 'Serval' launched on 11 January 2013 and its commitment to the sovereignty, unity and territorial integrity of Mali as a first step towards the reconstruction and democratisation of Mali; welcomes, subsequently, UN Security Council Resolution 2100 of 25 April 2013 and its strong human rights focus, as well as the instruction in the mandate of the UN Multidimensional Integrated Stabilisation Mission in Mali (MINUSMA) to monitor, help investigate and report to the Security Council on any abuses or violations of human rights or violations of international humanitarian law; welcomes the integration of a human rights training component into the European Union Training Mission (EUTM) in Mali;

17. Expresses its support for the International Support Mission (ISM) to Mali, MINUSMA, which took over from the ISM in 1 July 2013, and the EUCAP Sahel Mission; welcomes the proposal by the UN Secretary-General of 14 June 2013 to establish a 'United Nations integrated strategy for the Sahel' to tackle all aspects of the crisis: enhancing governance, combating crime (trafficking of drugs, people, weapons and cigarettes, money laundering) and terrorism, and delivering humanitarian aid; welcomes, in particular, those objectives of the strategy which aim to enhance effective and global governance throughout the region and to integrate humanitarian and development plans and interventions with a view to boosting long-term resilience;

18. Welcomes the important role played by the African-led International Support Mission to Mali (AFISMA), which has laid the foundations for MINUSMA; welcomes, furthermore, the substantial African contingent within the MINUSMA mission, and in particular the AU's decision to send human rights observers embedded within it; hopes that both these features continue as standard in African operations; welcomes the fact that both Malian authorities and armed groups promised in the interim peace accord to facilitate the observers' deployment; welcomes the arrival of observers in Gao and Timbuktu, and hopes that it will soon be possible also to deploy observers in Kidal, reflecting the importance of investigating allegations of human rights abuses in the north by all sides of the Mali conflict; welcomes, furthermore, the Commission's support to these observers and its endeavour to train and deploy additional local and regional civil society observers through the European Instrument for Democracy and Human Rights; urges the EU to learn lessons from this

**Tuesday 22 October 2013**

experience and, drawing on the assistance of stakeholders in Mali's national and local civil society, to explore appropriate ways to have available pools of trained experts, who could be quickly deployed on the ground in urgent situations to give professional advice to EU policy-makers if necessary;

19. Draws attention to the urgent need to enhance compliance with the international human rights and humanitarian law norms in armed conflict situations; calls on the High Representative to learn lessons from the tragic events in Mali and other recent conflicts in order to review the EU guidelines on international humanitarian law (IHL), seek more effective implementation of those guidelines, and support the ongoing initiative of the International Committee of the Red Cross and the Swiss Government to reform the current international governance framework regarding IHL;

20. Welcomes the conclusions of the International Donor Conference 'Together for a New Mali', held on 15 May 2013; stresses that donors have undertaken to donate EUR 3,25 billion to Mali in the next two years, with the EU leading the pledges with EUR 520 million; commends the Malian Government's Plan for the Sustainable Recovery of Mali (PRED); welcomes the particular attention given to ensuring the transparency of public accounts and those of the extractive industries; supports the Malian Government's approval of the draft law against illicit enrichment, and emphasises the importance of carrying out the Donor Conference commitment to monitor carefully the law's systematic application once it has been adopted; regrets that the conference conclusions did not reflect the stated EU commitment to move towards a rights-based approach in development cooperation; calls on the EU and its international partners to implement their mutual commitments as part of an effective and coordinated follow-up to the conference; reiterates the need to link aid with institutional reform and discernible social and political development; commends, furthermore, the constructive involvement of regional actors; calls, bearing in mind the extent of the widespread corruption within the Malian authorities, for all the necessary assurances and safeguards to be put in place in order to ensure that the sums paid out can be used as soon as possible to help the Malian people;

21. Reiterates the importance of the EU's human rights clause in any agreement with third countries, including those of the Sahel region; considers that the clause is one of EU's most efficient instruments which can lead not only to the sustainable development of least-developed countries, but also to the proper respect for and protection of human rights in those countries;

22. Considers that fighting impunity, providing redress to victims and prosecuting all perpetrators of serious human rights violations, irrespective of affiliation and status, including in connection with gender-based violence in conflicts, which is an affront to women's dignity, is key to ensuring lasting peace and stability in Mali; welcomes, therefore, the Malian Government's referral of the situation to the ICC and the ICC Prosecutor's opening of formal investigations, and the stated anticipation by the Malian Government and rebel groups, in Article 18 of the preliminary peace accord, of an international commission of inquiry to investigate alleged war crimes, crimes against humanity and other serious human rights violations and breaches of international and humanitarian law throughout Mali; calls on the EU and other international partners of Mali to prioritise the issue of impunity during peace negotiations, to help the government to pursue its objective of investigating and prosecuting perpetrators of abuses and implementing the provisions of the interim peace accord, and to ensure that the perpetrators of crimes of sexual violence are brought to justice; reiterates that this must include crimes and atrocities committed by all sides;

23. Welcomes the Malian Government's establishment of a National Commission for Dialogue and Reconciliation on 6 March 2013, to serve for a two-year term; maintains that the National Commission must be as broadly representative as possible, with practical results produced as soon as possible; welcomes in particular, to this end, the National Commission's inclusive membership, as evidenced by its vice-presidents, as a commitment to inclusiveness and plurality in the political process; notes that the National Commission is tasked with documenting human rights violations that have occurred since the beginning of the conflict; encourages further the Commission to explore the issues which gave rise to the Malian crisis, to investigate openly and comprehensively allegations of abuses and discrimination against Tuareg communities since Malian independence, and to make recommendations for meaningful improvements; further welcomes, furthermore, the Malian Government's appointment of an envoy to continue dialogue with the armed groups in the north; expresses, in this connection, its sincere hope that the post-electoral landscape in Mali will facilitate enhanced dialogue and trust between communities as a pre-requisite for peace and stability, and that all Malian communities will commit to educating children about mutual tolerance and respect; calls on the EU and its partners in the international community to support fully this process of national reconciliation and inclusive dialogue;

Tuesday 22 October 2013

24. Emphasises that the various conflicts in the Sahel region have led to greater population displacement within states and to an increase in the number of refugees; expresses grave concern at the multiple refugee crises and the situation of refugees in the region, including many unrelated to the Mali crisis; draws particular attention to the thousands of Darfuri refugees in eastern Chad, and Chadian returnees from Darfur, who lack clean water, adequate shelter and healthcare, and notes that the semi-arid climate risks heightening competition for resources with the host populations, and therefore also the potential for instability; draws attention, moreover, to the plight of many thousands of refugees from the Central African Republic (CAR) in southern Chad, where flooding threatens homes and agriculture; echoes, in this connection, the UNHCR's call to increase financial and logistical support to Chad's security forces protecting the camps, particularly in the light of reported attacks on humanitarian compounds; expresses further concern for those in Niger fleeing the recent fighting in northern Nigeria; calls on the international community in general to increase the proportion of aid to the Sahel's refugee camps where necessary, and to help avoid further humanitarian crises among the region's refugee populations; calls on the EU, the Sahel countries, the Office of the UN High Commissioner for Refugees, the African Union and ECOWAS to coordinate their refugee policies in order to provide assistance to refugees, guarantee human security for the most vulnerable groups and establish self-sufficiency programmes; encourages host countries to work with the UN and other actors to improve, in particular, access to shelter, sanitation, healthcare, water, nutrition and education, and to protect at-risk children; points out that, in addition to assisting refugees and internally displaced persons and guaranteeing their protection, efforts must be made to boost economic security and links with separated families for refugees and internally displaced persons, and to improve documentation for refugees so that, wherever possible, they can return to their home regions;

25. Calls on the Sahel countries and on local and regional authorities to implement policies to guarantee the safety of refugees, displaced persons and the most vulnerable groups, with a view to combating terrorism, violence against women, exploitation and trafficking (of drugs, weapons, goods, and human beings);

#### ***Accountability and reform of governmental, judicial and security institutions***

26. Considers that the current human rights challenges in the Sahel cannot be disaggregated from a general crisis of governance, encompassing widespread corruption in public office, weak provision of basic services, poor implementation of social and economic rights, and particularly in the vast and often sparsely populated Saharan regions, profound challenges in upholding the rule of law and maintaining effective border controls; regrets the ensuing harm to the legitimacy of the region's institutions and political systems; fears the risk of further conflict or disorder in the future if such issues are not adequately addressed; points out that populations have to enjoy access to their natural resources and to education, health, and public services, as these forms of access are fundamental rights that have to find effective expression in order to provide a sustainable solution to the instability in the Sahel;

27. Notes with great concern the role of these factors in facilitating the regional surge in international organised crime and terrorist networks; emphasises the serious threats that they pose to human rights, regional stability, state governance, the rule of law and consequently development prospects, and the need to confront such threats for the benefit of Sahelian populations; expresses particular alarm at the 'trafficking highways', which, helped by the porousness of the borders, stretch across Africa from west to east, and south to north from the West African coast, facilitating the transport of firearms, narcotics, cigarettes, oil, counterfeit medicine and people; draws attention to the impact of these activities on the wider region, as well as the EU, which is the destination for much of the illicit traffic; points to the UN Secretary-General's recent Sahel report, which concluded that the historic trade routes across the Sahel are the most vulnerable to terrorist and criminal networks; applauds the efforts of the Sahel countries to fight terrorism and organised crime, not least where heavy weapons traffic is concerned, and urges them to intensify regional coordination and cooperation, redouble their efforts to secure their shared land borders and, to this end, seek the involvement of the ECOWAS; encourages these states further, in conjunction with the UN and other international actors and partners, to develop a comprehensive anti-trafficking strategy, including the collection and analysis of data, the prosecution and punishment of traffickers, and measures for the rehabilitation and social integration of all those, mostly women and girls, who are victims of trafficking; urges the leaders of the Sahel countries to cooperate in strengthening law enforcement systems with a view to eradicating all forms of illicit trafficking, but in particular trafficking in human beings, which affects some of the youngest and poorest women in the region;

**Tuesday 22 October 2013**

28. Notes that the Sahel risks further destabilisation from the proliferation of light weaponry originating in Libya and other residual effects of the situation in that country; stresses that instability and poor governance in Libya aggravate regional arms trafficking and the proliferation of small arms and light weapons (SALWs), drugs trafficking and illicit trade;

29. Condemns the increased incidences of kidnapping and hostage-taking in the region, which have proved highly lucrative for criminal and terrorist groups; welcomes the work of the UN Human Rights Council Advisory Group on the impact of terrorist hostage-taking on human rights; calls for much greater cooperation among Sahel governments and with the governments of such key regional states as Algeria, Libya, Morocco and Sudan, as well as with the EU and other supranational bodies, to ensure effective and coordinated responses to these problems by political, security and judicial institutions;

30. Points out that terrorist operations know no borders and organisations are joining forces to pursue them; notes that the Boko Haram group is established in much of Nigeria and threatens the stability of Niger and that AQMI, led by three Algerians (Abou Zeid, Yahya Abou Al-Hammam, and Mokhtar Belmokhtar), is attempting to destabilise southern Algeria; welcomes the European Union border Assistance Mission (EUBAM) in Libya, aimed at securing Libyan borders; calls, therefore, on the Sahel countries, to coordinate their efforts to make the entire region secure, starting with the borders, and to intensify counterterrorism cooperation with all the countries concerned, including Algeria, Nigeria, Morocco, and Libya; calls on the EU, the AU, the ECOWAS, and the international community to provide the Sahel countries with every necessary form of technical, material and human support;

31. Warns against a perceived spread of extremism in the Arab Spring countries — Tunisia, Egypt and Libya — and invites the VP/HR to provide leadership in the process of cooperation with these countries' governments, institutions and civil society organisations in such a way as to support truly democratic transition processes, in order to ensure simultaneously the stabilisation of the conflict-prone neighbouring regions, namely the Sahel;

32. Calls on the Sahel countries to establish intensive cooperation with Senegal, Guinea-Bissau and Ghana, which are transit ports for drugs coming from Latin American criminal groups and bound for Europe; calls on the EU to help the Sahel countries fight this trafficking;

33. Considers it crucial, therefore, to encourage the reform of institutions responsible for the judiciary, security and basic services in the Sahel countries, in order to help restore the rule of law and create better conditions for democratic transition, human rights, sustainable development and institutional legitimacy; encourages Sahel governments to continue the process of decentralisation, to transfer more power and resources to local authorities and to boost their capacity, legitimacy and accountability; stresses, in particular, the importance of clear accountability structures for promoting efficiency and transparency, and calls on the EU to work with local authorities to strengthen mechanisms for civilian control and oversight; and to strengthen anti-corruption initiatives; draws further attention to the necessity, as stated in the new UN integrated strategy for the Sahel, of supporting the strengthening of internal and external oversight, as well as integrity safeguard mechanisms, for law enforcement officers, members of the judiciary and law court officials;

34. Points to the imperative in Mali, in particular, of ensuring adequate human and financial resourcing of the Ministry of Justice, as well as the professional training of its staff; urges the governments of the Sahel countries to respect the independence and the impartiality of the courts, since these are essential guarantees of democracy and the rule of law; calls on the Sahel countries to continue their efforts to improve judicial training; calls on the EU to support NGO projects aimed at raising human rights awareness among judicial practitioners; encourages, moreover, the Malian authorities to prosecute officials involved in corruption and organised crime, as crucial measures in restoring confidence and reducing the potential for future instability; notes that organised crime engenders corruption which permeates every sphere of the state; calls on the Sahel countries, therefore, to condemn roundly all forms of corruption;

35. Welcomes the emphasis in the new UN integrated strategy for the Sahel on the need to design and support truth-seeking processes, national consultations on transitional justice, judicial accountability mechanisms and reparation programmes, including for victims of sexual violence; calls for the EU to work with relevant UN agencies to assist Sahel governments in implementing these reforms;

Tuesday 22 October 2013

36. Applauds the agreement between Senegal and the AU to establish a Special Tribunal to prosecute former Chadian President Hissène Habré for war crimes, torture and crimes against humanity, and the agreement between the governments of Senegal and Chad to allow Senegalese judges to conduct investigations in Chad; encourages strongly political leaders in the Sahel countries and all public authorities to explicate and give swift effect to their resolve to end the culture of impunity for alleged war criminals and human rights violators in Chad and elsewhere in the region; notes, in this connection, that Chad remains the only Sahel country not to have signed up to the Protocol to the African Charter on Human and Peoples' Rights on the Establishment of an African Court on Human and Peoples' Rights; encourages Chad to do so, as a strong signal of its commitment to punishing systemic abuses of human rights and providing redress to victims; regrets, moreover, Burkina Faso's recent law granting amnesty to heads of state; fears that this sends the wrong signal to violators of human rights in the region and runs counter to the spirit of tackling impunity;

37. Welcomes the peaceful settlement of the border dispute between Niger and Burkina Faso brought by those two countries before the International Court of Justice, which handed down its ruling on 16 April 2013, and calls on the Sahel countries to follow this example;

38. Calls on the Sahel countries to cooperate with the International Criminal Court (ICC) so as to enable it to conduct investigations freely and with complete impartiality; calls on states parties to execute international arrest warrants issued by the ICC and to enforce its decisions with all due swiftness; proposes that the UN should help the Sahel countries to set up impartial and independent judicial bodies to try perpetrators of international crimes, following the example of the Special Court for Sierra Leone; notes that Mauritania is the only Sahel country — and one of the very few African countries — not to have acceded to the Rome Statute of the ICC; encourages it to do so, as a strong signal of rejecting the culture of impunity; emphasises, in this connection, the importance of developing an EU policy on transitional justice as specified in the EU Action Plan on Human Rights;

39. Calls on all countries in the region to act swiftly to tackle the persistent reports of alleged arbitrary arrests, ill-treatment and abuses, in spite of legislation prohibiting such practices; expresses particular concern over the reports of torture in detention centres and the arbitrary arrests of thousands of migrants in Mauritania, as well as the authorities' refusal after two years to communicate the whereabouts of certain convicted prisoners to their families; expresses alarm also at reports in Chad of mass ill-treatment in detention, detention without trial, and hundreds of forced evictions in N'Djamena, in addition to the forced disappearance of prisoners; points out that forced disappearances are considered a war crime under the Rome Statute; condemns the reports of extremely poor conditions in some of the region's prisons, particularly in Chad and Mali, which lack basic healthcare and inflict great suffering on inmates; calls on the Sahel countries to improve living conditions for prisoners and, in particular, to guarantee the safety and security of the most vulnerable groups, such as women and children; draws attention, moreover, to the recent death sentences imposed by the Malian judiciary for crimes including robbery, criminal association and the illegal possession of firearms;

### *Civic freedoms and democratic governance*

40. Stresses that the security imperative in the current Mali conflict should not detract from the primacy aim across the region of inclusive national dialogue, good governance and democratic reforms as the engine of political stability and sustainability; notes that these issues are inextricable from improvement in the spheres of development and human rights; urges all sides in Mali to be an example for the rest of the region in achieving these goals;

41. Supports the UN Security Council resolution commitment to assist the transitional authorities of Mali to implement the road map towards the full restoration of constitutional order, democratic governance and national unity, as essential building blocks of the overall peace process; considers it essential to create conditions conducive to the holding of free, fair and democratic elections, in keeping with international standards; stresses the need to overcome challenges related to the voting arrangements in the IDP and refugee camps, to avoid further political marginalisation; calls for immediate action on this issue by the Malian Government and its international partners; welcomes the agreement signed between the Malian Government and the Tuareg rebels which paves the way for the return of the Malian army and administration in the north, and which removed a major obstacle for the holding of the presidential elections in July; emphasises the need to ensure the safe participation of women in the electoral process;

**Tuesday 22 October 2013**

42. Welcomes the use of an EU election observation mission (EOM) in the Malian elections; recalls, however, the need for the EEAS to ensure adequate follow-up to the EOM recommendations and their longer-term integration into EU policy on a broader basis; believes, in particular, that the EOM could add value to elections in the Sahel through the ability to monitor aspects of human rights and report back to EU delegations to trigger appropriate actions, if necessary;

43. Calls on the Malian Government and the international community to learn lessons from the democratic transition in Niger and its constitutional process in 2010-2011, in particular regarding the extensive consultation with civil society and other stakeholders, the efforts to promote women's political participation as candidates, and the support of civil society partners to conduct citizen election observation, voter education and activities; emphasises the importance for the whole Sahel region of continued support to Niger in order to consolidate citizens' confidence in the democratic system, and to follow up on the new constitution's requirement to increase transparency and fight corruption in extractive industries management, including by publishing all sizeable mining contracts and information on the revenues generated from them;

44. Deeply regrets restrictions on freedom of expression, assembly and association in the Sahel; expresses particular concern at reports in Chad of the harassment, intimidation and arrest of journalists, political opponents, trade unionists, church figures and other civil society activists and human rights defenders; expresses further concern at the arrest of and alleged violence against peaceful protesters in Mauritania, and the alleged attempts to silence opposition in Mali, including through the arrest of journalists and political opponents, and by censoring media outlets; stresses, in this connection, the importance in the Sahel of supporting human rights defenders, independent civil society, including women's organisations, and a free media as key actors in the life of a democratic society, particularly in times of elections; welcomes positive developments on the freedom of expression, assembly and association elsewhere in the region, and encourages the EU to work with local partners to continue encouraging improvements; calls, furthermore, on the EU to encourage and assist a mapping of civil society as a basis for more effective support; recommends that the EU assist civil society and human rights defenders strategically as well as financially, opening up long-term exchanges, including through the relevant EU delegations;

45. Considers that the protection and promotion of freedom of speech is essential in developing an active and engaged civil society that can properly contribute to the development of the entire region; condemns, in this connection, any attempt at censorship, intimidation of journalists or human rights activists and any type of direct or indirect pressure exerted on private or state media;

46. Calls on the Sahel countries to cease all arbitrary arrests and intimidation campaigns aimed at the press and the media, human rights defenders, or opposition activists; calls on the Sahel-Saharan countries, including the North African countries, to respect fully the freedom of expression of non-violent groups and their freedom to demonstrate; calls on the judicial authorities to try imprisoned opposition figures fairly and in accordance with the law in force; calls on the Sahel countries to promote a multiparty system and both to allow political groupings which abide by the rule of law to contest elections without fear of reprisal and to enable the people to participate in elections;

#### ***Development, humanitarian aid and human rights***

47. Reiterates that human security and development in the Sahel countries are inextricably linked, as stated in the EU's 2011 Strategy for Security and Development in the Sahel; stresses that a stable security situation, economic and political stability, and stability as regards respect for human rights and fundamental freedoms are necessary for the long term success and sustainability of development policies in the Sahel; draws attention, however, to the fact that bringing security to the region requires investment in development aid so that the local population has sufficient resources to boost regional stability; takes the view that this would prevent much of the trafficking and illegal activities that stem from the extreme poverty and lack of resources and prospects in the region;

48. Notes with due seriousness the extreme and pervasive poverty across the Sahel, particularly in Mali, Niger, Chad and Burkina Faso, but also in Mauritania; acknowledges the detrimental impact of poverty on the prospects of realising human rights; notes that poverty and underdevelopment disproportionately impact upon women and girls, and expresses grave concern over the high maternal and under-five child mortality rates in the region; draws attention to the inverse relationship between the level of education among mothers and the infant mortality rate; points, accordingly, to the importance of promoting schooling for girls; stresses the UN's findings of lower mortality rates among better educated mothers as a rallying call for universal and accessible education; points out that fast population growth, often at annual

Tuesday 22 October 2013

rates of over 3 %, puts additional pressure on governments' capacity to protect even the most basic economic and social rights; considers it necessary, therefore, to provide better access to health services and — as far as sexual and reproductive rights are concerned — to family planning services in particular;

49. Emphasises the interdependence of development, democracy, human rights, good governance and security in the Sahel; reiterates its support for the human rights-based approach and democratic ownership in development co-operation, based on harnessing local participation and knowledge to achieve development goals on the ground and for strong, effective and independent follow-up enforcement mechanisms, involving parliaments, other genuinely representative bodies, and local and regional civil society both at national and international level; recalls and supports the EU commitments to implement a human rights approach to EU development co-operation, as also noted in the EU Strategy on Human Rights and its Action Plan;

50. Draws attention once again to the need to make development aid for states contingent on respect for fundamental rights; reiterates that the allocation of European development aid funding can be effective only if the Union is in a position to carry out proper scrutiny of the way in which that funding is used, in order to satisfy itself that it is not being diverted from its intended purpose; reaffirms the need, if human rights are to be safeguarded effectively, to make the EU's external and internal policies more consistent, in keeping with the EU's development aims;

51. Calls on the Commission, on the basis of the local population's previously identified needs, to release all the development funding earmarked for the Sahel: the European Instrument for Democracy and Human Rights, the EDF, the Financing Instrument for Development Cooperation and the Sahel Resilience Fund;

52. Calls on the EU to support all measures being taken by Sahel countries, NGOs, and civil society to improve access to care, especially for the most vulnerable populations; calls on international organisations to continue the efforts to eradicate HIV/AIDS, tuberculosis, malaria and meningitis, which cause numerous deaths; underlines the need to design and implement health programmes in order to strengthen health systems, taking into account the fact that the global economic crisis has undermined progress on HIV/AIDS, tuberculosis, malaria and other diseases; points out that some Sahel populations are nomadic and cannot easily gain access to care; calls, in this connection, for support to be given to care-related awareness and training campaigns;

53. Condemns the fact that budget cuts in areas such as food security, health and education, which are of key importance in achieving the Millennium Goals, continue to exacerbate food and humanitarian crises in the Sahel; emphasises the fundamental need for structural action in the fields of agriculture, food security and nutrition, as well as specific measures to eradicate land-grabbing, in order to promote inclusive and sustainable growth and to prevent the annual recurrence of food crises in the Sahel region;

54. Takes the view that political instability in the Sahel region, combined with the severe drought affecting millions of people, constitutes a serious threat to democracy, the rule of law and human and socio-economic rights, and in turn is having an adverse impact on people's living standards; points out that the rule of law, good governance and respect for human rights are essential for guaranteeing national stability, security, and respect for fundamental freedoms;

55. Calls on local and regional authorities, in cooperation with civil society, to enhance security and respect for human rights in the Sahel countries and at their borders in an effort to ensure that development and humanitarian aid policies can be implemented as effectively as possible;

56. Calls on the governments of the Sahel countries to address the root causes of the crisis on the basis of a sustainable economic development strategy that takes account of their citizens' political, economic and social concerns, such as access to food, education, health care, employment and housing, wealth redistribution and decent living conditions;

57. Emphasises the necessity of combating corruption to enhance institutional legitimacy and tackle the mounting development and human rights challenges in the region; notes that access to basic health care and education has been gravely hampered by various forms of corruption; stresses, furthermore, the importance of a free, organised civil society and media so as to monitor and report abuses;

**Tuesday 22 October 2013**

58. Notes that women have an essential role to play in the development of the Sahel region, particularly in terms of nutrition, food security and food production, as they are the ones principally engaged in agriculture, although they still have almost no access to ownership of the land they cultivate; calls on the Commission to recognise the fundamental role of women, as smallholder farmers, in food security, and to invest in programmes which specifically support them; insists that the EU strategy should also focus on actions intended to ensure that the most vulnerable people, especially in rural areas, are able to benefit from agricultural training opportunities, education on nutrition, good health and working conditions, and a safety net in times of need; emphasises that in order for smallholder farmers, in particular women farmers, to be able not only to farm sustainably but also to develop their productive capacity, they need to have increased access to microcredit loans so that they can invest in better seeds, fertilisers and irrigation methods, and obtain the tools they need to protect their crops from pests and disease;

59. Highlights the urgent need to grant EU humanitarian aid to help achieve the Millennium Goals; underlines the importance of the goal of improving maternal health in order to reduce maternal mortality and ensure universal access to sexual and reproductive health and family planning; stresses the importance of education and awareness-raising in the area of sexual and reproductive health as an integral part of the women's health agenda;

60. Notes that there are alarming signs that the Sahel region will be hit by a severe food and nutrition crisis this year, and calls on the Commission to provide adequate humanitarian aid funding for the region;

61. Emphasise the pressing issues of famines, droughts, persistent hunger, and the inability of the national government to provide for basic food security, which are driving forces for local disillusionment; reaffirms the need to improve the national government's ability to provide for food security through increased funding and political support for the AGIR-Sahel initiative also as a regional and Comprehensive Approach to tackle the root cause of food security;

62. Calls on the EU, in cooperation with the Sahel countries, to implement priority development policies, based on an approach rooted in human rights and fundamental freedoms, in order to alleviate the food crisis and the problems of malnutrition and famine and tackle problems caused by drought and natural disasters; calls on the Commission, in keeping with those priority policies, to make optimum use of the funds earmarked for combating malnutrition (EUR 123,5 million in 2012) in order to meet the needs of the people concerned and support local capacity building in the countries in question in an effort to ensure that the aid has a positive impact;

63. Points out that a long-term commitment is necessary in order to increase resistance to drought in the Sahel and thus prevent recurring food crises and obviate the need for large scale humanitarian assistance whenever there is a drought; stresses that a commitment of this kind needs to be underpinned by a sustainable partnership between governments, regional institutions, donors and financial institutions, along the lines of the 'AGIR Sahel' initiative launched by the European Union;

64. Notes, with particular concern, that access to drinking water still represents a problem throughout the Sahel region; reiterates that in order to achieve the development of the region, the main focus should be placed on ensuring the basic needs of the population of this area; underlines that an important part of the development aid provided by the EU must address this issue; welcomes, in this connection, all international initiatives which aim at reducing water scarcity in the Sahel region;

65. Stresses that a long-term approach based on universal access to education is necessary in order to improve the everyday lives of the Sahel's inhabitants and support the development of what will be a region with 150 million people in 2040;

66. Encourages the Sahel states and regional actors, in conjunction with the UN, to mobilise new resources for development; welcomes the consultations started by the UN Secretary-General's Special Envoy for the Sahel with the African Development Bank, and recommends that these consultations be extended to the World Bank and other international financial institutions, in order to create a Sahel Action Fund; applauds this proposed fund's integrated platform for resources, co-ordinating regional development projects with the specific needs of Sahel countries; encourages the EU to adapt and co-ordinate its own strategy accordingly;

67. Expresses concern about the general situation of uranium mining in the Sahel, particularly in the light of the attack by MUJAO on a mine in Arlit in northern Niger on 23 May 2013; stresses that major breaches of security around Niger's

Tuesday 22 October 2013

uranium mines could prove disastrous for local populations and regional stability, and calls, therefore, for security to be given the utmost attention by the Nigerien authorities and their international partners; highlights, moreover, the importance of guaranteeing safety in uranium mining; calls, furthermore, on mining companies to ensure that uranium is mined responsibly, with the full consent of local communities and with minimal detrimental impact to nearby populations and their environment;

68. Notes, with due gravity, the frequent food and nutrition crises and other humanitarian emergencies in the Sahel region, and their effect on the most fundamental human rights; welcomes the strong involvement of the EU and its Member States in the humanitarian crisis efforts in the Sahel; underlines that tackling food insecurity is key both to facilitating peace and enhancing human rights; believes that, to this end, local production and ownership should be stimulated, as well as distribution networks and resource mobility, enhanced; notes that in 2012 the Commission provided aid totalling EUR 338 million, including EUR 174 million in emergency humanitarian aid, to address food crises and that DG ECHO made EUR 172 million in humanitarian aid available, EUR 58 million of which was used in Mali;

69. Calls on the Union to continue and step up its efforts to boost humanitarian aid for the Sahel, ensure that there is close cooperation between international humanitarian aid agencies, civil society, local and regional authorities and governments, and to mobilise the funding earmarked under the 10th EDF (EUR 660 million for the period 2007–2013) and the Fund for the Global Alliance for Resilience Initiative (AGIR Sahel — EUR 172 million for 2012); welcomes the budget of EUR 1,5 million granted to AGIR-Sahel under the 11th EDF with the aim of increasing the resilience of the Sahel States;

70. Stresses the need for all the Sahel countries to implement policies on the establishment of basic social infrastructure and networks (sanitation, network of medical advisers, transport, telecommunications) which ensure that humanitarian aid can be channelled in a neutral, universal, unrestricted, proper and efficient way; looks to those countries and local and regional authorities to ensure that the networks remain operational and accessible;

#### ***Human rights situation of women, children and minorities***

71. Condemns in the strongest terms the ongoing slavery, often by inheritance, in the Sahel region, and particular in Mauritania, where it reportedly affects a sizeable minority of the population; notes that slavery exists within a rigid caste system, and persists despite the country's official abolition of slavery in 1981, and its explicit criminalisation in 2007; expresses deep concern at the institutionalised nature of this practice, which reaches as far as the civil service; notes, furthermore, the Mauritanian Government's extreme reluctance to acknowledge the continued widespread existence of slavery, and that to date only one legal case against a slave owner is known to have seen successful prosecution; urges the Mauritanian Government to live up to its national and international legal commitments and obligations to end effectively all forms of slavery and to enact anti-slavery laws providing, inter alia, compensation procedures; urges, moreover, the Mauritanian authorities to stop harassing and even imprisoning civil society activists who campaign for an end to slavery, including on charges of apostasy; calls on the Commission and the Member States, in this connection, to continue to support the work of Mauritanian as well as international anti-slavery organisations, including the UN Special Rapporteur (UNSR) on contemporary forms of slavery and the International Labour Organization;

72. Notes with great concern that slavery persists across the wider Sahel region, with large numbers of people in bonded labour in Mali, Niger and elsewhere; urges the responsible national and international authorities to take action in this regard, by monitoring the implementation of existing legislation prohibiting and criminalising slavery, with particular attention to the position and vulnerability of women and girls; encourages the development by the authorities of programmes that aim at, inter alia, assisting in the rehabilitation and reintegration of victims, collecting data, and organising awareness-raising campaigns, as slavery is considered by many as a natural state, and the social hierarchy is culturally entrenched; encourages the local authorities to develop strategies and programmes aiming to integrate former slaves into society by ensuring means of subsistence and adequate access to work;

73. Expresses concern at the violation of fundamental children's rights in the Sahel, in particular, gender-based violence and discrimination, prevalent child labour, the alleged detention of minors in adult jails in Mauritania, Mali and elsewhere, and Chad's recruitment of child soldiers into its regular army; calls for the EU to work closely with Sahel governments to ensure the eradication of these practices;

**Tuesday 22 October 2013**

74. Expresses deep concern about evidence of child labour in Malian gold mines, agriculture, forestry and other sectors of the economy, reportedly involving children as young as six years old; notes the laws in force in the Sahel states prohibiting child labour; notes also the particularly hazardous nature of gold mining; calls, therefore, on the Malian authorities to implement the policy proposals in its Action Plan for the Fight against Child Labour (PANETEM) of June 2011, and to promote universal education more actively; calls on the EU to work with the International Labour Organization (ILO) and other national and international organisations, to eradicate fully child labour in Mali; calls on all the Sahel states to combat child labour and promote education;

75. Notes, with great concern, that according to NGO statistics, over three million children under the age of 17 are working in Mali; deplores this situation, especially given that this results in reduced education rates and low literacy rates;

76. Points out that the EU endorses the principles underpinning the Kimberley Process, implements the Forest Law Enforcement, Governance and Trade (FLEGT) Action Plan programmes and endeavours wherever possible to encourage compliance with basic international standards in the areas of social protection, employment and the environment, and corporate social responsibility (CSR); calls on the EU and the Sahel states to consider introducing a gold traceability process along the lines of the Kimberley Process for diamonds; emphasises the need for European companies which have subsidiaries in the countries of the region to satisfy themselves that these basic standards and international guidelines on CSR are being complied with; points out that the EU will shortly introduce the principle of country-by-country reporting;

77. Is greatly concerned about reports of child abduction for ransom and sale in Chad, as well as in other countries in the region; notes that children are trafficked internally and abroad for forced labour, forced marriage and sexual exploitation; notes, furthermore, that in some cases children have been abducted and sold to international adoption agencies;

78. Calls on the Sahel states to promote access to education for all children, both boys and girls, and for nomad peoples, with no discrimination on the grounds of race, caste or ethnicity; calls on the Sahel states to promote policies on vocational training and access to higher education and employment, in order to offer young people in the Sahel a future and therefore keep them out of the clutches of terrorist groups; emphasises that conditions for children in schools must meet minimum criteria as regards health, safety and dignity and that steps must be taken to ensure that children are not mistreated or forced to engage in begging by their tutors;

79. Calls for effective health and education policies targeting the most vulnerable groups, such as women and children, to be implemented and monitored in order to make progress towards achieving the MDGs: universal primary education, improved maternal health, universal access to health care, and efforts to combat HIV/AIDS and all infectious diseases; calls on the EU, under the 11th European Development Fund (EDF), to make youth a priority action area in the Sahel and to develop an ambitious education policy; reiterates the importance of policies focusing specifically on women and access to employment;

80. Acknowledges the important role which women play in stabilising and developing the Sahel, and calls for their leadership role in conflict prevention, peace-keeping and peace-building processes, security, politics and economic development to be strengthened; encourages development partners to allocate financial support to projects which seek specifically to empower women in the region;

81. Expresses concern at the discrimination faced by women and girls in much of this region, the manifestations of which include forced marriage, child marriage, sexual exploitation, under-education and widespread female genital mutilation, including infibulation, and traditional practices such as sororate or levirate marriage, as well as regarding access to education, jobs with rights, and health; calls for the implementation, in cooperation with all of the development actors on the ground, of policies to safeguard human rights and gender equality, in particular respect for and the safeguarding and promotion of the rights of women, including sexual and reproductive rights, with no discrimination on the grounds of race, caste, age, ethnicity, religious belief, marital status, origin or status as a migrant or non-migrant; underlines that more efforts are necessary in order to guarantee that reforms related to governance and the rule of law respond to the specific needs of women;

Tuesday 22 October 2013

82. Calls on the Sahel countries to adopt laws and concrete measures prohibiting and establishing penalties for all forms of violence against women, including domestic and sexual violence, sexual harassment and harmful traditional practices, such as female genital mutilation and forced marriages, especially in the case of underage girls; highlights the importance of protecting the victims and providing specifically targeted services, while combating the impunity of attackers and ensuring that these crimes are investigated, tried and properly punished, as well as making justice fully available to all women, without any form of discrimination on religious and/or ethnic grounds; stresses that domestic violence is not a private family matter, and nor are excuses for violence which are entrenched in cultural or religious belief acceptable;

83. Urges the Sahel countries to revise their laws regarding women and property rights; stresses the importance of women's ownership over the land they farm and live on;

84. Urges the international community to dedicate more funds to advancing women's rights and empowerment in the region; welcomes the efforts of the African Union in respect of women's rights and recalls the importance of the ECOWAS for stability in the region; calls on the Sahel countries to step up their cooperation with a view to launching awareness campaigns on women's rights with NGOs, civil society, the UN and the EU; calls on the EU to work with regional actors to promote the education of girls and to support measures boosting the financial security and potential of women, as key to securing female social, political and economic empowerment; encourages, furthermore, a policy emphasis on improving women's healthcare;

85. Calls, furthermore, on the Sahel countries to ensure that all girls are registered at birth and subsequently enrolled in primary school education;

86. Calls on the Commission, the EEAS and the Council to encourage more countries in the region to make explicit statutory provisions for women's and girls' rights and to prioritise programmes that would secure those rights, in particular access to public services, including in the field of education, access to health, sexual and reproductive rights, and to secure loans for food, land and productive resources, especially in rural areas, as well as access to health care and the justice system, in order to enhance women's financial independence by helping them make the transition from informal to formal work, their participation in political and economic decision-making, and the elimination of all forms of violence against women and girls, including the eradication of early forced marriage and the barbaric practice of female genital mutilation;

87. Calls on the EUSR for the Sahel and the EUSR for Human Rights, respectively, to develop joint actions to secure women's rights in the region more effectively, by tackling impunity in connection with gender-based violence and all other forms of violence which are an affront to the dignity of women; urges the Commission, the EEAS and partner states to make women's rights and gender equality a priority for bilateral aid programmes and to provide sustainable and reliable funding for initiatives aimed at empowering women and boosting gender equality; particularly condemns violence as the principal obstacle to women's enjoyment of social and economic freedom; emphasises that the promotion of equality between men and women should be seen as a cross-cutting issue;

88. Welcomes the legal status of same-sex relationships in Mali, Niger, Chad and Burkina Faso; regrets, however, the societal discrimination still present; expresses its grave concern over the use of 'public indecency' laws and laws prohibiting association for 'an immoral purpose' when dealing with the LGBT community in Mali and the wider region; hopes that those oppressed during the insurgency in northern Mali may safely re-integrate into their society; expresses deep concern over the continuing criminalisation of LGBT relationships in Mauritania which, for men, nominally carry the punishment of death by public stoning; notes, however, that there are no documented incidences of this punishment ever having been applied; urges the Mauritanian Government, nevertheless, to work with civil society to reform its legislation and help to improve the lives of LGBT citizens;

89. Believes that a rights-based approach to the situation and development of the Tuareg people, which honestly addresses historic grievances, while bearing in mind the fact that the Tuareg people live in areas with other ethnic groups as well, is essential for peace and development in the Sahel region; welcomes developments in Niger on this issue, but urges all countries with significant Tuareg populations, including non-Sahel countries such as Algeria and Libya, to work with community representatives to resolve, politically and institutionally, the problems of underdevelopment and animosity; notes, furthermore, the variety of cultures across the Sahel; takes the view that all these peoples should once again be given the chance to live peacefully side by side; encourages the governments of the region to include all of them in social and political dialogues, and in the processes of decision-making;

Tuesday 22 October 2013

***EU Policy recommendations for the Sahel***

90. Welcomes the appointment of the EUSR for the Sahel, and the strong human rights element in his mandate; expects the new EUSR to cooperate closely with the EUSR for Human Rights, the Office of the Prosecutor of the ICC, the Office of the High Commissioner for Human Rights (OHCHR), and the human rights defenders and observers in the region; in promoting respect for human rights and international humanitarian law; calls for appropriate coordination between the EUSR for the Sahel with the EUSR for the Southern Mediterranean in particular, and with the EUSR for the Horn of Africa as well, given that crises in Africa bear strong regional implications, and they tend to have a spill-over effect and bear geostrategic considerations; urges the EU, in this connection, to invest itself in effectively coordinating all EU endeavours in Africa, especially crisis management and post-conflict efforts and, calls, therefore, on the VP/HR to ensure such coordination;

91. Stresses the importance of implementing the EU's human rights policy commitments, including its guidelines on children and armed conflict, on violence against women and girls and combating all forms of discrimination against them, on promoting compliance with international humanitarian law, on the protection of civilians in CSDP missions and operations, as well as the EU comprehensive approach policy regarding implementation of the UN Security Council Resolutions 1325 and 1820 on Women, Peace and Security, including by monitoring and reporting on developments in this regard;

92. Deplores the fact that neither the EU Strategy for Security and Development in the Sahel, adopted on 21 March 2011, nor the conclusions thereon adopted by the Foreign Affairs Council of 23 March 2012 contain any reference to the promotion of gender equality, the situation of women or the defence of women's rights;

93. Welcomes the strategic lines of action in the EU Sahel Strategy, including support for and promotion of good governance and internal conflict resolution; believes, however, that the strategy still does not adequately mainstream human rights, the rule of law, support for democracy, effective economic governance and strong anti-corruption measures as key elements to support the development-security nexus at its heart; urges the EU institutions to work together in the near future to revise the strategy, by including concrete proposals for:

- (a) addressing the plight of refugees and IDPs throughout the region,
- (b) tackling the scourge of slavery, human trafficking and other forms of trafficking and smuggling, which have proved so detrimental to human rights and security in the region,
- (c) improving the situation of women, children and minorities,
- (d) channelling aid in an effective and efficient manner, offering added support to governments on the 'more for more' principle,
- (e) ending the culture of impunity, including by supporting measures already being proposed or put in place in Mali and elsewhere,
- (f) protecting civic freedoms and improving democratic governance through inclusive electoral processes and credible representation, and by supporting civil society,
- (g) protecting cultural diversity and heritage;

94. Recommends that the EU consider the possibility of targeted sanctions, through asset freezes, visa bans or other instruments, of the most serious violators of human rights, both in Mali and elsewhere in the region;

95. Welcomes the UN Secretary-General's recent report on the situation in the Sahel; notes the 'four-by-four' approach, aiming to bolster governance, security, humanitarian requirements and development, as part of an integrated strategy; welcomes in particular the strong human rights dimension in the strategy, and calls on the EU to continue its support; commends, furthermore, the emphasis of the UN integrated strategy on building participation, supporting local and regional governance, strengthening social and security cohesion, developing early-warning systems for future threats and, in

Tuesday 22 October 2013

particular, strengthening or consolidating national and regional human rights mechanisms; encourages the EU to incorporate a similar holistic approach to sustainability, security, humanitarian and development concerns, and human rights, in coordination and in harmony with the UN, in a way which recognises the fundamentally transnational, cross-border and intertwined nature of the Sahel's challenges;

96. Emphasises the continuing crucial importance of increased EU engagement with African regional actors such as the AU, ECOWAS, the Arab Maghreb Union, and the African regional human rights instruments in generating sustained progress in the human rights and democracy initiatives in the Sahel; urges neighbouring countries such as Senegal, Algeria and Morocco to contribute leadership and help to create a genuine regional dynamic which will boost regional economic development and human rights; recognises ultimately that the lasting solutions to the Sahel's problems must come from within that region and be fully owned by its own people; calls, nevertheless, on the EU to continue its commitment to working with and assisting Sahel partners with all appropriate means at its disposal to improve the quality of life of the people in that region and to strengthen ties with their democratic governments;

#### ***Human rights considerations in Western Sahara and the Tindouf camps***

97. Welcomes and echoes the April 2013 report of the UN Secretary-General on the situation concerning Western Sahara, which stresses 'the critical importance of addressing the Western Sahara conflict as part of a broader strategy for the Sahel', and the fact that 'the issue of human rights remains important for any resolution of the conflict'; notes that the ongoing conflicts in the Sahel, in particular the presence of terrorist groups, such as AQIM in northern Mali and southern Algeria, are factors which risk destabilising Western Sahara, as well as the wider region; notes, furthermore, the negative impact of the conflict on regional integration, which should involve Morocco and Algeria, and which could offer significant opportunities for democratisation and economic development, enhancing human security throughout the Sahel and Sahara;

98. Reaffirms its support for the UN resolutions on Western Sahara; calls for full respect for the human rights and fundamental freedoms of Sahrawi people, including freedom of association, freedom of expression and the right to demonstrate peacefully;

99. Emphasises the need for human rights in Western Sahara and in the Tindouf camps to be addressed, even without anticipating any final political settlement or expressing a view on such a settlement; reiterates, nevertheless, that self-determination is a fundamental human right, as specified by Article 1 of the UN International Covenant on Civil and Political Rights and that territorial integrity is a principle enshrined in international law; recalls, moreover, UN Security Council Resolution 1754(2007), urging the parties to enter into negotiations in good faith, without preconditions, 'with a view to achieving a just, lasting and mutually acceptable political solution, which would provide for the self-determination of the people of Western Sahara; echoes this call to Morocco and the Polisario Front to continue negotiations for a peaceful solution to the conflict, reaffirming the rights of the Sahrawi people to self-determination; stresses the opportunity deriving from the political and democratic reforms undertaken in Morocco, while taking note of the stronger obligations necessitated by these reforms to respect and uphold human rights in Western Sahara in particular; fears that the 25-year delay in arranging a referendum, or reaching any other form of mutually acceptable negotiated political settlement, is increasing Sahrawi alienation and the potential for violence, particularly amongst the young; calls on the EU to become more closely involved and to support the United Nations in its efforts to encourage the parties to resume direct negotiations with a view to securing a peaceful and lasting resolution of the conflict;

100. Calls on the Commission and Member States — considering that the political solution to the Western Sahara conflict, reconciliation and the human rights situation are closely linked — to be more active in the resolution of the Western Sahara conflict, not only supporting the UN negotiations but also using its various external policy instruments (for example strengthening human rights monitoring and awareness among police and security forces, supporting democratic reforms, including decentralisation, fighting discrimination in the region) to promote much needed confidence building between the conflict parties;

101. Expresses deep concern at the recent report from the UNSR on Torture, who found evidence that Moroccan officials have detained individuals on political grounds, subjected Sahrawi inmates to torture and rape, kidnapped and abandoned protesters in the desert in order to intimidate them, and deliberately and frequently targeted pro-independence advocates, including in their homes; notes further widespread allegations of forced disappearances and unfair trials; draws particular attention to the dismantling of the Gdeim Izik protest camp in November 2010, where significant violence

**Tuesday 22 October 2013**

claimed thirteen lives, and the subsequent trial of 25 Sahrawis, many of whom were known human rights activists, in February 2013; notes Morocco's insistence regarding the trial's fairness and due process, and the positive conclusions of some international observers, but also recalls the UNSR's concern at the use of a military court, the allegations of torture and the failure on the part of the Moroccan authorities to investigate these allegations; notes the conclusions by some NGOs and human rights observers relating to the case's alleged politicised prosecutions, deficient evidence and excessive sentences, with twenty individuals having been sentenced to between twenty years and life imprisonment; welcomes, therefore, the Moroccan Government's endorsement of the National Council for Human Rights' (CNDH) recommendation that civilians should not be tried by military tribunals in the future; urges the Moroccan Government to guarantee that this becomes a reality; regrets, at the same time, that this decision will not affect those already convicted; urges, moreover, the Moroccan Government to implement all of the recommendations made in UN and CNDH reports, and to continue developing a human rights culture; calls, in this connection, on the Moroccan authorities to release immediately all Sahrawi political prisoners, to work with civil society and other actors to guarantee the transparency and fairness of its judicial processes, and to investigate and prosecute security officials alleged to have been involved in arbitrary detentions, torture and other abuses of power;

102. Condemns the human rights abuses, principally involving harassment and sexual violence, inflicted on Sahrawi women;

103. Reiterates the concerns of the unofficially leaked 2006 OHCHR report, about restrictions on freedom of speech, assembly and association in Western Sahara; notes Morocco's claim to allow sit-in demonstrations and other forms of protest; regrets Morocco's apparent institutional obstruction of NGOs advocating a pro-independence position by preventing their legal registration and recognition, which is necessary to advocate effectively in their communities; condemns the often severe punishments for 'undermining Moroccan territorial integrity', an item of legislation reportedly used to target Sahrawis peacefully advocating independence; recalls the findings of the UN Independent Expert on cultural rights that the Moroccan authorities suppress certain aspects of Sahrawi culture; repeats the UN Independent Expert's call to overturn such measures and to promote full cultural diversity; notes positively, in this connection, the provisions on respect for cultural rights that have been included in the new Moroccan constitution; welcomes the setting-up of a dedicated Sahrawi television station; encourages strongly the full implementation of these provisions;

104. Regrets deeply the fact that on Wednesday, 6 March 2013 Morocco expelled a delegation of four Members of the European Parliament; notes that the aim of the delegation was to visit the territories of Western Sahara, to inquire about the situation of human rights and to meet with representatives of the MINURSO; regrets deeply the behaviour of the Moroccan authorities and demands that the Kingdom of Morocco permit free access and free movement in Western Sahara to independent observers, members of parliaments, to the press and to humanitarian organisations;

105. Recalls the concerns of the UN Office for Project Services (UNOPS) that Western Sahara remains one of the world's most-mined areas; notes that landmines in Western Sahara have tragically caused at least 2 500 casualties since 1975, continuing to threaten many thousands of Sahrawi nomads, and representing a major obstacle to the resolution of the Western Saharan dispute and refugee situation; commends, therefore, the work of MINURSO, the Royal Moroccan Army, the Polisario Front, Landmine Action, and others to map and clear affected areas; welcomes the fact that the Polisario Front has signed the Geneva Call on the prohibition of anti-personnel mines; encourages all actors to do everything possible to educate the population, assist victims and remove all remaining munitions; notes, furthermore, that Morocco is one of the few countries — and one of only three African countries — not to have signed up to the Mine Ban Treaty; encourages it to do so as a confidence-building measure and a sign of commitment to peace;

106. Highlights the case of Sahrawi women and their important role in Sahrawi society, particularly in the refugee camps, where illiteracy has decreased sharply; emphasises the crucial role of women in organising Sahrawi institutions and

Tuesday 22 October 2013

their high level of participation in decision-making at all levels, from local committees to parliament and government; draws attention to the role played by the women of Western Sahara in peace-keeping, in promoting dialogue and conflict resolution, and in maintaining Sahrawi society and structures;

107. Expresses concern about the poverty and lack of basic services in the Polisario Front-administered refugee camps near Tindouf, particularly with regard to nutrition, healthcare and access to potable water; welcomes the humanitarian assistance provided by the EU through ECHO to the refugees concerned; calls, nevertheless, for international actors to channel, co-ordinate and consolidate aid more effectively and, where appropriate, to increase the amount of aid in order to guarantee the stability of the humanitarian situation and help improve the conditions in the camps; echoes the recommendations of the UNSR on adequate housing that sufficient international funding be directed at the provision of housing; notes, nevertheless, the functioning systems of governance in the camps and welcomes the active presence of civil society, with the strong participation of women within both; welcomes, furthermore, the social emphasis on education, in spite of scarce resources; notes, however, the lack of clear documentation about the precise number of inhabitants in the camps; calls upon the Polisario authorities, with the assistance of Algeria where appropriate, to conduct or facilitate regular censuses or formal registrations;

108. Expresses concern that the poverty in the Tindouf camps, coupled with the absence of long-term prospects for many refugees, leaves them vulnerable to radicalisation along religious fundamentalist lines; points to the danger of young people being recruited by criminal or terrorist organisations and draws attention to the region's porous borders, which risk facilitating deeper infiltration of the camps by jihadi groups from northern Mali and elsewhere; condemns the kidnapping of three European aid workers from the Rabouni camp in October 2011; stresses, therefore, the paramount importance of ensuring the safety and security of the camps; calls on the Algerian authorities to act upon its responsibility to alleviate the human rights situation in Tindouf camps; expresses full support for the UNHCR programme aimed at fostering confidence-building by facilitating family exchanges between Tindouf and Western Sahara;

109. Notes that while most international observers and reports from the OHCHR, the African Commission on Human and Peoples' Rights, the Robert F. Kennedy Center for Justice and Human Rights, and Human Rights Watch, have identified little evidence of systemic and institutional human rights violations in the camps, multiple actors, including the Moroccan Government, Moroccan NGOs and some former inhabitants of the Tindouf camps, have alleged that the Polisario authorities restrict inhabitants' freedom of expression and freedom of movement; notes Polisario's vigorous denials of these accusations and its willingness to cooperate with UN human rights agencies; calls, therefore, on Polisario to allow independent human rights observers full, regular and unfettered access to the camps, and for any allegations to be rigorously investigated;

110. Welcomes efforts to improve the documentation of alleged human rights abuses in Western Sahara, in particular through the institution of the CNDH, with offices in Laayoune and Dakhla, as recognised by the UN; notes the positive work of the CNDH and calls on the Moroccan Government to help strengthen its independence and remit, and to ensure the implementation of its recommendations; encourages, moreover, the CNDH to increase its efforts to build relationships with those Sahrawis who are hostile to Moroccan rule and to guarantee adequate follow-up to complaints; welcomes Morocco's adoption in 2012 of three of the five UN Human Rights Council recommendations on the human rights situation in Western Sahara, and calls on it to adopt the remaining two; welcomes, furthermore, Moroccan invitations to ad-hoc international delegations, including the UNSR on torture, and the fact that those invitations were accepted; urges the Moroccan authorities to give authorisation for fact-finding missions to be conducted by other international organisations, such as the African Commission on Human and Peoples' Rights and the European Parliament; urges all relevant parties to continue such engagement with UN human rights bodies; supports the creation of an official MINURSO-ICRC mission in the area of Fadret Leguiaa in order to proceed with the exhumation and the restitution of remains to families, following the discovery of common graves by the investigation team of the University of the Basque Country;

111. Notes, nevertheless, the serious and contested allegations against both the Moroccan and Polisario administrations; recalls also the UN Secretary-General's recent emphasis on 'independent, impartial, comprehensive and sustained monitoring of the human rights situation in both Western Sahara and the camps'; notes, in this connection, that the UN did not upgrade the mandate of MINURSO in April 2013 to incorporate a human rights dimension; encourages the UN to do

**Tuesday 22 October 2013**

so, or else to establish a new, permanent, impartial human rights body for the purpose of supervising and reporting on the overall situation of human rights, and investigating individual complaints; calls on such a body to encompass the Moroccan-controlled section of Western Sahara, the Tindouf camps, and other territory controlled by the Polisario Front;

112. Encourages the governments of Morocco and Algeria to develop and enhance their political dialogue to improve regional dynamics and avoid increasing tensions, and for the benefit of the wider international community;

113. Urges the VP/HR and the EUSR for Human Rights to offer the Moroccan authorities and the Polisario administration human rights training programmes in Western Sahara and in Tindouf, which would target police and other security agents, the judiciary, local administration officers, media and civil society organisations, building on the political reforms towards democracy, the rule of law and human rights initiated by Morocco, and without prejudice to a negotiated political settlement on the Western Sahara conflict but aiming at encouraging such a negotiation;

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114. Instructs its President to forward this resolution to the Council, the Commission, the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy, the EUSR for Human Rights and the EUSR for the Sahel, the EU Member States, the governments and parliaments of the Sahel countries, Morocco, Algeria, and the Polisario Front, the UN Secretary-General and Security Council, the UN High Commissioner for Human Rights, the AU Chair and Secretary-General of the Commission, and the ECOWAS Chair and President of the Commission;

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Tuesday 22 October 2013

P7\_TA(2013)0432

**Local authorities and civil society****European Parliament resolution of 22 October 2013 on local authorities and civil society: Europe's engagement in support of sustainable development (2012/2288(INI))**

(2016/C 208/02)

*The European Parliament,*

- having regard to Title V of the Treaty on European Union and, in particular, Article 21(2) thereof, establishing the principles and objectives of the EU in international relations, and Article 208(2) of the Treaty on the Functioning of the European Union,
- having regard to Articles 16, 18, and 87 of the joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, Parliament and the Commission on EU development policy: 'The European Consensus' <sup>(1)</sup>,
- having regard to the European Consensus on Humanitarian Aid,
- having regard to the UN Declaration on the Right to Development (41/128),
- having regard to the United Nations Millennium Declaration which established the Millennium Goals framework,
- having regard to the ACP-EC Partnership Agreement (the Cotonou Agreement),
- having regard to the proposal for a regulation of the European Parliament and of the Council establishing a financing instrument for development cooperation (SEC(2011)1469 and SEC(2011)1470),
- having regard to the European Charter on Development Cooperation in Support of Local Governance launched during the European Development Days on 16 November 2008,
- having regard to the Commission Communication entitled 'Increasing the Impact of EU Development Policy: An agenda for change' (COM(2011)0637),
- having regard to its resolution of 5 July 2011 on increasing the impact of EU development policy <sup>(2)</sup>,
- having regard to the Commission Communication entitled 'The Future Approach to EU Budget Support to Third Countries' (COM(2011)0638),
- having regard to the Commission Communication entitled 'The Roots of Democracy and Sustainable Development: Europe's engagement with civil society in external relations' (COM(2012)0492),
- having regard to the Council Conclusions of 15 October 2012 on 'The Roots of Democracy and Sustainable Development: Europe's engagement with civil society in external relations' (doc. 14535/12),
- having regard to the Council conclusions on EU Support for Sustainable Change in Transition Societies, adopted at the 3218th Foreign Affairs Council meeting of 31 January 2013,
- having regard to the Commission Communication of 15 May 2013 entitled 'Empowering Local Authorities in partner countries for enhanced governance and more effective development outcomes' (COM(2013)0280),
- having regard to the Commission Communication of 27 February 2013 entitled "A decent life for all: Ending poverty and giving the world a sustainable future" (COM(2013)0092),
- having regard to the international commitments under the 2011 Busan partnership on effective development cooperation,

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<sup>(1)</sup> OJ C 46, 24.2.2006, p. 1.

<sup>(2)</sup> OJ C 33 E, 5.2.2013, p. 77.

**Tuesday 22 October 2013**

- having regard to the Council conclusions of 22 July 2013 concerning local authorities in development cooperation (doc. 12584/13),
  - having regard to the opinion of the Committee of the Regions on “Empowering Local Authorities in partner countries for enhanced governance and more effective development outcomes” (CdR 2010/2013),
  - having regard to its declaration of 5 July 2012 on ‘development education and active global citizenship’ <sup>(1)</sup>,
  - having regard to the Commission staff working document entitled ‘Development Education and Awareness Raising (DEAR) in Europe’ (SWD(2012)0457),
  - having regard to the study on ‘The experience and actions of the main European actors active in the field of development education and awareness raising’ of November 2010 <sup>(2)</sup>,
  - having regard to the concluding paper of the Structured Dialogue Initiative, May 2011 <sup>(3)</sup>,
  - having regard to ‘the Lisbon Statement for Improving and Increasing Global Education in Europe to the Year 2015’ <sup>(4)</sup>,
  - having regard to the consultation on ‘Civil society organisations in development cooperation’ and the consultation on ‘Local Authorities in development’,
  - having regard to the DAC-OECD peer review of the European Union of 2012,
  - having regard to the ‘Thematic global evaluation of the Commission support to decentralisation processes’ <sup>(5)</sup> of February 2012,
  - having regard to its resolution of 15 March 2007 on local authorities and development cooperation <sup>(6)</sup>,
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Development (A7-0296/2013),
- A. whereas Article 208 of the Treaty on the Functioning of the European Union (TFEU) establishes the reduction and, in the long term, the eradication of poverty, as defined in the European Consensus on Development (ECD), as the primary objective of EU development policy;
- B. whereas the ECD remains the doctrinal framework for EU development policy;
- C. whereas the EU has a strong political commitment to promoting an enabling environment for civil society organisations (CSOs) at national level as well as at regional and international levels, and whereas the EU recognises that an empowered civil society, in all its diversity, is important in its own right and represents a crucial and integral component of any democracy;
- D. whereas the EU has a strong political commitment to implementing a Human Rights-Based Approach (HRBA) in development and whereas the UN statement on a common understanding of a Human Rights-Based Approach to Development Cooperation establishes that ‘all programmes of development co-operation, policies and technical assistance should further the realisation of human rights as laid down in the Universal Declaration of Human Rights and other international human rights instruments’;

<sup>(1)</sup> Texts adopted, P7\_TA(2012)0302.

<sup>(2)</sup> [https://webgate.ec.europa.eu/fpfis/mwikis/aidco/images/d/d4/Final\\_Report\\_DEAR\\_Study.pdf](https://webgate.ec.europa.eu/fpfis/mwikis/aidco/images/d/d4/Final_Report_DEAR_Study.pdf).

<sup>(3)</sup> [https://webgate.ec.europa.eu/fpfis/mwikis/aidco/images/e/ea/FINAL\\_CONCLUDING\\_PAPER.pdf](https://webgate.ec.europa.eu/fpfis/mwikis/aidco/images/e/ea/FINAL_CONCLUDING_PAPER.pdf).

<sup>(4)</sup> [http://www.gecongress2012.org/images/2012\\_GE\\_Congress\\_Report\\_FINAL\\_11feb201.pdf](http://www.gecongress2012.org/images/2012_GE_Congress_Report_FINAL_11feb201.pdf) (p. 27-31).

<sup>(5)</sup> [http://ec.europa.eu/europeaid/how/evaluation/evaluation\\_reports/2012/1300\\_docs\\_en.htm](http://ec.europa.eu/europeaid/how/evaluation/evaluation_reports/2012/1300_docs_en.htm).

<sup>(6)</sup> OJ C 301 E, 13.12.2007, p. 249.

Tuesday 22 October 2013

- E. whereas democratic ownership includes not only governments but also CSOs, local authorities (LAs) and national parliaments, which play crucial roles in linking citizens with government and in ensuring broad-based and democratic ownership of countries' development agendas;
- F. whereas domestic accountability includes the oversight role of CSOs, which are key actors in fighting corruption and promoting transparency;
- G. whereas the OECD-DAC report recommends that 'The EU institutions and bodies should pursue efforts to involve a broader range of civil society stakeholders in a strategic, structured dialogue. They should become more efficient in building civil society capacity in partner countries; instruments will need to be revised for this';
- H. whereas a legitimate post-2015 framework requires civil society and individuals — particularly the most marginalised — to be able to participate fully in decision-making processes and in monitoring and reporting on progress made;
- I. whereas the results of the public consultation on 'Local authorities in development' pointed out the link between local democratic governance, decentralisation, and territorial development;
- J. whereas territorial development (TD) has been defined as the interaction between multiple stakeholders and multilevel governance which aims at investing in local territorial assets (human, financial, physical and natural resources) to strengthen the territory's competitive advantages and raise living standards;
- K. whereas strong, transparent and needs-oriented CSOs and LAs and inclusive local governance actions are essential core issues of democracy and the peace-building process;
- L. whereas LAs from new Member States need to exchange knowledge with old Member States on development cooperation practices in order to overcome the gap in terms of expertise, and in order for the old Member States to profit from the new Member States' experience of transition and structural transformations, which is a valuable tool in the global development framework;
- M. whereas CSOs and LAs are crucial in ensuring sustainable and inclusive growth, environmental sustainability, human rights and good governance in the post-2015 development agenda;
- N. whereas equitable and long-term partnerships between EU CSOs and their counterparts in developing countries have proven to be an important tool for the development of strong, independent and diversified CSO and CS initiatives on different scales and at different levels, from local to international;

#### ***An enabling environment for CSOs and LAs***

1. Welcomes the recent policy developments at EU and international level which are focused on a more ambitious partnership with CSOs and LAs, founded on a human rights-based approach to development, including economic, social and cultural rights as well as international treaties on environment and biodiversity protection, and the clear commitment to strengthening the democratic process and accountability;
2. Underlines that creating accountable, human rights-based, and inclusive relations among governments, LAs, CSOs, the private sector and citizens offers a unique opportunity for the EU, including its citizens, LAs and the private sector to establish sustainable partnerships with developing countries;
3. Calls on the EC and the European External Action Service (EEAS) to develop guidance and implementation plans for a HRBA to EU development cooperation in dialogue with CSOs and to further the implementation of the European Union Guidelines on Human Rights Defenders;

**Tuesday 22 October 2013**

4. Calls on the Commission and the EEAS to mainstream the promotion of an enabling environment for CSOs and LAs and to consider this a priority for the EU's position in the ongoing negotiations on the post-2015 development framework; stresses the importance of defining a monitoring system which permits the evaluation of progress in the creation of an enabling environment at national level in terms of policy and regulatory provisions, in line with international human rights standards, as well as multiple stakeholder and multilevel dialogues; calls on the Commission to measure the enabling environment in order to fully appreciate its complexity and the characteristics of civil society actors;
5. Expresses great concern at the crackdown on CSOs cooperating with EU partners in a number of countries and calls on the Commission and the EEAS to develop strategies on how to overcome these difficulties and to continue the vital support for CSOs;
6. Encourages the EU to promote institutionalised mechanisms for multilevel and multiple stakeholder dialogue among CSOs, LAs, the private sector and partner governments on decent work agendas, sustainable and inclusive growth with redistribution of revenue through the state budget, and on the issue of the enabling environment for both CSOs and LAs; recommends that for each partner country the EU applies the provisions on consultations with LAs provided for in the Cotonou Agreement for ACP states;
7. Encourages the EU to systematically involve women's organisations and networks in the preparation and, possibly, the implementation of policy dialogue, in line with the commitments made under the EU Gender Action Plan for Development;
8. Expresses appreciation for the Policy Forum on Development, which aims to create a space for dialogue with CSOs and LAs in policy discussions and encourages all stakeholders involved to make it a strategic space for guiding and influencing policymaking at EU and international level on development issues, including policy coherence for development (PCD);

#### ***Development effectiveness***

9. Calls on the Commission and the EEAS to allocate adequate resources in the future programming period, to allow CSOs and LAs from partner countries to monitor and analyse progress towards PCD at local, national and international level;
10. Calls on the Commission and the EEAS to promote a 'partnership for accountability' for strategic cooperation between elected representatives at national and local level and CSOs which is based on transparency regarding official and non-official aid flows, as well as a participatory approach to development and accountability, including domestic social accountability and oversight, with a view to measuring policy impact;
11. Stresses the important role that local authorities and civil society organisations can play in fighting corruption at all levels, including tax evasion and illicit financial flows from developing countries;
12. Calls on the Commission to support the inclusion of LA representatives in the Steering Committee of the Global Partnership for Effective Development Cooperation;
13. Believes that PCD must be the guiding principle of any EU cooperation with local authorities which aims to develop the local economy in order to provide decent livelihoods for people at community level,
14. Recalls that all development actors should be accountable for their development efforts and results, and should promote the accountability of each other;
15. Calls on the Commission to promote a balanced approach between the principle of harmonisation and the right of initiative of CSOs and LAs; reminds the Commission that simplification and harmonisation of donor administrative procedures should be done in dialogue with CSOs and LAs;

Tuesday 22 October 2013

16. Welcomes the Commission's proposal to draft road maps (RMs) for engagement with CSOs aiming to identify a global strategy for CSO inclusion in all forms of European cooperation; calls on the Commission to clarify how CSOs can contribute meaningfully to the process and to ensure that their participation is timely and significantly taken into account in the drafting phase and that priorities are jointly defined;
17. Encourages the Commission to establish country RMs for LAs as well, and to consider the development of joint CSO and LA country RMs;
18. Calls on the Commission to consider PCD as a key element of future RMs;
19. Calls on the Commission to adopt the sustainable development agenda, taking account of the fact that its three core components (environmental, social and economic) are equally important and inseparable parameters;
20. Recalls the importance of the partnership between LAs from European and partner countries in achieving sustainable development; in this context urges the EU to make efficient use of knowledge-sharing and capacity-development methods, including the use of the transition experience of LAs in EU Member States;
21. Encourages the EU to adopt a scaled-up agenda with a view to achieving a proportional increase in the effective experiences of projects and initiatives of both CSOs and LAs financed by the EU;

#### ***Decentralisation and territorial approach to development (TAD)***

22. Calls on the Commission and the EEAS to establish a more ambitious policy dialogue with and within partner countries to promote TAD and a comprehensive approach to decentralisation, and to give priority in the future programming period to strengthening the capacity of LAs and CSOs to influence and monitor decentralisation reform processes;
23. Recalls that an effective decentralisation process requires public sector reforms, such as the transfer of power, functions, and resources, as well as the active participation of citizens, through their representatives, and CSOs in participatory planning and budgeting; calls on the Commission to take due account of decentralisation and TAD in its support to public sector-wide reforms and to make them a cross-cutting priority in all geographic programmes;
24. Stresses that sustainable TAD needs as its basis an accountable, transparent and well- functioning decentralisation process; recommends that the EU consider TAD and decentralisation as important factors in achieving poverty eradication in the future post-MDGs development agenda;
25. Recalls that TAD is contributing to development effectiveness through strengthening ownership, multi-stakeholders and multi-actors dialogues and programmes and policy coordination at the sub-national level; calls on the Commission to launch pilot initiatives to support TAD through geographic and thematic programmes;
26. Recalls the added-value of decentralised cooperation in promoting both TAD and decentralisation; stresses that European LAs are very well placed to cooperate with their counterparts in the process of decentralisation, notably fiscal decentralisation;
27. Stresses the importance of strengthening EU staff expertise and commitment, in particular at delegation level, on decentralisation and on the role of CSOs and LAs in sustainable development, including on how to coordinate with CSOs, and encourages the participation of civil society organisations, including women's organisations, in order to add a gender perspective to those processes;

Tuesday 22 October 2013

### ***Fragile States***

28. Stresses that the EU should engage with partner countries, in the context of the New Deal for Fragile States, to elaborate, as part of wider development strategies, national resilience strategies and specific programmes that aim to address the underlying causes of long-term vulnerability, including community-based and participatory risk analysis, management tools and in-depth research about the drivers of conflict or fragility, taking into account the views and perceptions of directly affected local people;

29. Recalls that resilience should also be a key theme of the EU's partnerships with CSOs and LAs; recalls that it is essential to strengthen the role of both communities, through community-owned and -led risk reduction activities, and LAs in fragile states, and to work closely with them in crisis and post-crisis situations; encourages LA partnerships in fragile states to provide for the development, transfer and exchange of administrative and technical skills;

30. Recalls that local elected representatives regularly act as mediators between antagonistic parties and in that regard assume an important role in conflict prevention and resolution;

31. Calls on the EC and the EEAS to establish guidelines for EU delegations on how to deal with CSOs and LAs in situations of crisis and fragility, using a human rights-based and gender-sensitive approach;

32. Stresses that in contexts where public authorities, local and regional authorities included, do not have the capacity to provide basic services, and where circumstances allow it, the Commission should support multi-actor partnerships to develop LA capacities so that they are able to provide services;

33. Expresses deep concern at the Commission's proposal to limit financial support in service delivery only to CSOs working in LDCs and fragile states; recalls that the key added value of CSOs in all countries, whatever their level of development, is their capacity to interpret the needs and rights of poor and marginalised groups and to provide innovative solutions for their benefit, while raising awareness and political support for addressing the root causes of poverty, inequality and exclusion;

### ***Development education and awareness raising (DEAR)***

34. Recalls that Parliament's written declaration on 'development education and active global citizenship' calls for a European strategy on DEAR which should be more focused on a critical reflection about development policy and, in particular, on PCD;

35. Calls on the Commission to develop an overarching DEAR strategy in close collaboration with CSOs to increase the financial resources which will be allocated in the future programming period to DEAR, and to develop, in close consultation with CSOs and LAs active on DEAR, flexible funding modalities that respect their right of initiative and allow the participation of a wide and diversified range of actors;

### ***Programming documents and aid modalities***

36. Welcomes the Commission's engagement to systematically introduce political economy analysis at country level and recommends that this include an analysis of the political and legal situation of CSOs and LAs;

37. Is of the view that tax revenues are essential for local economic development and considers that priority should be given to putting in place effective and viable tax collection systems to ensure a sustainable source of development financing;

Tuesday 22 October 2013

38. Calls on the Commission to improve the coordination and complementarity between thematic and geographic programmes and instruments; recalls that CSOs and LAs should be considered a key implementing partner in particular in the Global Public Good programme and should be consulted at an early stage on the programming of both geographic and thematic programmes;

39. Recalls that LAs are eligible in all DCI programmes, and calls on the Commission and LAs representative organisations to encourage a wider participation of LAs in all DCI programmes;

40. Calls on the Commission to continue its support of decentralised cooperation and partnerships between LAs from EU and partner countries; these partnerships have proven to be efficient tools in the reinforcement of the capacity of LAs in key sectors which contribute to poverty eradication; at the same time and for the same reason, calls on the Commission to continue its support of cooperation between CSOs from European and partner countries;

41. Calls on the Commission to facilitate experience- and expertise-sharing between LAs from EU and partner countries in order to provide access to knowledge on relevant areas of sustainable development, especially good governance, capitalising on the transition experience of LAs in EU Member States;

42. Calls on the Commission to engage in more strategic partnerships with national, regional, and international associations and networks of LAs;

43. Encourages the Commission to further develop a mix of more flexible, transparent and predictable funding modalities to reach the broadest possible range of civil society actors; asks the Commission to identify and develop these modalities through an inclusive dialogue with CSOs and LA associations, building on the Structured Dialogue;

44. Calls on the Commission to promote the participation of CSOs and LAs in the ongoing discussion on blending mechanisms in the framework of the EU Platform for Blending in External Cooperation; asks the Commission to draft guidelines and create inclusive impact assessment and monitoring mechanisms to ensure that concerned populations are consulted at and participate in all stages of the project cycle and that blending contributes to poverty eradication;

45. Calls also on the Commission to allow CSOs to participate in all new forms of cooperation under the EU Platform for Blending in External Cooperation;

46. Asks the Commission to strengthen national decentralisation reforms in the elaboration and implementation of good governance and development contracts, sector reform contracts, and state building contracts;

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47. Instructs its President to forward this resolution to the Council and the Commission.

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Tuesday 22 October 2013

P7\_TA(2013)0433

## Rethinking education

### European Parliament resolution of 22 October 2013 on Rethinking Education (2013/2041(INI))

(2016/C 208/03)

*The European Parliament,*

- having regard to Articles 165 and 166 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to the Commission Communication of 20 November 2012 entitled ‘Rethinking Education: Investing in skills for better socio-economic outcomes’ (COM(2012)0669),
- having regard to the Commission Communication of 28 November 2012 entitled ‘Annual Growth Survey 2013’ (COM(2012)0750),
- having regard to Council conclusions of 15 February 2013 on investing in education and training — a response to ‘Rethinking Education: Investing in skills for better socio-economic outcomes’ and the 2013 Annual Growth Survey,
- having regard to the Commission Communication of 23 November 2011 on the proposal for a regulation of the European Parliament and of the Council establishing ‘ERASMUS For All’ — The Union programme for Education, Training, Youth and Sport (COM(2011)0788),
- having regard to the Commission Communication of 10 September 2012 on a Draft 2012 Joint Report of the Council and the Commission on the implementation of the renewed framework for European cooperation in the youth field (EU Youth Strategy 2010-2018) (COM(2012)0495), and the corresponding Commission staff working document (SWD(2012)0256),
- having regard to Council conclusions of 26 November 2012 on education and training in Europe 2020 — the contribution of education and training to economic recovery, growth and jobs <sup>(1)</sup>,
- having regard to the Commission Communication of 20 December 2011 entitled ‘Education and Training in a smart, sustainable and inclusive Europe’ (COM(2011)0902),
- having regard to the Commission Communication of 3 March 2010 on ‘Europe 2020: A strategy for smart, sustainable and inclusive growth’ (COM(2010)2020),
- having regard to the Council conclusions of 11 May 2010 on the social dimension of education and training <sup>(2)</sup>,
- having regard to the Council Resolution of 28 November 2011 on a renewed European agenda for adult learning <sup>(3)</sup>,
- having regard to the Council conclusions of 12 May 2009 on a strategic framework for European cooperation in education and training (ET 2020) <sup>(4)</sup>,
- having regard to the Council recommendation of 20 December 2012 on the validation of non-formal and informal learning <sup>(5)</sup>,

<sup>(1)</sup> OJ C 393, 19.12.2012, p. 5.

<sup>(2)</sup> OJ C 135, 26.5.2010, p. 2.

<sup>(3)</sup> OJ C 372, 20.12.2011, p. 1.

<sup>(4)</sup> OJ C 119, 28.5.2009, p. 2.

<sup>(5)</sup> OJ C 398, 22.12.2012, p. 1.

Tuesday 22 October 2013

- having regard to its resolution of 1 December 2011 on tackling early school leaving <sup>(1)</sup>,
  - having regard to its resolution of 12 May 2011 on early years learning in the European Union <sup>(2)</sup>,
  - having regard to its resolution of 12 May 2011 on ‘Youth on the move — a framework for improving Europe’s education and training systems’ <sup>(3)</sup>,
  - having regard to its resolution of 18 May 2010 on key competences for a changing world: implementation of the Education and Training 2010 work programme <sup>(4)</sup>,
  - having regard to its resolution of 18 December 2008 on delivering lifelong learning for knowledge, creativity and innovation — implementation of the Education and Training 2010 work programme’ <sup>(5)</sup>,
  - having regard to the opinion of the Committee of the Regions of 12 April 2013 on Rethinking Education <sup>(6)</sup>,
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Culture and Education and the opinion of the Committee on Employment and Social Affairs (A7-0314/2013),
- A. whereas one of the Europe 2020 headline targets is to reduce the share of early school-leavers to less than 10 % and to increase the share of the younger generation with a third-level education degree or proper professional training to at least 40 %;
- B. whereas the Education and Training Strategic Framework 2020 (ET 2020) includes benchmarks for at least 95 % of children between the age of four and the age for starting compulsory primary education participating in early childhood education; for the share of 15 year olds with insufficient abilities in reading, mathematics and science being less than 15 %; for an average of at least 15 % of adults (aged between 25 and 64 years) participating in lifelong learning;
- C. whereas one of the EU’s main priorities is to promote mobility, and whereas a target of ensuring that 20 % of EU graduates have spent part of their time at university abroad has been set for 2020; whereas student, teacher and worker mobility plays a key role in European integration;
- D. whereas youth mobility programmes for the 2014-2020 period should provide genuine opportunities to gain knowledge and new skills, thereby helping to increase youth employment rates;
- E. whereas in its Annual Growth Survey 2013, the Commission calls for promoting growth and competitiveness and tackling unemployment and the social consequences of the crisis through sound investment in education and training;
- F. whereas in March 2013, the unemployment rate among young people up to the age of 25 in the EU was 23,5 %, while at the same time more than two million vacancies could not be filled; whereas in several Member States, the number of unemployed and the duration of unemployment is increasing, and matching on the labour market is becoming less efficient;
- G. whereas the persisting economic crisis and austerity measures aimed at fiscal consolidation in several Member States place the lives of EU citizens under heavy pressure due to unemployment, social exclusion and poverty; whereas the impact of the crisis, particularly on young people, is leading in extreme cases to instances of malnutrition or mental health problems; whereas especially in those Member States with more fragile economies, budget cuts in education have made access more difficult and undermined teaching standards;

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<sup>(1)</sup> OJ C 165 E, 11.6.2013, p. 7.

<sup>(2)</sup> OJ C 377 E, 7.12.2012, p. 89.

<sup>(3)</sup> OJ C 377 E, 7.12.2012, p. 77.

<sup>(4)</sup> OJ C 161 E, 31.5.2011, p. 8.

<sup>(5)</sup> OJ C 45 E, 23.2.2010, p. 33.

<sup>(6)</sup> OJ C 139, 17.5.2013, p. 51.

**Tuesday 22 October 2013**

- H. whereas the crisis and austerity policies are having a direct adverse impact on young peoples' prospects for gaining access to and remaining in education and employment; whereas education spending is an investment in the future and should therefore be shielded from austerity measures;
- I. whereas young people face increasing difficulties in their transition from education to work, and the lack of formal interaction between education institutions and the labour market increases the risk of high unemployment; whereas high-quality vocational training is dependent on close cooperation between the public and private sectors, with a high degree of involvement by social partners;
- J. whereas accessible, flexible and high-quality education and training have a crucial impact on the personal development and fulfilment of young learners, also promoting their active citizenship and wellbeing, and enhancing their ability to adjust and contribute to society and the world of work; whereas economic and social problems are increasing euroscepticism among citizens;
- K. whereas school bullying undermines young people's well-being and leads to under-achievement and early school leaving;
- L. whereas open educational resources (OER) improve the quality, accessibility and equity of education and facilitate an interactive, creative, flexible and personalised learning process through the use of ICT and new technologies; whereas open education enhances sustained employability by supporting lifelong learning;
- M. whereas, despite high overall levels of youth unemployment, certain sectors such as information and communications technology (ICT) and health care have increasing difficulty in filling vacancies with qualified personnel; whereas an increasing gap between the qualifications of graduates and the skills requirements of the labour market can be observed in some Member States;
- N. whereas labour market needs are changing fast; whereas it is necessary to aspire to a quality education and individual development, and to examine closely future trends in labour market needs in order to adapt and modernise educational and training curricula so as to meet the need to provide a core of basic knowledge and lifelong learning strategies, and to offer the right skills for the right jobs, such as the use of new technologies and social networks, without detracting from the academic goal of passing on knowledge; whereas, as education models change, the teaching profession needs to adapt accordingly, in terms of skills and qualifications, and status and careers, for example;
- O. whereas skills, technology and jobs are changing rapidly and everyone will be obliged to adapt several times to new technologies throughout the course of their working lives, and must therefore have a core of basic knowledge that is sufficiently robust to enable them to do so;
- P. whereas the stimulation of economic growth, productivity and comprehensiveness at national level has proven to have an immense impact on the jobs market, with an increase in the number and quality of jobs being created, along with better integration of young people into the labour market;

### ***General observations***

1. Welcomes the Commission communication, in particular its strong focus on combating youth unemployment through investing in skills, calling for the modernisation of higher education systems, as well as promoting world-class vocational education and training (VET), flexible learning pathways, including through the promotion of OER, work-based learning and the involvement of social partners in their design; welcomes, furthermore, actions to address the shortages of well-qualified teachers and trainers, such as more effective teacher recruitment and retention, and professional support;
2. Considers the role of education to be much broader than just fulfilling the economic targets of European and national strategies; reaffirms, in this connection, the primary mission of education as being the preparation of individuals for life as well as for being active citizens in increasingly complex societies;
3. Notes that as a result of the economic and financial crisis, many families can no longer afford to pay for higher education, a fact which has led to an increase in drop-out rates at this level; considers that Member States should uphold the right of all persons, whatever their economic circumstances, to free and universal education of high quality;

Tuesday 22 October 2013

4. Recalls that increased language competences contribute to fostering mobility and improving employability, people's understanding of other cultures and intercultural relations; fully supports the Commission's proposal for a new EU benchmark on language competences, according to which at least 50 % of 15 year olds should have knowledge of a first foreign language and at least 75 % should study a second foreign language by 2020;
5. Acknowledges that poor language skills constitute a major obstacle to the free movement of workers and to the international competitiveness of enterprises in the Union, particularly in areas where European citizens live close to the border of a neighbouring country with a different language; recalls that language learning is deemed to be much more effective at an early age;
6. Insists that student mobility be guaranteed, with a view to broadening students' knowledge of languages and communications skills, which are prerequisites for their adaptation to the common labour market in the EU;
7. Calls for a holistic approach to education and training which addresses both academic and vocational aspects and recalls that the broader mission of education should be recognised with regard to personal growth and development; urges further support of the acquisition and recognition of competences based on non-formal and informal learning, and highlights the role of such learning as part of an overall lifelong learning strategy aimed at a socially inclusive knowledge society with strong individuals and active citizens; points out that the realisation of such a strategy will hinge on the degree of independence which our young people can achieve;
8. Calls on the Member States to perform consistent benchmarking with relevant European best-practice models in the field of education and employment;
9. Recalls the headline targets and goals to which the EU has committed itself under the Europe 2020 Strategy, namely the realisation of smart, inclusive and green growth, the creation of a strong and innovative European Union, and the promotion of social inclusion and a higher level of solidarity, while also preparing citizens for a successful and fulfilling life; draws attention to the headline target of spending 3 % of GDP on research and innovation;
10. Calls on the Member States to make public expenditure and investments in education, training, research and innovation a priority; recalls that budget cuts in these fields will have a negative impact on education, and that investment in these areas is essential for the economic recovery and global competitiveness of the Union and for progress to be made in achieving the Europe 2020 objectives;
11. Strongly supports the observation of national situations and the launch of a debate at Union level with relevant stakeholders on investment efficiency and benefits in education and training; underlines that education guarantees sustainable development, which should remain a priority regardless of the current crisis;
12. Urges Member States to adopt legislation prohibiting discrimination on the grounds of gender, sexual orientation, gender identity, disability, religion or belief, and age in the area of education; urges the Council to adopt promptly the horizontal anti-discrimination directive which is key to guaranteeing genuine equality and combating bias and discrimination, including at school;
13. Invites the Member States to ensure equality of access to education and to bring forward measures which are in tune with learners' needs, in particular those of members of vulnerable groups, such as people who are not in education, employment or training;
14. Calls for the creation of specific measures to establish a better link between education and training and the working environment, in order to enhance competitiveness and anticipate the future needs of the labour market; stresses the importance of regional policies which foster the establishment of regional innovation incubators bringing creative firms, universities, investors and cultural bodies together in promoting education and training;
15. Recommends that education and science be included as priority areas in the Member States' strategy papers for the 2014-2020 programming period, with a view to the provision of resources for developing those areas, the introduction of new educational technologies, including the training of teaching staff and the raising of teaching standards;

**Tuesday 22 October 2013**

16. Calls on Member States to pursue a closer link between the key strategic policy challenges identified throughout the European Semester and Open Methods of Cooperation (OMC) activities aimed at supporting Member States to ensure high quality and accessible education and training also in times of fiscal constraints;

***Youth — investment for future***

17. Recalls that young people have great potential and a crucial role to play in achieving the Europe 2020 targets for education and employment; reminds the Member States of the close link between early school leaving, lack of employment-related skills and youth unemployment; also recalls that early childhood education and care and the significant role played by parents lay the foundation for future learning and the development of young people, but that such education should be provided exclusively in a playful manner and not using school methods or pressure in the form of attainment targets;

18. Emphasises that young people are also the most vulnerable segment of society; stresses the importance of recognising young people as a priority group in the Union's social vision and stresses the importance of enhancing youth mobility; calls on Member States, in addition, to promote anti-bullying policies to reduce early school leaving and to ensure genuine access to education for all;

19. Calls for the recognition and involvement of youth and civil society organisations in the design and implementation of lifelong-learning strategies; highlights the role of youth and civil society organisations as complementary educational providers for non-formal and informal learning and volunteering opportunities, benefiting learners and young people in the development both of transversal skills and individual personal competences, such as creative and critical thinking, sense of initiative, information processing and problem solving, team work and communication, as well as self-confidence, leadership and entrepreneurship;

20. Calls for the recognition of qualifications gained by young people during their studies at non-home universities, particularly those qualifications gained in the context of the Erasmus programme;

21. Calls for learners and the organisations to which they are attached to be involved in decision-making processes concerning education, and highlights the fact that learning should be based on a structured dialogue with learners, with respect to the tailoring of curricula and methods fostering a lifelong learning approach;

22. Urges the Member States to promote the attractiveness and improve the labour market relevance of VET, make it an integral part of the education system and ensure its quality; calls for a stronger focus on the acquisition of basic skills through formal and informal training from an early age, but also among adults, and on transversal skills, in particular through the introduction of entrepreneurial and ICT training, in cooperation with the business sector, and by bolstering creativity to help young people enter the labour market and enhance their employability, as well as develop opportunities to set up their own businesses; stresses the need for Member States to provide support mechanisms for failed start-ups and to eliminate red tape;

23. Acknowledges the importance of developing and implementing entrepreneurship-based education systems across Europe; underlines that students' access to entrepreneurship education varies and is often determined at institution level; calls, therefore, on Member States and local and regional authorities, in cooperation with education institutions, to include elements of entrepreneurship education in the curriculum content in basic education, vocational training and higher education; considers that special focus should be placed on overcoming the disparities and substantial differences in the development of entrepreneurship education, as evidenced by the 2008 survey on entrepreneurship in higher education and confirmed at the 2011 Budapest high level symposium;

24. Highlights the fact that better knowledge and skills are essential; stresses the need to enhance the attractiveness and value of STEM (science, technology, engineering, and mathematics) subjects in education as well as the areas with predictable job shortages and which will require an increasing number of qualified workers in the coming years and are likely to ensure quality and sustainable jobs (for example, green economy, business services, ICT, healthcare and education); acknowledging that STEM subjects are of extreme importance to help more young people finding jobs in times of crisis, also calls for the right balance between the acquirement of theoretical knowledge and practical skills during studies, without neglecting the study of social sciences;

Tuesday 22 October 2013

25. Calls on the Member States also to provide more efficient education with a focus on transversal skills, language skills and entrepreneurial skills, in order to achieve a greater level of EU-wide employability; calls on the Member States to educate their citizens about EU citizenship rights, civic duties and commitments and how they can benefit from their right to free movement in the EU; stresses that, with a view to developing active citizenship and social integration, sufficient attention must also be devoted to the human sciences throughout schooling;

26. Stresses the need for curricula to be multidisciplinary and designed to provide open-ended, transferable skills, and for people to be able to switch from one area of studies to another; recalls that special emphasis should be placed on the teaching of subjects and content in which a shortfall has been highlighted in national and international statistics for individual Member States;

27. Stresses the need to focus on the link between education, young people's expectations and labour market needs, so as to ensure an easier and high-quality transition from education into the labour market, which is also aimed at ensuring the autonomy of young people;

28. Highlights the importance of supporting young people, especially those not in education, employment or training (NEETs), by promoting high-quality traineeships and apprenticeships, second-chance education programmes, well-established dual learning and work-based learning, as well as specific measures to foster their access to higher education and their active integration into education and work; considers these to be valuable steps in the transition from education to professional life as well as in lowering rates of youth unemployment;

29. Calls on the Member States to take measures to increase the participation of employees and unemployed persons in vocational re-orientation and retraining programmes, in order to reduce the risks of unemployment, especially long-term unemployment, for that section of the workforce whose professional activities are less and less in demand;

30. Calls on Member States to encourage employers to offer more quality apprenticeship placements, to develop clear quality criteria aimed at preventing abuses and to ease the administrative procedures for enterprises offering work or training opportunities for young people in order to improve their career pathways;

31. Reminds the Member States of the role of the EU programmes in promoting education, mobility, language skills, active citizenship, European values, cultural awareness and other valuable skills, all of which contribute to better employability and the strengthening of young people's intercultural understanding; stresses the need for their further support in the Multiannual Financial Framework (MFF) for the period 2014–2020, focusing on learning mobility, cooperation and policy reform;

32. Draws attention to the added value of experience abroad in helping early school-leavers and young people without educational qualifications to find jobs; considers that the Erasmus+ programme is an excellent framework through which to enable people in this category, too, to receive part of their vocational training abroad;

33. Welcomes the renewed focus on achieving the automatic recognition of comparable academic degrees and its objective of placing all students on an equal footing, irrespective of the place of award of their qualification; calls on Member States, in this connection, to increase their efforts on academic degree recognition;

34. Emphasises how difficult it can be to enter the labour market upon completing one's studies, when a long period of unemployment and forced inactivity can ensue, in particular at times of economic crisis, as is the case at present; calls on the Member States to establish the necessary support policies to address these problems;

35. Urges the Member States to invest in early labour-market activation mechanisms and employment schemes, to offer work experience and to promote employment opportunities, to establish better guidance and tailored career service centres and to provide training or refresher courses for young people who lose their jobs or who have completed formal education, in order to enable them to become independent, to live an autonomous life and to secure professional development;

**Tuesday 22 October 2013**

36. Calls on the Member States to implement swiftly the European Youth Guarantee, work-based learning, apprenticeships and dual learning models which are easily accessible and career-oriented, to offer appropriate working conditions which have a strong learning component and are associated with a qualification process, and to work with regions in ensuring that the Youth Employment Initiative (YEI) will be truly complementary and additional to existing regional and national actions to combat youth unemployment; recalls that these types of temporary employment should act as stepping stones towards permanent work; calls also for the use of cohesion-policy financing instruments as a support measure;

37. Stresses that the Youth Guarantee Scheme cannot replace structural efforts and reforms which must make the education systems and labour markets in some Member States fit for the challenges of the future;

38. Urges the Member States to halt the decline in spending on support for youth employment and education; stresses that funds and instruments from the guarantee system should be used preferentially to this end; considers that the Member States should also use cohesion policy resources as a support measure, and that such resources should specifically target projects that support youth employment and education;

39. Calls for an integrated approach which harnesses the financing possibilities offered by the European Social Fund (ESF), the Cohesion Fund and national sources of financing for the achievement of smart growth; stresses the role of the ESF in supporting investment in education and training, skills and lifelong learning; urges, therefore, for the safeguard of the minimum overall share for the ESF as 25 % of the budget allocated to cohesion policy; considers it important also for Member States to raise their education institutions' awareness regarding other EU funding opportunities for educational purposes;

40. Stresses the need to raise teacher awareness regarding key competences, such as techniques for learning to learn, social and civic skills, initiative, cultural awareness and self-expression; draws attention, therefore, to the importance of investing in lifelong learning schemes for teachers;

41. Recalls that it is at the sub-national level that the most accurate and timely information on regional labour markets can be sourced and where local and regional authorities can play a significant role in identifying skills mismatches, providing appropriate retraining and vocational training programmes, and incentivising investment in response to local demand;

42. Emphasises that in many remote and disadvantaged micro-regions, students have a severe problem in physically accessing schools, which contributes to a significant increase in school dropout rates; calls on the Member States, given the severe economic distress afflicting the majority of European citizens, to take concrete steps to overcome barriers of this kind;

43. Welcomes the creation of the new European Alliance for Apprenticeships; calls on the Member States to include vocational practices in their reforms and actions as part of the plans for delivering on the Youth Guarantee, and to mobilise European and national financing to this end;

### ***Strong focus on partnerships***

44. Highlights the fact that strong partnerships draw on synergies between financial and human resources and contribute to sharing the cost of lifelong learning, which is particularly important in times of austerity and which will help to halt the decline in public investment in youth employment and education; recalls that partnerships also have a positive impact on education and training by contributing to improve their quality and accessibility, while at the same time maintaining the integrity and independence of education institutions;

45. Calls for the enhancement of social and civil dialogue on education and training both at national and Union level, and for the strengthening of the role of social partners in policy making;

46. Considers the encouragement of public-private partnerships to be an important step towards ensuring shared responsibility for education and career development, with the aim being to help graduates to adapt more swiftly to the requirements of industry and the market, and to ensure that additional resources are available for updating the educational process in response to technological change;

Tuesday 22 October 2013

47. Notes that the Commission Communication of 20 November 2012 entitled 'Rethinking Education: Investing in skills for better socio-economic outcomes' does not specify any concrete implementation measures for cooperation between the educational sector and different social and business partners; calls on the Commission to seek support and initiatives actively, as well as other forms of cooperation with the private sector for the improvement of education in order to better prepare students for the transition from education to the job market;

48. Calls upon the Member States to improve cooperation and partnerships between businesses and the education sector at all levels, including social partners and employers, and students and youth organisations, in particular with regard to the planning of curricula, the provision of guidance and the provision of education, training and specialisation, with a range of curricula which better meet the demands of the labour market and contribute to finding a sustainable solution to the problem of skills mismatches; calls also for the enhancement of social and civil dialogue both at national and Union level, and for the strengthening of the role of social partners in policy making;

49. Welcomes the knowledge alliances and sector-skills alliances included in the Commission proposal on the new multiannual programme in the field of education, training, youth, and sport; considers these alliances to be innovative and sustainable ways of increasing human capital;

50. Highlights the shared responsibility of different actors in the field of lifelong learning, such as education institutions, public authorities and enterprises, as well as individuals responsible for their own lives;

51. Calls on the Commission and Member States to reflect carefully on the concept of cost sharing as a way of funding education; warns that cost-sharing mechanisms cannot be pursued at the expense of the individual; equity and universal access must be given priority in any reform of education and training systems;

52. Calls for further cooperation between education institutions and providers, the business sector, social partners, civil organisations, and local, regional and national authorities, as well as employment services in order to exchange best practices, to promote partnerships and to work towards providing quality placements, internships and apprenticeships as an effective means of addressing vacancies and the sustainable integration of people in a period of transition from education to work; stresses the need to ensure the compatibility of these practices with the measures and initiatives taken at EU level; calls also for greater use to be made of the various EU programmes and funds available, in particular regional funding;

53. Considers it vital to recognise the importance of combining public and private investment in education and training; underlines, at the same time, the need to safeguard against possible undesirable side-effects such as hindering access of socio-economically disadvantaged groups to education and training;

### ***Lifelong learning perspective***

54. Notes the demographic changes within the Union, such as an ageing population, low birth rates, as well as brain drain and the flight of human capital; notes, consequently, the need to acquire new skills and competences throughout life in order to be able to deal with the challenges presented by the world economy and respond to new labour market requirements;

55. Notes the importance of recognising education as a human right to which everyone must have access, aimed at personal and societal development and at acquiring skills for life; urges Member States to improve open access to educational and scientific materials, with the aim of lowering costs for education and research, particularly in the light of recent budget cuts in these areas throughout the Union;

56. Encourages the Member States to promote cooperation and synergies in the field of lifelong learning, in particular to widen access to learning and design, and to adapt and modernise the curricula of education institutions — for example by using the rapidly developing potential of digital learning and OER — in order to fulfil young people's aspirations and to address the new challenges of the contemporary world;

57. Welcomes the 'Opening Up Education' initiative announced by the Commission, which is aimed at improving the efficiency, accessibility and equity of education, training and learning systems by strengthening the integration of ICT and new technologies in education and training; calls on all Member States to encourage initiatives to open up education;

**Tuesday 22 October 2013**

58. Notes with concern the wide divergence in available ICT resources and knowledge in schools and higher education institutions between and within the Member States; stresses that the uptake of ICT infrastructure and knowledge should be mainstreamed in all education and training sectors in order to equip students for the digital age as best as possible;

59. Recalls the importance of high-quality teacher and trainer education which needs to be complemented by mobility and the professional training of educational staff throughout the duration of their career; highlights the fact that the selection and training, including in-service training, of teachers are essential in order to guarantee the overall quality of the educational system;

60. Stresses the need for innovative teaching methods and content which instruct learners about approaches to education ('learning how to learn'), also taking into consideration learners from vulnerable social groups or those with special educational needs; notes, in particular, the rapid changes in ICT, digital media and entrepreneurship education; highlights the important role of other educators (for example, youth workers, adult educators, career advisors and parents) and their valuable cooperation in response to the changing nature of education;

61. Urges the Member States to invest in lifelong learning for teachers, so as to assist in their professional and personal development, and also to promote the status of teachers' and improve their working conditions; stresses, furthermore, the possible advantages of gaining teaching experience in another European country;

62. Calls for teachers to be valued and given proper recognition in order to improve the quality of teaching provided to pupils;

63. Emphasises the importance of introducing uniform and objective criteria for assessing the effectiveness and efficiency of teachers' work and their influence on students' academic results and personal development;

64. Highlights the importance of individualised learning pathways in order to help people to update and upgrade their productive, social and economic skills throughout their lives; considers individual coaching, tutoring and mentoring to be a means of transmitting knowledge and expertise to mentees, as well as identifying their personal strengths and required competences, with regard to a specific profession;

65. Considers the need to widen access to learning as a key priority for the Union, with a clear focus on those who do not have a sufficient level of basic skills; encourages the Member States to introduce specific measures in the form of financial support to people from lower socio-economic backgrounds, in order to ensure for everybody the opportunity of reaching the highest possible level of education and also to ensure that learners' needs and welfare are met;

66. Calls on the Member States to ensure that the education system addresses the needs of all prospective students throughout the period of their studies, in order to further and safeguard an inclusive and integrated education and training system and to offer supportive, tailor-made arrangements and individualised pathways, especially to members of vulnerable social groups who are at risk of non-participation or exclusion, such as the Roma and other minorities, migrants, and those with mental and/or physical disabilities and special educational needs;

67. Stresses the need to mainstream gender equality, particularly in fields of science, technology, engineering, and mathematics) (STEM), where women are highly underrepresented, in order to overcome occupational segregation and wage discrimination, and to eliminate discrimination based on gender and sexual orientation in education, and calls for policies to attract and ensure the social inclusion of the most vulnerable and disadvantaged groups, including older people, in learning; encourages the Member States, in this connection, to introduce specific measures in the form of practical assistance, financial support or further training;

68. Calls on the Member States to provide a wide range of support structures, such as scholarships, grants, student loans on favourable terms, tutoring, mentoring and networking assistance to disadvantaged students throughout their studies, in order to prevent them dropping out at the secondary or tertiary stage, and at tertiary level help them gain access to the Erasmus programme, in which current participation rates for students coming from low-income families are lower than average, as well as promoting their access to quality internships in business, public administration and the media, in order to enable them to acquire appropriate work experience and a support network for their future job success, as well as to integrate their specific views into the institutional culture;

Tuesday 22 October 2013

69. Insists that a targeted approach be adopted in the vocational training of children with special educational needs and of children and adults with disabilities, with a view to broadening access to education, supporting their families and enabling them to fulfil their potential;

70. Considers that all Member States should make a major effort to reduce dropout rates, thereby meeting the EU 2020 headline targets which are aimed at a figure below 10 %, by launching high-quality early childhood education, development and care programmes which are appropriate to the age group, cover the entire period of early childhood from birth to the age of six, and to which equal access is guaranteed for all children;

71. Recalls that the provision of a wide range of extracurricular activities and the engagement of parents in the educational process are vital in order to tackle inequalities arising from early childhood disadvantage, to avoid educating disadvantaged students in special segregated schools, and to stop the reproduction of poverty and social exclusion across generations, which may be monitored with the involvement of relevant stakeholders, such as established local NGOs;

72. Shares the Commission's concerns about the alarmingly low participation levels in adult learning in most Member States, with the average rate of uptake for the EU standing at 8,9 %; stresses, therefore, the need to focus on low-skilled adults and on the role played by adult education and training in reaching out to these groups, as well as focusing on intergenerational learning; recalls the opportunities that digital learning and OER can bring with respect to access to education and training; recalls the importance of promoting digital literacy and access to and use of ICT to all age groups of the population;

73. Calls on the Member States, for the purposes of social solidarity and addressing demographic challenges, to promote voluntary activities for all age groups, and urges them to promote training courses needed by the care and support sectors;

74. Underlines the possibilities offered by massive open online courses (MOOCs) in terms of accessibility to high-quality education for everyone, allowing more flexible and creative ways of learning, promoting equality for all learners, and also in terms of cutting education costs incurred by learners as well as those incurred by universities;

75. Recognises the fact that overcoming the prejudices which prevent students from taking educational paths which are not necessarily perceived as leading to highly recognised careers and positions in society is crucial in combating unemployment and increases the attractiveness of vocational training and informal education; highlights, moreover, that in times of high youth unemployment, students should be actively informed of the realistic employment perspectives based on their education choices; urges the Member States, in this connection, to promote programmes providing vocational guidance and support for learners in choosing a career;

76. Considers the implementation of vocational guidance and careers development systems to be an important step in steering young people along the right educational and career path, and that this will increase their motivation to study and acquire vocational training;

77. Strongly supports the creation of a European area of skills and qualifications in order to achieve transparency and recognition of qualifications acquired in VET or higher education; proposes, where appropriate, to extend recognition also to qualifications gained outside of the formal education and training system, which can be seen as a tool for empowerment, democratic participation, social inclusion and as a pathway to involve or bring people back into the labour market;

78. Stresses the importance of the timely implementation and reporting on the implementation of initiatives aimed at improving the cross-border recognition of qualifications within the Union, in particular the European Qualifications Framework, the European Credit Transfer System (ECTS) and the European Credit System for Vocational Education and Training (ECEVET);

79. Calls on the Member States to develop a comparative framework concerning university degrees and providing a reference point on the education and skills obtained under educational systems;

80. Urges the Member States to monitor and evaluate regularly — with the involvement of relevant stakeholders, whether their education system and programmes have managed to reach out to the members of vulnerable social groups, whether they have managed to safeguard equal access to inclusive and quality education at all levels, and whether the skills provided by their education and training have indeed enhanced the employability of students, social integration and active

**Tuesday 22 October 2013**

citizenship; calls also on the Member States to act, as soon as possible, on the education-related recommendations in the European Semester and on other Commission recommendations;

81. Calls on the Commission to monitor whether the Member States have taken the necessary steps to reform their education systems in order to achieve the above-mentioned goals;

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82. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.

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Tuesday 22 October 2013

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**EU pre-accession funds: judicial systems and the fight against corruption**

**European Parliament resolution of 22 October 2013 on budgetary management of European Union pre-accession funds in the areas of judicial systems and the fight against corruption in the candidate and potential candidate countries (2011/2033(INI))**

(2016/C 208/04)

*The European Parliament,*

- having regard to the European Commission's Communications on Enlargement Strategy and Main Challenges for the years 2007-2008, 2008-2009, 2009-2010, 2010-2011, 2011-2012 and 2012-2013,
  - having regard to the multiannual indicative financial frameworks, multiannual indicative planning documents, national programmes and project fiches negotiated between the Commission and the respective candidate and potential candidate countries,
  - having regard to Special Report No 12/2009 of the European Court of Auditors on the effectiveness of the Commission's projects in the area of justice and home affairs for the Western Balkans,
  - having regard to Special Report No 16/2009 of the Court of Auditors on the Commission's management of pre-accession assistance to Turkey,
  - having regard to Special Report No 14/2011 of the Court of Auditors on whether EU assistance has improved Croatia's capacity to manage post-accession funding,
  - having regard to Special Report No 18/2012 of the Court of Auditors on EU assistance to Kosovo <sup>(1)</sup> related to the rule of law,
  - having regard to the Commission's 'Thematic Evaluation on Judiciary and Fundamental Rights in Turkey' of October 2012,
  - having regard to the Commission's 'Thematic Evaluation of Rule of Law, Judiciary Reform and Fight against Corruption and Organised Crime in the Western Balkans' — Lots 2 and 3 of May 2012 and February 2013,
  - having regard to the Commission's information note of March 2013 <sup>(2)</sup> on the use of pre-accession funds in the areas of judicial systems and the fight against corruption in the countries of the Western Balkans and Turkey,
  - having regard to the 2012 Progress Reports for the candidate and potential candidate countries,
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on Foreign Affairs (A7-0318/2013),
- A. whereas potential candidate and candidate countries should continue their efforts to improve their judicial systems and fight against corruption if this is deemed necessary for accession, even when they have become EU Member States; whereas at the 1999 Helsinki Summit, the European Council gave Turkey the status of candidate country for EU membership and the EU-Turkey Accession Partnership was adopted in 2001, and whereas at the 2003 Thessaloniki European Council the Stabilisation and Association Process was confirmed as the EU policy on the countries of the Western Balkans region, thus making them eligible for EU accession; whereas the Instrument for Pre-Accession Assistance (IPA) is not the only means through which the EU is supporting rule of law reform in Bosnia and Herzegovina and Kosovo, as support for law sector reform in Kosovo is also provided by EULEX and a police mission was conducted in Bosnia and Herzegovina between 2003 and 2012;

<sup>(1)</sup> This designation is without prejudice to positions on status, and is in line with UN Security Council Resolution 1244 (1999) and the ICJ opinion on the Kosovo declaration of independence.

<sup>(2)</sup> Annex 1 to the Commission's replies to Written Questions Nos E-011447/2012, E-011448/2012, E-011449/2012, E-011661/2012, E-011662/2012, E-011663/2012, E-011664/2012 and E-011665/2012.

**Tuesday 22 October 2013**

- B. whereas the enforcement of the rule of law, notably through judicial reform, and the fight against corruption and organised crime in the countries of the Western Balkans and Turkey are considered by the Commission as top priorities, and whereas starting from 2012 the 'New Approach' has been applied under the enlargement policy tackling justice reforms and home affairs early in the accession process through the establishment of a new negotiation methodology including clear priorities and conditionalities in the areas of Chapters 23 and 24, thus aiming at a better prioritisation of financial assistance under IPA II;
- C. whereas the European Union delivers financial assistance to candidate and potential candidate countries through the Instrument for Pre-Accession Assistance (IPA) which replaced the programmes TPA, PHARE and CARDS as of 2007, and whereas, with the exception of Iceland, all candidate and potential candidate countries benefit from EU pre-accession funds in the framework of the reform of their judicial system and the fight against corruption;
- D. whereas the new pre-accession instrument IPA II must be more strategic, efficient and better targeted than its predecessors in order to achieve more sustainable results in improving the readiness of these countries for membership, and where possible favouring the sector approach in order to support comprehensive reform strategies by the beneficiary countries;
- E. whereas EU support for reforms relating to the rule of law in Bosnia and Herzegovina and Kosovo is not limited to IPA assistance — in Bosnia and Herzegovina, a police mission was conducted between 2003 and 2012, and support to Kosovo was also provided in the form of the EU Rule of Law Mission in Kosovo (EULEX) which was deployed in 2008 — and whereas with a total of over 2 000 staff on 1 July 2013 (of which over 730 were seconded by EU Member States) and with an annual budget of just over EUR 100 million (June 2012-June 2013), EULEX has a substantial role in supporting Kosovo institutions in the field of the rule of law, including on judicial reform and the fight against corruption;
- F. whereas since 2007 regional projects supporting cooperation between beneficiaries in different countries and horizontal projects addressing the shared needs of several beneficiaries are eligible for funding under IPA multi-beneficiary programmes;
1. Recalls that the fight against corruption and organised crime is one of the most important priorities for any candidate or potential candidate country wishing to fulfil its European perspective;
2. Reiterates the importance of an independent judiciary, of the protection and promotion of fundamental rights and of an effective fight against corruption in strengthening the rule of law and democracy; welcomes the EU's new negotiating approach, which firmly anchors these core areas at the heart of the accession process and includes an early opening of Chapters 23 and 24 on the basis of clear and detailed action plans, stimulating the establishment of the necessary legislation, institutions and solid track records of implementation; stresses the need for setting transparent and fair benchmarks for the entire process that can translate the criteria into concrete steps towards accession;

### ***Budgetary and financial management***

#### ***Judiciary reform***

3. Notes that since 2001 EU pre-accession assistance to Turkey in the area of judiciary reform has amounted to EUR 128 938 935 for 30 projects, of which EUR 66 645 666 was paid out as of 31 December 2012; highlights that at present nine projects have been completed, 11 are ongoing and 10 are to be started<sup>(1)</sup>;

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<sup>(1)</sup> Annex 1 to the Commission's replies to Written Question Nos E-011447/2012, E-011448/2012, E-011449/2012, E-011661/2012, E-011662/2012, E-011663/2012, E-011664/2012 and E-011665/2012.

Tuesday 22 October 2013

4. Acknowledges that the Commission initiated a recovery procedure in February 2012 regarding two completed projects developed in Turkey, i.e. Construction of three Courts of Appeal Houses in Ankara, Erzurum and Diyarbakır <sup>(1)</sup> and Support to the establishment of Courts of Appeal in Turkey <sup>(2)</sup>; takes note that EUR 21 767 205,29 was recovered in April 2012 and that the amount corresponds to the payments made by the Commission for both projects; notes that the Commission's decision for a full recovery was challenged by the external evaluators; calls on the Commission to provide by December 2013 detailed information regarding this issue and explain the choice of a full recovery;

5. Notes that since 2005, EU pre-accession assistance to the countries of the Western Balkans in the area of judiciary reform has amounted to EUR 240 064 387,48 for 124 projects, of which EUR 85 749 243,96 was paid out as of 31 December 2012; highlights that at present, 53 projects have been completed, 47 are ongoing and 23 are to be started <sup>(3)</sup>;

**Table 1: Pre-accession assistance in the Western Balkans countries in the area of judiciary reform covering PHARE, CARDS and IPA projects**

Country	Total EU pre-accession assistance (in euro)	Payments as of 31.12.2012 (in euro)	Number of projects	Status of projects		
				To be started	Ongoing	Completed
<b>Albania</b>	46 954 563,08	12 681 306,32	17	2	14	1
<b>Bosnia and Herzegovina</b>	35 918 893,00	14 148 643,76	26	4	13	8
<b>Croatia</b>	34 443 208,36	12 356 399,21	17	4	6	7
<b>FYROM</b>	11 295 000,00	3 236 000,00	13	2	1	10
<b>Kosovo</b>	63 613 000,00	25 641 584,77	15	6	6	3
<b>Montenegro</b>	4 790 085,00	3 406 910,19	9	0	2	7
<b>Serbia</b>	43 049 638,04	14 278 399,71	27	5	5	17
<b>Total</b>	240 064 387,48	85 749 243,96	124	23	47	53

#### *Fight against corruption*

6. Notes that since 2001 EU pre-accession assistance to Turkey in the area of the fight against corruption has amounted to EUR 6 160 000 for 5 projects, of which EUR 1 661 732 was paid out as of 31 December 2012; highlights the fact that at present one project has been completed, two are ongoing and two are to be started;

<sup>(1)</sup> Project TR0501.07, EU contribution: EUR 22 500 000, payments on 31/12/2012: EUR 20 559 457,71

<sup>(2)</sup> Project TR0401.02, EU contribution: EUR 1 400 000, payments on 31/12/2012: EUR 1 207 747,58

<sup>(3)</sup> Ibid.

**Tuesday 22 October 2013**

7. Takes note that since 2005 EU pre-accession assistance to the countries of the Western Balkans in the area of the fight against corruption has amounted to EUR 55 160 227,76 for 45 projects, of which EUR 16 060 007,57 was paid out as of 31 December 2012; highlights the fact that at present 18 projects have been completed, 17 are ongoing and 10 are to be started <sup>(1)</sup>;

**Table 2: Pre-accession assistance in the Western Balkans countries in the area of the fight against corruption covering PHARE, CARDS and IPA projects**

Country	Total EU pre-accession assistance (in euro)	Payments as of 31.12.2012 (in euro)	Number of projects	Status of projects		
				To be started	Ongoing	Completed
<b>Albania</b>	3 500 000,00	3 184 112,00	2	0	1	1
<b>Bosnia and Herzegovina</b>	4 553 791,00	1 878 730,36	16	1	9	6
<b>Croatia</b>	9 684 397,12	3 753 821,95	9	2	2	5
<b>FYROM</b>	14 647 000,00	1 182 000,00	5	3	0	2
<b>Kosovo</b>	6 500 000,00	1 394 670,10	4	2	1	1
<b>Montenegro</b>	6 391 722,00	2 690 106,00	5	1	2	2
<b>Serbia</b>	3 383 317,64	1 976 567,16	4	1	2	1
<b>Total</b>	55 160 227,76	16 060 007,57	45	10	17	18

8. Emphasises the Commission's new approach to address justice reforms and home affairs issues early in the accession process; observes however that on average only 3,13 % of the total EU pre-accession envelope for 2007-2012 was devoted to justice and only 0,52 % to the fight against corruption; notes that for the same period the total amount allocated to all policy areas covered by chapters 23 and 24 (Judiciary and Fundamental rights and Justice, Freedom and Security) is approximately 7,41 % of the total pre-accession assistance; notes further that approximately 16,29 % of funds allocated to Component I aim at strengthening the rule of law in candidate and potential candidate countries;

9. Acknowledges that the IPA 2007 project 'Support to the capacities in the Ministries of Justice in Bosnia and Herzegovina for Strategies Planning, Aid Coordination and EU Integration' had its contract suspended; calls on the Commission to provide detailed information regarding the suspension of the contract and the state of play of the project by December 2013;

*Funding, enlargement priorities and co-financing*

10. Emphasises the Commission's new approach to addressing justice reform and home affairs issues early in the accession process; observes, however, that on average only 2,87 % of the total EU pre-accession assistance envelope for the period 2007-2013 is devoted to justice and only 0,52 % to the fight against corruption;

<sup>(1)</sup> Ibid.

Tuesday 22 October 2013

**Table 3: Level of funds invested in specific projects with focus on judiciary reform and the fight against corruption compared with the total EU pre-accession assistance envelope in candidate and potential candidate countries for the period 2007-2012 <sup>(1)</sup>**

Country	Total EU pre-accession assistance envelope	Funds invested in judiciary reform	%	Funds invested in the fight against corruption	%
<b>Albania</b>	591 200 000,00	46 954 563,08	7,94	3 500 000,00	0,59
<b>Bosnia and Herzegovina</b>	655 300 000,00	35 918 893,00	5,48	4 322 690,00	0,66
<b>Croatia</b>	998 000 000,00	28 124 764,60	2,81	9 552 355,11	0,96
<b>FYROM</b>	615 100 000,00	8 903 000,00	1,45	13 285 000,00	2,16
<b>Kosovo</b>	635 300 000,00	63 613 000,00	10,01	6 500 000,00	1,02
<b>Montenegro</b>	235 600 000,00	4 377 111,00	1,86	6 391 722,00	2,71
<b>Serbia</b>	1 385 400 000,00	43 049 638,04	3,11	3 383 317,64	0,24
<b>Turkey</b>	4 799 000 000,00	79 287 735,00	1,65	4 810 000,00	0,10

11. Notes that the level of co-financing by domestic authorities differs widely from one country to another, with Croatia and Turkey co-financing most of their projects and Serbia having all its projects fully covered by the EU pre-accession assistance; is of the opinion that co-financed projects, especially in the areas of the judiciary and the fight against corruption, bring a higher degree of ownership from the beneficiaries; calls therefore on the Commission to increase, under IPA II, the number of projects co-financed by domestic authorities;

12. Is of the opinion that the level of pre-accession assistance invested in judiciary reform and the fight against corruption does not reflect the priority set by the Commission in this respect; given the importance of judiciary and corruption-related issues, the severity of the problems faced in the field, as well as the positive spillovers and synergies that other sectors would benefit from if judiciary and anti-corruptions reforms were duly completed and implemented, urges the Commission and the beneficiary countries to allocate a more substantial and adequate level of funding to these two sectors; notes nevertheless that other factors, such as country-specific structured dialogues on the rule of law and the judiciary, have a substantial impact on the efficiency of the EU pre-accession assistance in the reform of judicial systems and the fight against corruption; recognizes therefore that the share of overall financing is not the only criterion for the efficiency of the EU efforts to strengthen the rule of law and anti-corruption practices;

13. Regrets the fact that funding under IPA I appears to be limited when set against the importance of these areas; observes, however, the weak absorption capacity of IPA I in the area of the rule of law in some candidate and potential candidate countries; considers it essential to improve the management of pre-accession funding in this area under IPA II, and stresses that progress in meeting specific objectives relating to an independent and efficient judiciary, the rule of law and combating corruption, including their implementation, should be monitored and assessed on the basis of quantitative and qualitative indicators; considers it also important to provide for a performance incentive under IPA II in order to reward performance in making substantial progress in meeting the objectives specified in the strategy papers;

<sup>(1)</sup> The statement on the averages for the total pre-accession envelope for 2007-2012 devoted to justice and the fight against corruption reflects the allocation to these areas up to February 2013.

**Tuesday 22 October 2013**

14. Regrets that the Commission does not have a tool to provide an execution rate in an automated manner for the EU pre-accession projects and emphasises that knowledge on execution rate is crucial in order to monitor the efficient implementation of projects and, therefore, in order to point out potential bottlenecks at an early stage; calls on the Commission to centralise data on a 6 monthly basis on the execution rate of the projects for which EU pre-accession assistance is allocated;

15. Notes that cooperation on the reform of judicial systems and the fight against corruption also takes place at the political level with country-specific structured dialogues on the rule of law and the judiciary set up with candidate and candidate countries;

### **General remarks**

16. Stresses that the effectiveness of pre-accession projects implemented in the areas of the judiciary and the fight against corruption depends primarily on the authorities' political will to adopt and fully implement the reforms; deplores that in most candidate and potential candidate countries there is a lack of strong political support for putting in place effective reforms regarding the fight against corruption and organised crime or a fully independent judiciary; points out that candidate and potential candidate countries receive EU pre-accession assistance in order to bring their legal systems — both the legislative framework and in practice — in line with European standards;

### *Judicial reform*

17. Welcomes those changes that bring the legal and institutional framework more in line with the EU acquis, as well as the modernisation of the institutional set-up of the judiciary; acknowledges, for instance, the positive impact on the impartiality and efficiency of courts of introducing the Case Management System (CMS), though its functioning and effectiveness are sometimes hindered by over-ambitious objectives such as in Kosovo;

18. Invites the Commission to work on a clearer definition of the scope of projects in the areas of judicial systems and the fight against corruption, which would allow for more consistent monitoring and reporting in these areas;

19. Stresses that Parliament should be actively involved in the supervision of the allocation and spending of pre-accession funds in the candidate and potential candidate countries in all areas, including judicial systems and the fight against corruption; stresses, therefore, that Parliament should be kept informed about the implementation of the IPA and the allocation of funds for candidate and potential candidate countries;

20. Recalls that the rule of law is the cornerstone of democracy and a pre-condition for a functioning market economy, and stresses the need to see judicial reforms in a wider context; insists on the fact that the justice system should be fully independent, more predictable, efficient and fair in order to ensure that the people and the business community trust the judiciary; stresses in this respect the need to establish the random distribution of cases in all courts and to ensure timely justice together with the unification of jurisprudence, the publication of, and easy access to, all judicial decisions immediately after adoption, as well as the advantages, including financial advantages, of using e-justice; points out that adequate and continuous training of judges, prosecutors and clerks is essential; notes that the 'New Approach' should focus on these issues in the context of the accession negotiations;

21. Considers it essential to link EU financial assistance more closely to the priorities of enlargement policy, especially in relation to the rule of law, in order to improve the independence, accountability, impartiality, professionalism, transparency and efficiency of the judicial systems; stresses that predictable and sufficient funding is a key precondition for sustainable judicial reforms; underlines the importance of continuous professional training for judges, prosecutors and officials; calls for further financial assistance to and engagement with relevant civil society actors in order to enhance the transparency of the judiciary and improve its long-term capacities, as well as those acting as watchdogs or whistle-blowers as regards misuse of funds;

22. Deplores the fact that the impact and sustainability of the EU financial assistance is largely impeded by a lack of predictable justice systems and predictable and sufficient domestic funding;

23. Notes that the 'New Approach' intends to focus on these issues in the context of the accession negotiations;

Tuesday 22 October 2013

*Fight against corruption*

24. Notes that corruption is a major challenge for the majority of candidate and potential candidate countries; is concerned that in several countries of the Western Balkans, progress reports note that the linkages established between criminals, organised crime networks and political elites during the conflicts in the region have been carried over into today's societies; is deeply worried by the phenomenon of 'state capture' which is present in some of those countries;

25. Notes that genuine implementation and concrete results in fighting corruption, in particular in the cases of high-level political corruption and corruption in the judiciary, are still a big challenge and that a convincing track record of prosecution and conviction cases should be built up in order to measure the progress; welcomes the fact that the 'New Approach' will focus on these issues in the context of the accession negotiations; stresses the need for better planning and funding of anti-corruption activities, based on the cooperation of a broad range of stakeholders; calls on the Commission to develop a longer-term and broad-based strategic perspective of EU funding for civil society organisations which are working in transparency and anti-corruption areas at both national and European levels; notes that the 'New Approach' intends to focus on these issues in the context of the accession negotiations;

26. Wishes to see a track record of unbiased and successful prosecutions and court rulings in the field of combating corruption, including in high-profile cases, in order to enhance citizens' trust in the rule of law and public institutions; invites the relevant authorities to improve interinstitutional cooperation, especially with law enforcement structures, raise public awareness and develop capacities for planning, enforcing and monitoring anti-corruption rules and activities, as well as to cooperate closely with the Group of States against Corruption (GRECO) and to engage closely with independent state bodies such as anti-corruption agencies; calls for the implementation of strategies to prevent and combat corruption nationally and internationally;

27. Believes that freedom of the press and media and digital freedom represent a crucial check on power and an important component in the fight against corruption, both by providing a platform for freedom of expression and by providing the public with access to information; calls, therefore, for these freedoms to be actively pursued through programmes under the IPA aimed at governments, citizens and press and media outlets;

28. Is concerned that EU pre-accession assistance is not always used in a consistent manner due to the lack of a regional approach and strategy; underlines, for instance, that whereas in Croatia EU pre-accession assistance funded an anti-corruption agency with investigative powers, in Kosovo it funded an anti-corruption agency without such powers, thus raising doubts as to its efficiency; calls therefore on the Commission to establish a clear regional strategy in order to avoid funding contradictory models in candidate and potential candidate countries;

*Implementation of projects*

29. Notes that pre-accession projects have a time span of between one and 3,5 years; acknowledges, based on the external thematic evaluations, that such deadlines are challenging, if not overambitious, given the wide scope of most projects and their numerous and often complicated components; given the complexity of reforms in the areas of justice and the fight against corruption, and the time consumed solely in pre-programming activities, recommends that the Commission takes adequate measures within the framework of IPA II programming and projects which would lead to a longer timescale (five to seven years), incorporating predetermined and periodical reviewing exercises which would allow for more flexible adjustments, including the financial envelope;

30. Is concerned about the chronic delays incurred in the implementation of projects and, ultimately, their efficiency; notes, for instance, that projects in Turkey incur on average a one-year delay before contracts are executed, because of bottlenecks in tendering and contracting, while in Croatia contracts for PHARE programmes were signed on average more than one year later than scheduled, just a couple of days prior to the contracting deadline established in the Financial Agreement;

31. Is further concerned that the complexity of pre-accession assistance rules and their rigidity whenever new activities need to be included in a project eventually create a counterproductive incentive to repeat an activity or to accept an unsatisfactory project design; is nevertheless of the opinion that the right balance between flexibility serving project efficiency and the need to avoid irregularities and ensure best value for money still needs to be found and calls on the Commission to act in this respect under IPA II;

**Tuesday 22 October 2013**

32. Is of the opinion that preparatory ('pilot') activities should always be carried out in cases of broad projects prior to their full deployment in order to identify and mitigate potential shortcomings, limit avoidable delays and difficulties and measure the achievable results;

33. Notes that a more comprehensive sectoral approach in the areas of judiciary reform and the fight against corruption would entail positive changes, such as better focused national reform efforts, enhanced donor coordination and better interaction between individual projects; calls on the Commission to ensure that sectoral approaches are introduced in accordance with the guidelines on sectoral approaches in pre-accession assistance and that the capacities of the beneficiary countries to draw up and implement meaningful sectoral strategies are enhanced; calls on the Commission to continue to provide guidance on the implementation of the sectoral approach during the planning and programming stages of IPA II; considers that in most countries neither institutional set-up nor budgeting processes are at a level suitable for sectoral budget support and calls on the Commission to promote the necessary institutional and procedural improvements in the beneficiary countries;

34. Emphasises that cooperation and coordination with other donors and international financial institutions is of paramount importance to avoid duplication, ensure aid effectiveness and foster capacity building in the candidate countries and potential candidates countries; regrets that judiciary reform and the fight against corruption do not fall within the scope of the Western Balkans Investment Framework, which is a joint initiative by the EU, international financial institutions, bilateral donors and the governments of the Western Balkans to strengthen the coherence of donors' support; calls on the Commission and its partners to establish a mechanism in the same spirit as the Western Balkans Investment Framework whereby cooperation and coordination in the field of judiciary reform and the fight against corruption will be strengthened, and to keep the Parliament informed of all progress made;

#### *Performance and sustainability*

35. Acknowledges that, following its audit of pre-accession projects for the period 2001-2005, the European Court of Auditors stated that project sustainability could be improved if: (i) beneficiary involvement was increased; (ii) no projects were launched without a maintenance plan; (iii) the Commission monitored distribution more closely and evaluated the use of EU-funded equipment and infrastructure; and (iv) the delivery of technical assistance was adequately complemented by active encouragement for institutional change; underlines the fact that despite improvements under the IPA programme some weaknesses still remain, notably in terms of stakeholder involvement and maintenance, and notes, for instance, that during the 2011 programming process in Turkey the beneficiaries were hardly involved in the last 12 months;

36. Takes note that pre-accession projects are based on project fiches which present their overall and specific objectives, the activities intended to be implemented, their timeframe, costs and means of implementation and the indicators against which the success of the projects can be measured;

37. Points out that Article 30 of the financial rules applicable to the annual budget of the Union (Regulation (EU, Euratom) No 966/2012 — Financial Regulation) requires SMART objectives to be established for all policy measures covered by the EU budget and to be set out in the annual activity reports as part of the activity-based budgeting and management processes;

38. Observes that project fiches have improved over time with the inclusion of more and better-designed SMART objectives as well as specific indicators for the different components of a project; is, however, concerned that external evaluation reported that some projects lacked focus due to inappropriate indicators, with SMART indicators not always suited to the justice sector; insists on the need for designing qualitative indicators capable of measuring the long-term impact of the projects; calls on the Commission to continue to issue guidance on the utilisation of performance indicators to be used for programming, monitoring and evaluation purposes for the 2014-20 financial framework in relation to IPA II; is of the opinion that specific indicators in the sector of Justice, Liberty and Security should be developed and used in line with the more strategic approach under IPA II;

39. Is of the opinion that high quality training is a vital aspect of judicial reform and welcomes the fact that over 30 % of TAIEX activities are devoted to Justice, Freedom and Security, but questions the relevance of the objective indicators defined in the project fiches, which are used to measure the added value of training activities; points out that indicators such as 'quality and quantity of training activities carried out by trainers' or 'trained judicial advisors satisfied with the training' mainly focus on output and overlook outcomes; points out, for instance, that the fact that participants state in a

Tuesday 22 October 2013

questionnaire that training will influence their work is not in itself an impact indicator; calls, therefore, on the Commission to further fine-tune its training-related indicators and to organise a thorough impact assessment of the training activities implemented in the candidate and potential candidate countries;

40. Deplores the fact that relevant baseline data serving as a starting point to measure improvement is often missing, thereby preventing the measurement of changes attributable to pre-accession projects;

41. Observes that support for legislative reforms is one of the most common pre-accession projects; notes that institutional frameworks are now in line with European standards, but is concerned that the sustainability of those changes in laws and frameworks in candidate and potential candidate countries is at risk due to the lack of an overall strategy as noted by external evaluators; notes in particular that bylaws and complementary regulations are often missing, changes in roles and responsibilities are not made clear, and staff are not properly trained and thus cannot apply the new laws as intended; insists that support for judiciary reform and the fight against corruption must be long-term and comprehensive with evaluation criteria covering the whole process from the production of new frameworks, laws, bylaws and regulations to actual prosecution in high-level cases;

42. Notes that the performance and sustainability of multi-beneficiary programmes have not yet been evaluated; calls on the European Court of Auditors to include these projects in the scope of a future Special Report on the pre-accession assistance in candidate and potential candidate countries;

#### *Monitoring and evaluation*

43. Acknowledges that the Commission assesses the impact and sustainability of pre-accession programmes through results-oriented monitoring (ROM) reports, but regrets that those reports are not made publicly available; is of the opinion that the Commission's Progress Reports (PR) should reflect on the findings of the ROM reports and provide an assessment of the programmes and their impact once implemented; urges the Commission therefore to introduce a chapter on the inclusion of ROM conclusions in each PR;

44. Points out that the number of ROM (results-oriented monitoring) reports is uneven across countries, ranging from 31 for Albania to none for Bosnia and Herzegovina, Croatia, Montenegro and Serbia; points out, furthermore, that countries using the decentralised implementation system (DIS) are not required to carry out external ROM, and therefore that little independent performance tracking takes place in Croatia; calls on the Commission to ensure regular and thorough independent external monitoring of programmes financed with EU pre-accession assistance in all candidate and potential candidate countries;

45. Is concerned that ROM reports are considered to be structurally biased in favour of positive ratings and that they are inappropriate for longer-term performance monitoring; stresses that monitoring should track sector performance and not just project results; urges the Commission to develop a comprehensive monitoring action plan including evaluation tools other than ROM reports, such as sector performance assessment frameworks with SMART indicators, in order to make comprehensive monitoring of project outcomes possible over time; would like to be informed on progress made before the end of 2014;

46. Recalls Parliament's call on the Commission to assess the impact and results achieved through the allocation of EU funds in the reform of the judiciary and the fight against corruption in candidate and potential candidate countries<sup>(1)</sup>; welcomes the publication by the Commission in 2012/2013 of an evaluation on Judiciary and Fundamental Rights in Turkey and an evaluation of Rule of Law, Judiciary Reform and Fight against Corruption and Organised Crime in the Western Balkans; regrets nevertheless that the evaluation on Turkey did not include a review of the projects related to the fight against corruption;

47. Is aware that the European Court of Auditors is currently preparing a Special Report on EU pre-accession assistance in Serbia; strongly recommends that projects implemented in the areas of judiciary reform and the fight against corruption be included in the scope of the performance audit;

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<sup>(1)</sup> OJ C 188 E, 28.6.2012, p. 19; OJ C 199 E, 7.7.2012, p. 106; OJ C 296 E, 2.10.2012, p. 94.

**Tuesday 22 October 2013**

*Transparency*

48. Is of the opinion that a database listing all of the projects funded under pre-accession assistance programmes should be established and made publicly available; calls on the Commission, therefore, to develop measures to increase the transparency of legal arrangements and to design a system whereby all beneficiaries of EU funding are published on the same website, independently of the administrator of the funds, and on the basis of standard categories of information to be provided by all Member States in at least one working language of the EU;

49. Notes the Commission's commitment to address these issues by 2015 through the publication of information on IPA assistance in line with the International Aid Transparency Initiative which established common standards for the electronic publication of timely, comprehensive and forward-looking information on resources provided through development cooperation; emphasises that such an initiative will only prove fruitful if information is regularly updated; urges the Commission therefore to update the database monthly as planned;

**Country-related remarks**

*Albania*

50. Welcomes the improvements that EU support has brought both in the legal and institutional framework and the infrastructure of the judiciary in Albania; is concerned, however, about the insufficient reporting of results on the actual use, implementation and concrete impact of all these transformations;

51. Recognises the results in terms of adoption of strategic documents in the field of anti-corruption; is seriously concerned, however, about the low effectiveness of measures undertaken in the area; stresses that in 2012 Albania ranked as Europe's most corrupt country; calls on the Commission and the Albanian authorities to urgently reassess the implementation of the anti-corruption strategy and action plans in this country;

*Bosnia and Herzegovina*

52. Deplores the lack of application of some of the enhanced capacities of the judiciary in Bosnia and Herzegovina; is concerned that, in its 2009 audit, the Court of Auditors noted the lack of funding for operations and maintenance of the acquired infrastructure entailing a risk that improvements will lack sustainability;

53. Is seriously concerned about the limited performance of the anti-corruption agency in Bosnia and Herzegovina and the lack of reporting on the specific results of EU funding in the area of the fight against corruption;

*Croatia*

54. Notes the progress achieved by Croatia in some areas of judicial reform and their implementation and that their sustainability was ensured through follow-up projects;

55. Notes some positive developments in the field of the fight against corruption presented in the annual progress reports for Croatia; is, however, concerned about the risk that the measures adopted prior to the country's accession to the European Union are not irreversible and sustainable; stresses, for instance, that it is unclear which institution plays the lead role in overseeing all the anti-corruption reforms, that the members of the Commission on Conflict of Interest were only appointed in early February 2013 casting doubts on its actual operability and results, and that politically motivated appointments to ministries and the supervisory boards of companies are still ongoing and are in fact increasing;

*Kosovo*

56. Notes that the lack of control by the Pristina-based Kosovan authorities over the northern part of the territory means that IPA projects such as the 'Legal Education System Reform' project intended to cover all of Kosovo have generally had a negligible impact in the north;

Tuesday 22 October 2013

57. Is seriously concerned that the Court of Auditors has not found EU assistance in Kosovo in the field of the rule of law to be sufficiently effective; recognises that specific circumstances in Kosovo, such as the low starting point for building up the rule of law and the insufficient priority accorded to this area by the Kosovan authorities, explain to a certain extent the limited effectiveness of EU action; stresses, nevertheless, the existence of areas where improvements should be expected from the Commission and the EEAS:

- better definition of capacity-building objectives and their link to specific benchmarks against which progress could be assessed;
- better coordination of external and internal objectives;
- better coordination between EU institutions and their coordination with the Kosovan authorities and the international community, ensuring that EULEX operates with the full authorised number of staff and that they are deployed for the necessary time period and have the appropriate skills to be effective, and;
- ensuring that policy dialogues with the Kosovan authorities focus particularly on strengthening the rule of law and are linked to incentives and priority conditions;

58. Is particularly concerned by the lack of tangible progress in the field of the fight against corruption in Kosovo; considers that corruption is a major challenge and a serious obstacle for the functioning of the public institutions;

#### *FYROM*

59. Welcomes the progress achieved in the legislative framework for judiciary reform and the positive changes in terms of efficiency and impartiality made by the installation of the Automated Court Case Management Information System; recognises FYROM's active approach to reforming its judiciary and its position as front-runner in the area;

60. Is concerned that no reporting is available on the effectiveness of IPA projects on anti-corruption in FYROM;

#### *Montenegro*

61. Welcomes the improvement of regional cooperation in the areas of the police and judicial cooperation, strengthening the legal framework required to ensure the independence of the judiciary and enhancing the efficiency of the judiciary in Montenegro; is concerned about weak donor coordination and the low sustainability ratings of projects;

62. Notes that corruption is a serious concern in Montenegro; recognises the efforts undertaken by Montenegro in the fight against corruption and welcomes, in particular, the strengthening of the Directorate for Anti-Corruption Initiative brought about by the EU funding;

#### *Serbia*

63. Is worried that the independence of the judiciary remains a serious concern in Serbia, especially because of undue political influence; regrets further that the new legislation is neither consistently nor properly enforced, thus putting at risk its efficiency;

64. Welcomes the positive evaluation of the project 'Support to the establishment of the Anti-Corruption Agency' and notably the fact that the project should have a significant impact on all the targets groups and society in general; insists, however, on the need for constant monitoring in order to ensure that political developments do not hinder the project;

#### *Turkey*

65. Acknowledges that projects implemented in the area of the judiciary give reasonable evidence of sustainability and welcomes the political willingness of the Turkish authorities to continue the reform process initiated, as demonstrated by the increased budgetary allocation for judicial training; notes nevertheless a number of weaknesses in the design of projects, such as the absence of baseline data and the lack of SMART indicators, that need to be addressed in order to allow a proper assessment of the impact of the pre-accession projects;

**Tuesday 22 October 2013**

66. Notes that the EU financial assistance in the area of the fight against corruption started quite recently with the 2006 Ethics for the Prevention of Corruption in Turkey; acknowledges the information from the Commission that no EU funds could be programmed prior to the establishment of an independent single anti-corruption body and the adoption of a National Anti-Corruption Strategy; notes that the aforementioned project is considered as moderately satisfactory, but that it lacked SMART indicators;

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67. Instructs its President to forward this resolution to the Council, the Commission, the Court of Justice of the European Union, the European Court of Auditors, the OLAF Supervisory Committee and OLAF.

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Tuesday 22 October 2013

P7\_TA(2013)0435

**Patient safety**

**European Parliament resolution of 22 October 2013 on the report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections (2013/2022(INI))**

(2016/C 208/05)

*The European Parliament,*

- having regard to the Luxembourg declaration on patient safety of 5 April 2005,
- having regard to the report of the second meeting of the Informal Network on Infection Prevention and Control in Health Care (June 2008),
- having regard to the communication of 15 December 2008 from the Commission to the European Parliament and the Council on patient safety, including the prevention and control of healthcare-associated infections (COM(2008)0837),
- having regard to the Commission's Impact Assessment of December 2008,
- having regard to its resolution of 23 April 2009 on the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare-associated infections <sup>(1)</sup>,
- having regard to the Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections,
- having regard to the special Eurobarometer survey (No 327) on 'Patient Safety and Quality of Healthcare', published in April 2010,
- having regard to the report of the World Health Organisation (WHO) entitled 'Core components for infection prevention and control programmes',
- having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare,
- having regard to the report of 13 November 2012 from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections,
- having regard to the annual epidemiological reports for 2008 and 2012 of by the European Centre for Disease Prevention and Control (ECDC),
- having regard to the ECDC's technical document entitled 'Core competencies for infection control and hospital hygiene professionals in the European Union', published on 26 March 2013,
- having regard to the Commission's staff working paper of 18 November 2009 on antimicrobial resistance (SANCO/6876/2009r6),
- having regard to the joint technical report of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), published on 17 September 2009, entitled 'The bacterial challenge: time to react — A call to narrow the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents',

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<sup>(1)</sup> OJ C 184 E, 8.7.2010, p. 395.

**Tuesday 22 October 2013**

- having regard to the special Eurobarometer survey (No 338) on antimicrobial resistance, published in April 2010,
- having regard to its resolution of 12 May 2011 on antibiotic resistance <sup>(1)</sup>,
- having regard to the Commission recommendation of 27 October 2011 on the research Joint Programming Initiative ‘The Microbial Challenge — An Emerging Threat to Human Health’ (C(2011)7660),
- having regard to its resolution of 27 October 2011 on the public health threat of antimicrobial resistance <sup>(2)</sup>,
- having regard to the Commission communication of 15 November 2011 on an action plan against antimicrobial resistance (COM(2011)0748),
- having regard to the Council conclusions of 22 June 2012 on ‘The impact of antimicrobial resistance in the human health sector and in the veterinary sector — a “One Health” perspective’,
- having regard to its resolution of 11 December 2012 on ‘The Microbial Challenge — Rising threats from Antimicrobial Resistance’ <sup>(3)</sup>,
- having regard to Rule 48 of its Rules of Procedure,
- having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0320/2013),

#### **General remarks**

- A. whereas patient safety <sup>(4)</sup> and wellbeing are key to overall healthcare quality, and efforts to increase the safety of patients are dependent on the implementation of effective and long-term policies and programmes across Europe;
- B. whereas high-quality healthcare is the cornerstone of any high-quality health system and whereas access to high-quality healthcare is recognised as a fundamental right by the EU, the European institutions and European citizens;
- C. whereas Article 168 of the Treaty on the Functioning of the European Union stipulates that Union action must complement national policies and must be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health;
- D. whereas, therefore, the EU’s action in the field of patient safety consists in helping Member States to coordinate their efforts in this area and supporting their actions in fields where its intervention can provide added value;
- E. whereas it is essential to maintain citizens’ confidence in the health systems of the European Union;
- F. whereas the volume of data available on the prevalence and incidence of adverse events <sup>(5)</sup> in EU Member State healthcare systems is, at present, limited, but is steadily growing;

<sup>(1)</sup> OJ C 377 E, 7.12.2012, p. 131.

<sup>(2)</sup> OJ C 131 E, 8.5.2013, p. 116.

<sup>(3)</sup> Texts adopted, P7\_TA(2012)0483.

<sup>(4)</sup> Patient safety is defined by the WHO as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

<sup>(5)</sup> An adverse event is an incident which results in harm to a patient.

Tuesday 22 October 2013

- G. whereas the issue of patient safety is becoming a growing concern in health systems throughout the world, including in Europe;
- H. whereas the results of the Eurobarometer survey on 'Patient Safety and Quality of Healthcare' indicate both that European public opinion is highly aware of this issue and also that there is a marked lack of information on patient safety;
- I. whereas healthcare-related adverse events for the patient or his or her unborn or future descendants are: healthcare-associated infections (HAIs) <sup>(1)</sup>, medication- or medical device-related events, including those resulting from off-label use, diagnostic errors, and complications arising during or after surgical operations;
- J. whereas some adverse events are the result of risks inherent in operations or courses of medication deemed necessary by healthcare personnel, while others are the result of avoidable medical errors, shortcomings and failings in the healthcare supply chain;
- K. whereas it is estimated that between 8 % and 12 % of patients admitted to hospitals in the EU suffer from adverse events while receiving healthcare, including HAIs, errors during treatment or surgery, problems arising from failure or inadequate decontamination of medical equipment, errors in diagnosis, and failure to act on the results of tests;
- L. whereas demographic changes are leading to an increase in the proportion of older patients, who are frequently prescribed a large number of different medicines but are often unable to cope with taking them correctly;
- M. whereas, furthermore, older patients and patients with immunodeficiencies or chronic diseases, in particular degenerative diseases, are especially vulnerable to healthcare-related adverse events, such as: diagnostic errors; lack of follow-up to medical examinations; the prescription, dispensing or administration of an inappropriate (e.g. off-label) medicine, of an incorrect dose or of two medicines which should not be combined; failure or poor decontamination of medical equipment; and infection of surgical scars;
- N. whereas international studies estimate that between 13 % and 16 % of hospital costs (or one euro in seven) are incurred as a result of healthcare related incidents;
- O. whereas, however, it is estimated that between 30 % and 40 % of adverse events in both hospital and out-of-hospital (ambulatory) care appear to be caused by systemic factors and are therefore avoidable;
- P. whereas a lack of financial, technical and human resources is particularly associated with an increased risk of healthcare-related adverse events;
- Q. whereas the economic crisis has slowed down the implementation of measures adopted by the Member States in 2009, as a result of changed priorities in public health;
- R. whereas any natural or legal person has the right to make public or distribute, in good faith and in safety, information on a fact, an item of data or an action, as soon as a lack of knowledge of this fact, this item of data or this action appears to present a danger to public health;

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<sup>(1)</sup> For the purposes of this report, HAI means any infection which occurs during or following the provision of medical services (for diagnostic, therapeutic or preventive purposes) and which was not present or incubating prior to such provision. The infectious micro-organisms (bacteria, fungi, parasites and other transmissible agents) involved in HAI cases may come either from the patient's own organism (intestines, skin, etc), in which case they are called endogenous infections, or from the patient's environment, in which case they are known as exogenous infections or cross-infections. The term 'healthcare associated infection' covers all infections associated with healthcare systems in general and with individual treatment pathways. These include nosocomial infections (acquired in healthcare establishments, either as an inpatient or an outpatient) and infections acquired during treatment provided outside healthcare establishments, in collective facilities (such as medium- and long-stay facilities, in particular care homes for older people) or in the home.

**Tuesday 22 October 2013**

- S. Whereas patient safety enjoys a high priority on the political agenda; whereas the Member States established a mechanism for debate related to patient safety issues and other work in this area in 2005; whereas a working group was established, through which the Commission intends to promote the work and activities of the Member States, its active members being the WHO (especially through the World Alliance for Patient Safety), the Council of Europe, the OECD, and European associations of patients, physicians, nurses, pharmacists, dentists and hospitals;
- T. whereas HAIs are among the most common and the most dangerous causes of involuntary harm to patients;
- U. whereas HAIs, which, on average, are acquired by 5 % of patients admitted to hospital, are a major public health problem in the Member States and place a heavy burden on limited health service budgets;
- V. whereas for the period 2011-2012 the annual number of patients acquiring at least one HAI during a stay in an acute care hospital in the EU as a whole was estimated to be 3,2 million <sup>(1)</sup>.
- W. whereas HAIs, which have a high impact in terms of morbidity, mortality (with 37 000 people dying directly of such infections in the EU) and cost (estimated at over EUR 5,5 billion per annum Union-wide), constitute a major public health problem in the Member States;
- X. whereas HAIs can occur as a result of time spent in all settings in which healthcare is provided, including primary, community, social, private, acute and chronic care, during the provision of any healthcare services, or at home (in particular as a result of errors in dosage, errors in packaging the medicine, contamination through medical instruments or equipment, or contact with patients and healthcare professionals);
- Y. whereas a HAI contracted during a hospital stay may not display symptoms until after the patient has been discharged;
- Z. whereas the average length of a hospital stay in the Member States is falling;
- AA. whereas the ECDC has the task, with the involvement of international experts, of developing scientific recommendations for evidence-based measures for the effective prevention of HAIs;
- AB. whereas patients with chronic or degenerative diseases often receive home care instead of being admitted to hospital;
- AC. whereas the condition of some people with chronic or degenerative diseases often requires permanent and continuous medical assistance, very frequently necessitating, in particular, the use of medical devices (cardiac stimulators, respiratory devices, catheters, urinary catheters, etc.);
- AD. whereas the use of such medical devices carries a risk of infection;
- AE. whereas pathogens, in particular antimicrobial-resistant pathogens, can also be spread as a result of failure to follow basic hygiene precautions in environments such as healthcare establishments and in the home;
- AF. whereas simple and cost-effective action to prevent HAIs, such as sanitation education (in particular, the promotion of hospital hygiene), already exists or is currently being tested on an experimental basis, with promising results, and whereas potential alternative, cost-effective ways of combating HAIs could usefully be explored;
- AG. whereas, since the micro-organisms responsible for HAIs are capable of colonising the human body for long periods, patients can spread them not only during their hospital stay but also afterwards, and whereas HAIs can thus affect all care premises, medium- and long-term care establishments, and even the patient's home;

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<sup>(1)</sup> According to the Commission's answer to written question E-004648/2013, given on 14 June 2013.

Tuesday 22 October 2013

- AH. whereas only 13 Member States have implemented national surveillance of *Clostridium difficile* infections <sup>(1)</sup> and in only three of these surveillance systems are general practitioners also involved in the data collection — a situation that should be improved;
- AI. whereas, furthermore, people's increasing mobility within and between national healthcare systems inside the EU, the increasingly cross-border nature of healthcare in Europe and freedom to seek medical treatment outside one's country of residence are making it easier for resistant micro-organisms to spread rapidly from one Member State to another;
- AJ. whereas the issue of antimicrobial resistance is a serious, and in some countries growing, threat to patient safety that can complicate recovery from and treatment of infections and increases national health costs;
- AK. whereas HAIs are often difficult to treat, as the micro-organisms responsible for them are frequently resistant to antimicrobial agents;
- AL. whereas in the EU, Iceland and Norway alone antimicrobial resistant bacteria cause some 400 000 infections and 25 000 deaths annually, with at least EUR 1,5 billion spent on extra healthcare costs and productivity losses;
- AM. whereas antibiotic resistance in Europe is continuing to increase, and for certain bacteria may be 25 %, or even more, in several Member States;
- AN. whereas the latest available data indicate that antibiotic resistance markers for the bacteria involved in HAIs highlight an increasing global trend towards multi-resistance, and, in particular, increases in the percentages of *Enterobacteriaceae* resistant to third-generation cephalosporins and of methicillin-resistant *S. aureus*;
- AO. whereas there is a decline in the development of new antimicrobials;
- AP. whereas development of resistance to antimicrobial agents is a natural and unavoidable consequence of their use, but whereas it can be limited if they are used prudently and rationally;
- AQ. whereas the development of resistance to antimicrobial agents can be accelerated, in particular, by the inordinate and indiscriminate use of these products in human medicine, which, combined with insufficient hygiene and infection control, can compromise the effective use of an already limited number of existing antimicrobial agents;
- AR. whereas, in view of the lack of development of new antibiotics/antimicrobial agents, it is vital for current antimicrobial agents to be used effectively for as long as possible;
- AS. whereas, in view of the lack of development of new antibacterial medicines, the Commission and the Member States should work together to support the development and availability of such products, making use of the ECDC and the expertise of the European Medicines Agency (EMA);
- AT. whereas farming policies promote the occurrence of antibiotic resistance, both through the food chain and through animal waste entering the water cycle;
- AU. whereas consumption of antibiotics is higher among people who are objectively the least well-informed, and whereas better objective knowledge of antibiotics is associated with more responsible behaviour in terms of their use;

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<sup>(1)</sup> According to the Commission's reply to written question E-004649/2013 these 13 countries are: Austria, Belgium, Bulgaria, Denmark, Germany, Finland, France, Hungary, Ireland, the Netherlands, Spain, Sweden and the UK: <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2013-004649&language=EN>

**Tuesday 22 October 2013**

- AV. whereas certain Member States do not have a solid regulatory and legal framework to support and make compulsory the rational use of medicines, and whereas there are considerable disparities in Europe in terms of consumption of antibiotics, in the context of both community and hospital care;
- AW. whereas there is a need to educate and raise awareness among those involved in antimicrobial use, including policymakers, health professionals and the general public, in order to encourage the necessary changes in the behaviour of prescribers, dispensers and citizens;
- AX. whereas, since the adoption in 2009 of Council Recommendation 2009/C 151/01, substantial effort has been invested in improving patient safety in the Member States, particularly by embedding it as a priority in public health policies in all Member States, by designating a competent authority responsible for patient safety (in 19 Member States), and encouraging training in patient safety in healthcare establishments (in 23 Member States);
- AY. whereas, since the adoption in 2009 of Council Recommendation 2009/C 151/01, substantial effort has been invested in adopting and implementing strategies (national and regional) for the prevention and control of HAIs in the Member States, particularly through the adoption of guidelines on their prevention and control and by setting up active HAI surveillance systems (or strengthening those that already exist);
- AZ. whereas, on the other hand, some of the actions recommended by the Council in its Recommendation 2009/C 151/01 on how to improve patient safety in the Member States have thus far been implemented by only a limited number of Member States, and whereas there is room for improvement — in both hospital and non-hospital care — particularly in respect of patient empowerment and the overall training of health professionals and carers, as well as in the implementation of European classifications on patient safety and the development of European guidelines on patient safety standards;
- BA. whereas some of the specific measures the Council recommended for preventing and combating HAIs in the Member States have been implemented in only a limited number of Member States, and whereas progress is still possible, particularly in respect of provision of information to patients by healthcare establishments and support for research into the prevention and control of HAIs;

***Implementation of the Council's recommendations: major improvements made, but further progress required***

1. Welcomes the measures put in place by Member States with the principal aim of improving general patient safety and preventing the incidence of HAIs, in particular by:

- all Member States drawing up patient safety policies and the fact that many Member States have made these policies a priority of their healthcare policy;
- the designation of a competent authority responsible for patient safety (in most Member States);
- the gradual establishment of mechanisms for reporting adverse events and learning lessons from such failings;
- the widespread introduction of patient safety training campaigns in healthcare establishments;
- the implementation, in France, Slovakia and the Netherlands, of cross-border patient safety strategies (in addition to the national strategy);
- collaboration between countries and between regions with a view to carrying out the actions recommended by the Council and implemented by 21 Member States (plus Norway), in many cases in the context of projects cofinanced by the EU;

but asks as a matter of urgency that these efforts be increased;

2. Welcomes the steps taken by the Commission to improve general patient safety by promoting exchange of best practice between Member States and devising definitions and terminology for patient safety, and in particular:

- the Commission's fostering of exchange of information on initiatives concerned with patient safety and quality of care, in the context of the Working Group on Patient Safety and Quality of Care;

Tuesday 22 October 2013

- the Commission's cofinancing of the OECD-led project on healthcare quality indicators, which has made it possible to collect comparable indicators of patient safety in 11 countries;
  - the EU's cofinancing, under the Seventh Framework Programme for Research, of six research projects on general patient safety;
  - the adoption of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, which seeks not only to clarify the rights of patients when accessing care in another Member State, but also to ensure that such care is safe and of good quality;
3. Welcomes the work conducted by the Commission and the ECDC, in conjunction with health authorities in the Member States, on HAI prevention and control;
4. Welcomes the Commission's action in the area of preventing and combating HAIs, which is closely linked to its action in the area of resistance to antimicrobial agents; welcomes, in particular, the financing provided by the Commission for research projects on HAIs and antimicrobial resistance, especially those having a European dimension, such as IPSE (Improving Patient Safety in Europe), IMPLEMENT (Implementing Strategic Bundles for Infection Prevention and Management), and PROHIBIT (Prevention of Hospital Infections by Intervention and Training), which seeks to analyse existing practical guidelines on prevention of HAIs in European hospitals and test a strategy for preventing bloodstream infections linked to central venous catheters (infections which are particularly worrying in that they are associated with significant morbidity and a high level of directly related mortality);
5. Welcomes the coordination and monitoring work of the ECDC, and in particular:
- its activities in coordinating the European network for surveillance of HAIs, particularly surgical site infections, HAIs acquired in intensive care units and antimicrobial use in long-term care facilities (HALT-2), as well as its support for the European project to support capacity building for surveillance of *Clostridium difficile* infections (ECDIS-Net);
  - its coordination of a European study on HAI prevalence and antimicrobial use in acute care hospitals;
  - its development of guidance for the prevention and control of *Clostridium difficile* infections;
  - its publication of recommendations to prevent the spread of carbapenemase-producing *Enterobacteriaceae*;
  - its support for the development of guidelines and indicators (on structure and method) for preventing HAIs;
6. Recognises that no classification or reporting system for patient safety exists at EU level for the purpose of identifying, understanding and analysing the factors involved in patient safety, with a view to learning and improving the relevant systems;
7. Acknowledges that, to date, too few Member States:
- have integrated patient safety into the education and training of health professionals;
  - have action plans in place for combating HAIs;
  - have taken steps to improve the provision of HAI-related information to patients by healthcare establishments;
  - have provided support for research into HAIs;
8. Calls for the collection of comparable indicators on patient safety by Member States to be continued, and for all the Member States, with support from the Commission, to become involved in this work;
9. Calls on the Member States to continue and step up bilateral and multilateral cooperation on patient safety, as well as national and/or regional action in this area;

Tuesday 22 October 2013

***Improving patient safety in Europe, including by preventing and controlling HAIs: general recommendations***

10. Recommends that the issue of patient safety, and in particular the prevention and control of HAIs, be given a place near the top of the political agenda in the EU, both at national level in the Member States and at regional and local level;

*Measures to improve general patient safety*

11. Urges the Member States to continue their efforts to improve patient safety by taking, if they have not already done so, additional measures, including setting up action plans for combating HAIs, in order to fall fully into line with the Council's recommendations;

12. Urges the Member States, in particular, to take, or step up if they are already being implemented:

- measures to make the public more aware of initiatives in the area of patient safety and empower patients in this area;
- measures for the thorough and continuous training, based on well-defined standards, of healthcare workers in the area of patient and healthcare worker safety, and in particular the introduction of patient safety training modules (covering various areas including medical devices and rational and diligent use of medicines) in one or more study or training variants for healthcare professionals and carers, as well as measures for education and awareness-raising aimed at patients and their carers in the area of patient safety;
- cross-border activities in the area of patient safety;
- measures to encourage research into patient safety using an evidence-based approach with a focus on implementation and focusing in particular on forms of therapy that offer an alternative to treatment with antibiotics and a response to resistance to antibiotics, including bacteriophage therapy;
- measures to support multidisciplinary wound care as part of patient safety programmes at Member State level;
- measures to prevent the occurrence of and combat the spread of antimicrobial resistance, including the development of new antimicrobials;

13. Calls on the European Medicines Agency (EMA) to draw up a list of off-label medicines which are used in spite of there being an approved alternative; calls on the Member States to ensure that medical professionals and patients are informed when a medicine is used off-label;

14. Urges the Commission and the relevant EU agencies to introduce, or strengthen if they already exist, arrangements for reporting adverse events — in particular those involving medicines and medical devices — which make it possible to identify those responsible in the event of a breakdown in the chain of care and learn lessons from such breakdowns, to make those arrangements known to the public and easy to use, and to ensure that all procedures are transparent;

15. Urges the Member States to re-evaluate their adverse event reporting structures, to assess whether such reporting is taking place in a 'no-blame' culture, and to ensure that healthcare professionals can come forward with information candidly, without negative consequences for themselves personally;

16. Calls on the Member States to adopt measures which raise the quality — and not just the quantity — of reporting on adverse events, so that reporting contains information which can really improve safety, and which makes it easy to call up data from the system for a comprehensive and systematic evaluation;

17. Calls on the Member States to do far more to incorporate patients' information into electronic systems dealing with patient safety and adverse events, and to systematically evaluate that information, precisely in order to prevent errors;

18. Urges the Member States, the Commission and the relevant EU agencies to use all relevant technological and statistical tools to describe and analyse adverse events;

19. Urges the Commission and the Member States to make the public more aware of initiatives in the area of patient safety, and to empower patients in this area;

Tuesday 22 October 2013

20. Urges the Commission to consider once again the calls for the introduction of a database listing good practices with a view to fostering exchanges of such practices among the Member States; believes that an adverse events database could prevent such events occurring in future and could serve as an example of good practice for providers;

21. Encourages the Member States to share best practices through a data-based approach and, in particular, to draw up, on the basis of case studies and feedback, common guidelines to be applicable throughout the Union;

22. Calls on the Member States to apply, wherever possible, hospital patient safety strategies and programmes in non-hospital care environments (in long- and medium-stay facilities, but also in the home);

*Measures designed to guard against and reduce the number of HAIs*

23. Urges the Member States to set clear national targets for the reduction of HAIs, and to implement, if they have not already done so, additional measures to guard against and reduce the number of HAIs, with a view to falling fully into line with the Council's recommendations, and in particular measures to:

- prevent HAIs both inside and outside hospitals by the systematic implementation of the One Health approach, whereby both medical and veterinary professionals undertake to prevent resistant infections and reduce the use of antibiotics;
- improve the information provided to patients by healthcare establishments, including information on the prevalence of HAIs in those establishments;
- support research into the prevention and control of HAIs, particularly those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* and other emerging difficult-to-treat infections and focusing in particular on forms of therapy that offer an alternative to treatment with antibiotics and a response to antibiotic resistance, including bacteriophage therapy;

24. Urges the Commission to consider the scope for the conclusion of partnership agreements between itself and individual Member States or directly between Member States with a view to preventing and resolving HAI problems in hospitals and in the context of home care; calls on the Commission to support further work on the prevention and control of HAIs through the forthcoming EU Health Programme;

***Improving patient safety in Europe, including by preventing and controlling HAIs: specific approaches and recommendations***

*Prevention*

25. While acknowledging that the EU may not interfere with the Member States' competences in the field of health, and acknowledging the differences existing in terms of healthcare policies and systems among Member States, encourages the Member States and their delegated partners to:

- make sufficient human, financial and technological resources available to ensure that care provided in the home or in hospital is of the highest possible quality, calling on them, in particular, to allocate adequate budgets to patient safety and to ensure that care provided in the home or in hospital is of the highest possible quality;
- also prioritise effective workforce planning as a means of ensuring that staffing levels are adequate to deal with increasing patient throughput and the attendant negative impact on infection control practices;

26. Calls on the Member States and the Commission to foster, including by means of awareness-raising campaigns, good practices in all areas, in particular all those linked to hygiene (hand hygiene; sterilisation and optimum decontamination of medical instruments and devices), both inside and outside hospital (in particular vis-à-vis patients and their families);

27. Calls on the Member States to draw up national guidelines for hand hygiene and general cleaning of hospitals and care homes;

28. Calls on the Member States to promote targeted action to prevent errors in hospitals, including the implementation of the WHO Surgical Safety Checklist;

**Tuesday 22 October 2013**

29. Calls for more and better coordinated research to avoid the spread of HAIs;
30. Calls on the Member States to encourage efforts to study hospital outbreaks and find a way of preventing the spread of healthcare associated infections;
31. Encourages Member States to develop their national practices on the appropriate use of antibiotics, in order to limit the spread of antimicrobial resistance and ensure that antibiotic treatment remains effective;
32. Calls on the Commission and the Member States to develop platforms and protocols allowing health data portability, while ensuring that such activities respect the relevant European data protection legislation;
33. Calls on the Member States to draw up specific safety protocols for chronic degenerative and disabling diseases which necessitate round-the-clock assistance outside hospital (in long- and medium-stay facilities, but also in the home);
34. Emphasises, as regards home care, that:
  - the state of health of patients (particularly older persons and persons with reduced mobility) returning home after a period of hospitalisation must be assessed thoroughly when they leave hospital, with a view, in particular, to evaluating and countering the risk of falls;
  - patients and their carers must be properly informed, in particular about hand hygiene and the need to decontaminate reusable medical instruments and devices, as well as the need to comply with procedures and prescriptions;
  - equipment used should be disposable or subject to thorough decontamination procedures if reused;
  - the taking of basic precautions should be encouraged, in particular as regards the storage and use of medicines, and patients should, in particular, be made aware of the risks involved in using medicines that have no marketing authorisation;
35. Urges the Member States to provide the Commission with information on vaccination programmes for healthcare professionals, including the levels of coverage achieved within healthcare institutions;
36. Urges the Member States to encourage information input by health professionals on how patients can avoid being harmed as a result of contact with the health system;
37. Calls on the Member States to take measures to increase patients' families' involvement in preventing errors in medication and self-treatment;

*Communication, education and training*

38. Recommends that Member States conduct specific awareness-raising and training measures concerning HAIs which are aimed not only at healthcare professionals (doctors, nurses, paramedics, etc), but also, for example, formal and informal carers and hospital volunteers who have contact with patients;
39. Calls on the Member States to introduce national guidelines for health professionals on how to train patients in the use of antibiotics;
40. Calls on the Member States to conduct specific information and training campaigns to raise awareness among patients and healthcare professionals of the issue of antimicrobial resistance;
41. Calls on the Member States to draw on, and accord proper importance to, the expertise built up as a result of patients' own experience when compiling best practices;

*Patients' rights*

42. Calls on the Member States to do what they can to ensure that patients trust their health systems and, in particular, to involve patients closely in patient safety;
43. Calls on the Member States to involve patient organisations in the development of new laws and health programmes;

Tuesday 22 October 2013

44. Calls on the Member States to designate at local level an authority or a contact person responsible for providing patients with information and data concerning patient safety, in order to strengthen public confidence in the safety of health systems through the increased provision of adequate and understandable information;
45. Encourages the Member States to provide patients with information on risks, safety levels and the measures taken to prevent adverse events in healthcare, in order to ensure that patients can give informed consent to the treatment they are being offered and, more generally, to enable patients to learn more about the issue of patient safety; requests that the Member States inform patients, through the appropriate organisational structures, about complaints procedures and the legal options available to them should adverse events in healthcare occur (e.g. through a patients' rights representative);
46. Encourages the Member States and regional and local authorities to prioritise, as far as possible, approaches based on mediation when adverse events in healthcare occur;
47. Calls on the Member States to encourage practising doctors to inform patients of their rights and the possibilities open to them in terms of lodging complaints and reporting errors and adverse events;
48. Acknowledges that the EU may not interfere with the Member States' competencies in the field of health; encourages the Commission, nonetheless, to establish collective redress mechanisms in cross-border cases where multiple patients are affected by healthcare-related adverse events resulting from the same cause;

*Control, diagnosis and follow-up*

49. Calls on the Commission, the relevant EU agencies and the Member States to consider action to ensure the provision of feedback on patient safety, not only from medical staff but also from patients; stresses that their reporting should be transparent at all levels;
50. Calls on those Member States which conduct specific national HAI prevalence surveys using a harmonised ECDC methodology to do so on a regular basis, and encourages all Member States to introduce such surveys; urges the Commission to look more closely at the Global Microbial Identifier system<sup>(1)</sup>, which is supported by a large number of researchers throughout the world, and which can monitor and detect alert healthcare-associated organisms and boost capacity to respond to the spread (including the cross-border spread) of infections;
51. Recommends that regional or local working parties be set up to consider specific issues relating to patient safety; suggests by way of example that such working parties could focus on accident prevention among older people, reducing operation-related risks, or reducing the risk of medication-related errors;
52. Calls on the Member States to encourage hospitals and care homes to focus on basic care tasks such as observation of patients and assessment of pressure sores, which are a major but often hidden problem for hospitalised patients and inmates;
53. Calls on the European Medicines Agency to develop guidelines on the off-label use of medicines, on the basis of medical need and taking account of patient protection;
54. Calls on the ECDC to draw up, in cooperation with the EMA, a list of pathogens that can cause serious or potentially fatal antibiotic-resistant infections and pose a serious health risk; calls for that list to be updated on a regular basis with information supplied by the ECDC's European Surveillance of Antimicrobial Consumption Network (ESAC-Net) and European Antimicrobial Resistance Surveillance Network (EARS-Net);
55. Recommends that a list of HAIs which should be screened for in all hospitals and healthcare establishments in the EU be drawn up in cooperation with the EMA and the ECDC;

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<sup>(1)</sup> <http://www.globalmicrobialidentifier.org/>

**Tuesday 22 October 2013**

*European and international cooperation*

56. Calls on the Member States and the Commission, in conjunction with the WHO and the OECD, to improve cooperation with a view to developing standardised definitions, terminology and indicators in the area of patient safety, in particular so as to ensure that high-risk patients can be isolated should a pandemic or cross-border threat emerge;

57. Emphasises the importance of establishing an effective European network of national surveillance systems which would work, on the basis of standardised criteria to be adopted by the Commission and the Member States, to identify and monitor places where contamination with HAIs occurs (including facilities outside hospitals), as well as the way in which HAIs spread; urges the Member States to continue their efforts to collect comparable, up-to-date reference data on general patient safety and HAIs; calls on the Member States to publish the data concerned on an annual basis;

58. Calls on the Member States to share, where they exist, good practice benchmarks in the area of general patient safety, and, in particular in the area of the prevention and control of HAIs and the transmission of multi-resistant bacteria (e.g. measures to prevent the spread of legionella bacteria in hospital hot-water systems);

59. Acknowledges the importance of the ECDC's Antimicrobial Resistance and Healthcare-associated Infections Programme (ARHAI), particularly in its efforts to support and standardise the monitoring of HAIs, offer scientific advice, and provide training and communication;

60. Calls on the Member States collaborate in the creation of platforms which allow the sharing of information concerning adverse events in healthcare, encouraging the use of all relevant data collection mechanisms whilst ensuring that such activities respect the applicable European data protection legislation; stresses that patients must be dealt with in accordance with ethical principles and their personal data must be protected;

61. Calls on the Commission and the Member States to cooperate in introducing incentives for the development of new antibacterial medicines; considers that such incentives should be introduced as part of an appropriate EU legislative framework, with a view to fostering cooperation between the public and private sectors in order to revitalise antimicrobials-related research and development;

62. Believes that, under the Eighth Framework Programme for Research, which is to commence in 2014, the EU should cofinance research into general patient safety, HAIs and resistance to antimicrobial agents;

*Monitoring and reporting*

63. Urges the Member States and the Commission to extend by at least two years the monitoring of the actions taken to implement the recommendation on patient safety, including the prevention and control of HAIs;

64. Urges the Member States to step up their cooperation with the ECDC in the area of the prevention and control of HAIs; encourages national authorities in particular to ask the ECDC to carry out regular in situ audits and to publish the reports submitted to them by the ECDC, and emphasises, in that connection, the need to ensure, under future multiannual financial frameworks, that the ECDC receives the adequate funding that it needs to fulfil its coordination and monitoring remit;

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65. Instructs its President to forward this resolution to the Council, the Commission, the Committee of the Regions and the Member States.

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Tuesday 22 October 2013

P7\_TA(2013)0436

**Misleading advertisement practices****European Parliament resolution of 22 October 2013 on misleading advertisement practices (2013/2122(INI))**

(2016/C 208/06)

*The European Parliament,*

- having regard to the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on protecting businesses against misleading marketing practices and ensuring effective enforcement (COM(2012)0702),
- having regard to Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (codified version) <sup>(1)</sup>,
- having regard to Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (the 'Unfair Commercial Practices Directive') <sup>(2)</sup>,
- having regard to Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation) <sup>(3)</sup>,
- having regard to Directive 98/27/EC of the European Parliament and of the Council of 19 May 1998 on injunctions for the protection of consumers' interests <sup>(4)</sup>,
- having regard to its resolution of 9 June 2011 on misleading business directories <sup>(5)</sup>,
- having regard to its resolution of 13 January 2009 on the transposition, implementation and enforcement of Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market and Directive 2006/114/EC concerning misleading and comparative advertising <sup>(6)</sup>,
- having regard to its resolution of 16 December 2008 on misleading directory companies <sup>(7)</sup>,
- having regard to the study entitled 'Misleading practices of "directory companies" in the context of current and future internal market legislation aimed at the protection of consumers and SMEs', commissioned by its Committee on the Internal Market and Consumer Protection <sup>(8)</sup>,
- having regard to the draft opinion of the European Economic and Social Committee of 19 April 2013 on the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entitled 'Protecting businesses against misleading marketing practices and ensuring effective enforcement — Review of Directive 2006/114/EC concerning misleading and comparative advertising' (COM(2012)0702) <sup>(9)</sup>,
- having regard to Rule 48 of its Rules of Procedure,
- having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinion of the Committee on Legal Affairs (A7-0311/2013),

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<sup>(1)</sup> OJ L 376, 27.12.2006, p. 21.

<sup>(2)</sup> OJ L 149, 11.6.2005, p. 22.

<sup>(3)</sup> OJ L 364, 9.12.2004, p. 1.

<sup>(4)</sup> OJ L 166, 11.6.1998, p. 51.

<sup>(5)</sup> OJ C 380 E, 11.12.2012, p. 128.

<sup>(6)</sup> OJ C 46 E, 24.2.2010, p. 26.

<sup>(7)</sup> OJ C 45 E, 23.2.2010, p. 17.

<sup>(8)</sup> IP/A/IMCO/ST/2008-06.

<sup>(9)</sup> INT/675 — CES1233-2013\_00\_00\_TRA\_PA.

**Tuesday 22 October 2013**

- A. whereas misleading marketing practices can take many forms, with the most prominent being business directories, payment forms, internet domain name and trademark protection scams and misleading 'business opportunity', 'work from home' or 'get-rich- quick' schemes;
- B. whereas the scope of Directive 2006/114/EC is currently related to misleading and comparative advertising and its consequences for fair competition within the internal market;
- C. whereas there is a clear demand from businesses, especially SMEs and microbusinesses, for better protection and effective action against misleading practices in a business-to-business context, which, however, lies outside the scope of Directive 2005/29/EC;
- D. whereas the level of financial loss in the EU arising from misleading marketing practices is not known, but on the basis of certain national statistics could be estimated at billions of euros each year;
- E. whereas misleading marketing practices cause market failures and distortions of competition, impairing the ability of businesses to make informed and hence effective choices;
- F. whereas SMEs, and in particular small businesses and microbusinesses, are the main victims of misleading marketing practices, although such companies are a key driver for growth in Europe; whereas schools, churches, hospitals, NGOs, and municipalities and other public authorities are also being targeted;
- G. Whereas Parliament has repeatedly expressed its concern over the problem of misleading marketing practices, which are often of a cross-border nature, and has called on the Commission and the Member States to step up their efforts in terms of raising awareness, strengthening cooperation, enforcement and legislation;
- H. whereas misleading marketing practices have a knock-on effect on consumers, who are, as a result, charged more for products and services;
- I. whereas these practices go under-reported, as victims of misleading marketing practices often feel ashamed and refrain from reporting such practices to enforcement authorities or comply with payment demands; whereas in view of this it is extremely important that those authorities facilitate reporting and give sufficient priority to such cases;
- J. whereas Member States have implemented Directives 2005/29/EC and 2006/114/EC differently, leading to significant differences between national provisions in those fields; whereas such differences contribute to market fragmentation and create uncertainties over the legal enforcement of EU rules concerning businesses, especially in a cross-border context;
- K. whereas rogue traders exploit the highly uneven levels of protection for businesses existing across the Member States, with only Austria and Belgium having included a specific ban on misleading directory schemes in their legislation, while the Netherlands is currently preparing a similar law;
- L. whereas it is essential to apply a coherent approach, striking a balance between prevention and punishment; whereas unless there are clear legal provisions addressing the problem the enforcement authorities will remain hesitant to act;
- M. whereas at present rogue traders are very difficult to trace and prosecute, as they often send invoices from one country to another while their bank account is in yet another country, thus also making money transfers difficult to trace;
- N. whereas, owing to their small scale and limited resources, it is often unfeasible for SMEs, and microbusinesses in particular, to individually mount legal challenges against rogue traders established in a different jurisdiction;
- 1. Welcomes the Commission communication, but stresses that an additional effort is needed, especially with regard to enforcement;

Tuesday 22 October 2013

2. Is deeply concerned about the negative impact of deceptive, misleading and unfair marketing practices on economic growth, especially for SMEs, and on fair competition within the internal market, especially in Member States that are less developed and worst affected by the financial crisis;

3. Asks the Commission to clarify the scope of Directive 2006/114/EC in order to allow better protection for businesses against misleading marketing practices;

#### ***Prevention and information***

4. Stresses that a better exchange of information between Member States is needed; calls on all Member States to create or assign a national focal point to which businesses and other victims of misleading practices can report them and can obtain information on judicial and non-judicial means of redress, as well as help and expertise regarding the prevention and tackling of various forms of fraud; considers that each focal point should maintain a database recording all types of misleading marketing practices and including easy-to-understand examples; calls on the Commission to ensure coordination of a smooth exchange of information from the national databases, inter alia by facilitating the setting-up of a rapid alert system identifying new practices, whilst taking account of the budgetary limitations;

5. Believes that the national focal points should play an active role in sharing information between public authorities, citizens and businesses, and should work together in order to warn each other of new misleading practices and assist SMEs in the settlement of cross-border disputes by providing defrauded companies with information on judicial and non-judicial means of redress; believes that these national focal points should be responsible for communicating their general findings to the public of the Member State concerned on a regular basis;

6. Calls on national as well as international business organisations, and in particular SME organisations, to work closely together with the national focal points; in this regard, also welcomes public-private cooperation;

7. Supports the Commission's intention to investigate the possibility of introducing, on the basis of validated criteria, an EU-wide blacklist of misleading marketing practices, and, if practicable, of companies who have been repeatedly convicted for such practices; recommends that such a blacklist should be coherent with that which already exists under the Unfair Commercial Practices Directive, should be exhaustive, and should include clear definitions of misleading marketing practices;

8. Calls on Europol to play a more active role in tackling these forms of fraud by collecting information regarding cross-border forms of misleading marketing practices and by analysing the structures behind the perpetrating companies, and also to provide mechanisms for quick exchanges of up-to-date information on these practices and structures among national enforcement authorities;

9. Underlines the need for national enforcement authorities to work more closely together with providers whose services have been used by perpetrators of misleading marketing practices, such as banks, telephone companies, postal services and collection agencies, in particular by stepping up the exchange of information, in order to help prevent rogue companies from operating;

10. Urges the Commission and the Member States jointly to promote initiatives to educate and inform all business undertakings and promote exchanges of best practice between them, thereby ensuring that they are aware of the dangers;

#### ***Enforcement and prosecution***

11. Emphasises the fact that different levels of protection and public enforcement mechanisms among Member States are an obstacle to running advertising campaigns across national borders, and that this leads to major legal and operative uncertainties for businesses;

12. Notes with concern that the investigative authorities in a number of Member States are extremely unwilling to take up cases of misleading marketing practices because of the lack of clarity of the existing provisions, and that they have no confidence that the burden of proof can be sufficiently established; underlines the need for government to be proactive in tackling financial and economic crime;

**Tuesday 22 October 2013**

13. Stresses that the investigation and prosecution of misleading marketing practices need to be improved; calls on the Commission, therefore, to draw up guidelines for national enforcement bodies on best practices for national enforcement bodies regarding priorities for investigation and prosecution; calls on the Member States to boost the capacity and expertise of the relevant investigative and judicial authorities;
14. Stresses the need to introduce effective, proportionate and dissuasive penalties, recalling that sanctions can have a preventive effect;
15. Calls on the Commission to establish a mutual cooperation network between national enforcement bodies to improve the implementation of the Directive in cross-border cases;
16. Calls on the Commission to evaluate Parliament's recommendation for a partial extension of the scope of the Unfair Commercial Practices Directive by having Annex I (the blacklist) cover business-to-business (B2B) contracts, in parallel to the consideration of a possible review of Directive 2006/114/EC in order to assess whether this would result in a more coherent approach since it would extend the concept of unfair commercial practices, together with the blacklist, to B2B relations;
17. Welcomes the Commission's intention to propose a clearer definition of misleading marketing practices; in this respect, calls on the Commission to introduce additional definitions for 'green claim' practices;
18. Calls on the Commission to examine, as a matter of priority, how any convictions for using serious and repeated misleading marketing practices could affect the eligibility of the companies concerned for taking part in EU procurement procedures and/or receiving EU funding;
19. Calls on the Member States to ensure that their tax authorities cooperate closely with national focal points by actively inspecting companies which have been reported to use misleading marketing techniques;
20. Stresses the need for a more proactive role for organisations responsible for company registration, such as chambers of commerce, with a view to the identification of suspicious behaviour and the prevention of fraudulent practices;
21. Draws attention, in particular, to the role played by fraudulent debt collection agencies which do not hesitate to put pressure on businesses to pay invoices which they know or could have known to be fraudulent; calls on the Commission and the Member States to propose means of better controlling such agencies, both before and after their formal establishment, and also to consider the possibility of introducing a mandatory requirement for debt collection agencies to report misleading practices;
22. Notes with concern that dispute resolution processes have proven inefficient, lengthy and costly, and that they offer no guarantee of adequate and timely compensation for the damage caused; stresses the need to remedy this state of affairs, and thus enable victims to obtain fair compensation; calls on the Member States to introduce, where applicable, national laws making it possible for the victims of misleading marketing practices to act collectively in a case against a rogue company, in line with the recently published Commission Recommendation C(2013)3539 and Commission Communication COM(2013)0401; stresses that, in order to avoid abusive litigation, the victims should be represented by a qualified entity, as outlined in the Commission documents;

#### ***International cooperation beyond the EU***

23. Stresses that misleading marketing practices constitute an international problem which extends beyond individual Member States as well as the EU; calls on the Commission and the Member States, therefore, to pursue international cooperation on the matter, with both third countries and the competent international organisations;
24. Calls on the Commission to step up its involvement in the International Mass Marketing Working Group, which consists of law enforcement, regulatory, and consumer agencies in the US, Australia, Belgium, Canada, the Netherlands, Nigeria, and the UK, and also includes Europol;

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25. Instructs its President to forward this resolution to the Council and the Commission.
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Wednesday 23 October 2013

P7\_TA(2013)0438

**Marine knowledge 2020****European Parliament resolution of 23 October 2013 on marine knowledge 2020: 'Seabed mapping for promoting sustainable fisheries' (2013/2101(INI))**

(2016/C 208/07)

*The European Parliament,*

- having regard to the Commission Green Paper of 29 August 2012 entitled 'Marine Knowledge 2020: from seabed mapping to ocean forecasting' (COM(2012)0473),
- having regard to the Commission communication of 8 September 2010 entitled 'Marine Knowledge 2020: marine data and observation for smart and sustainable growth' (COM(2010)0461),
- having regard to Council Regulation (EC) No 199/2008 of 25 February 2008 concerning the establishment of a Community framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the common fisheries policy,
- having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy,
- having regard to the Commission proposal of 12 March 2013 for a directive establishing a framework for maritime spatial planning and integrated coastal management (COM(2013)0133),
- having regard to the Commission communication of 13 September 2012 entitled 'Blue growth: Opportunities for marine and maritime sustainable growth' (COM(2012)0494),
- having regard to the Directive of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (Directive 2008/56/EC),
- having regard to the Directive of the European Parliament and of the Council of 14 March 2007 establishing an infrastructure for spatial information in the European Community (INSPIRE) (Directive 2007/2/EC),
- having regard to the Directive of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information (Directive 2003/98/EC),
- having regard to Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013),
- having regard to the Commission communication of 17 July 2012 entitled 'Towards better access to scientific information: Boosting the benefits of public investments in research' (COM(2012)0401),
- having regard to the Commission recommendation 2012/417/EU of 17 July 2012 on access to and preservation of scientific information,
- having regard to the Recommendation 2002/413/EC of the European Parliament and of the Council of 30 May 2002 concerning the implementation of integrated coastal zone management in Europe,
- having regard to the Commission report of 11 September 2012 entitled 'Progress of the EU's Integrated Maritime Policy' (COM(2012)0491),
- having regard to the Commission staff working document of 29 August 2012 on the interim evaluation of the European Marine Observation and Data Network (SWD(2012)0250),
- having regard to the Commission document of 8 March 2012 entitled 'Roadmap for a European marine observation and data network' (Ares(2012)275043),
- having regard to the Commission staff working document of 8 September 2010 on the impact assessment of the European Marine Observation and Data Network (SEC(2010)0998),

**Wednesday 23 October 2013**

- having regard to the Commission communication of 3 March 2010 entitled 'Europe 2020 — A strategy for smart, sustainable and inclusive growth' (COM(2010)2020),
  - having regard to the Commission staff working document of 22 January 2010 on the outcome of the public consultation on marine data infrastructure (SEC(2010)0073),
  - having regard to the Council conclusions on integrated maritime policy at its 2973rd meeting (General Affairs and External Relations Council) on 16 November 2009,
  - having regard to the Commission report of 15 October 2009 entitled 'Progress report on the EU's Integrated Maritime Policy' (COM(2009)0540),
  - having regard to the Commission staff working document of 7 April 2009 entitled 'Building a European marine knowledge infrastructure: Roadmap for a European marine observation and data network' (SEC(2009)0499),
  - having regard to the Commission communication of 3 September 2008 entitled 'A European Strategy for Marine and Maritime Research: A coherent European Research Area framework in support of a sustainable use of oceans and seas' (COM(2008)0534) and to the resolution of Parliament of 19 February 2009 on applied research relating to the common fisheries policy<sup>(1)</sup>,
  - having regard to the Commission communication of 10 October 2007 on an integrated maritime policy for the European Union (COM(2007)0575),
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Fisheries (A7-0295/2013),
- A. whereas knowledge of the marine environment is fundamental to promoting, developing and expanding the 'Blue Economy', which represents the maritime dimension of the Europe 2020 strategy, linking knowledge and technical innovation, sustainable use of resources, competitiveness and job creation for smart, sustainable and inclusive growth;
- B. whereas knowledge of the marine environment is essential in order to increase and improve information about ecosystems and anthropogenic impacts on the marine environment and permit proper environmental protection, a rational use of resources that is environmentally sustainable in the long term, and a balanced and sustainable growth of ocean-based human uses and activities;
- C. whereas existing data on the marine environment is currently held by numerous different bodies in a dispersed and fragmented way; whereas it is fundamental to ensure availability of and ease of access to the vast reserve of data existing on the marine environment in Europe, in order to maximise resources and promote development, innovation and job creation in the marine and maritime sectors;
- D. whereas fisheries are one of the main human activities carried out in the marine environment, contributing to the availability of food supplies and having tremendous importance, especially for certain coastal communities, and are thus an essential element of the Integrated Maritime Policy; whereas it should be recalled that fishing activities often have significant adverse impacts on marine ecosystems, owing to the variety and quantity of the fish stocks exploited; whereas fisheries are also the sector most affected by the many uses and activities taking place in the marine environment, such as maritime transport and tourism, or urban and coastal development, marine pollution, extractive industries and renewable energies, whose impacts may be cumulative with those resulting from fishing activities;
- E. whereas European seas are highly diverse, with variations in the fishing fleets and types of fishing carried out by the different Member States; whereas the recognition and appreciation of this diversity and specific characteristics depend heavily on the information available regarding fishing activity;

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<sup>(1)</sup> OJ C 76 E, 25.3.2010, p. 38,

Wednesday 23 October 2013

- F. whereas there is an increasing trend not only towards use of information technologies linked to the fishing sector, a factor which has increased the accessibility and transparency of information, but also towards computerising data collection and transfer systems in national and regional administrations and in producer organisations; considers, therefore, that there is no doubt that increased availability of information on fishing activity can unleash a process of encouraging more sustainable fishing practices, not just in environmental terms but also economically and socially;
- G. whereas there is a need to identify and define biogeographically sensitive areas and establish fish stock recovery areas and marine protected areas, in order to ensure the effective protection and preservation of vulnerable marine ecosystems from high-impact fishing practices; recalling that the more and the better the information available on the marine environment and fishing activity, the greater will be the understanding, acceptance and application of better measures to protect ecosystems and manage fisheries and maritime spatial planning;
- H. whereas the Marine Knowledge 2020 initiative opened an exchange of ideas on this topic and undertook a public consultation to sound out opinions regarding the opportunities and challenges provided by access to information on marine monitoring in Europe; whereas the Commission's initiative in publishing the Green Paper 'Marine Knowledge 2020: from seabed mapping to ocean forecasting' is to be welcomed;
- I. whereas it is necessary to release, in line with the established rules, the potential of the huge amount of data on the marine environment which has been collected and stored by numerous public and private bodies at European level, and to make it available and accessible to potential users, highlighting the need for a paradigm shift in relation to data collection and use, in order to replace the current system under which multiple collections of data are made for specific and single uses by a model allowing data to be collected and made available for multiple purposes;
- J. whereas greater availability of and ease of access to data will promote the use of such data in multidisciplinary studies and encourage the creation of intersectoral partnerships, particularly between the public and private sectors, thus providing the mass of data with a capacity and usefulness far greater than the sum of its parts;
- K. whereas this initiative is based on an interdisciplinary strategy which integrates and links all marine observation activities currently being undertaken in the EU; stressing the usefulness and advantages of accessing multiple forms of data via a single-entry digital platform providing data on the marine environment;
- L. whereas the huge importance and diversity of the fishery sector, as an ancestral and traditional marine activity, fully justifies the inclusion of information on fishery management and exploitation among the data to be mapped and made available under the Marine Knowledge 2020 initiative;
- M. whereas the EU has since 2001 been supporting the management of the common fisheries policy (CFP) by funding the collection of data on the fishing sector and its dissemination by the Member States' national authorities; recalling that the EU's fisheries are increasingly being managed by multiannual management plans and subject to precautionary and ecosystemic approaches, with the aim of minimising the impact of fishing activity on marine ecosystems, and that this management strategy involves multidisciplinary research requiring the collection of countless scientific data concerning fish stocks;
- N. whereas the CFP reform currently under way increases Member States' obligations in terms of collecting environmental, biological, technical and socio-economic data on fishing activity, within the context of the Data Collection Framework (DCF) for fisheries, which is to be allocated increased funding for the 2014-2020 period under the new European Maritime and Fisheries Fund (EMFF);

#### ***Information sources and types of data***

1. Highlights the existence of a wide range of public and private bodies which store data on fishing activity in the EU, which should be integrated into the publicly available multi-resolution digital seabed map;

**Wednesday 23 October 2013**

2. Stresses that in order to meet their obligations to the EU under the DCF, Member States collect and forward data that constitute an excellent source of information on fishing activity, and that this huge reserve of information is compiled by the Joint Research Centre (JRC) and assessed by experts from the working groups of the Scientific, Technical and Economic Committee for Fisheries (STECF); adds that the data collected by the Member States under the DCF are used by the International Council for the Exploration of the Sea (ICES) to provide scientific information on resources and advice on fisheries management;
3. Emphasises the huge volume of data generated by fishing fleets equipped with vessel monitoring systems (VMS), which would be of great use in mapping fishing activity; recalls the importance of VMS data in mixed fisheries; stresses the desirability of including and mapping additional information, particularly data recorded in electronic and paper-format fishing logbooks, records made by fisheries observers, and data collected during resource monitoring campaigns;
4. Recalls that some producer organisations, especially in the industrial fishing sector, store data on fishing activity which should complement the information currently available; adds that in the case of small-scale fishing, on which fairly limited information exists, fleets should be encouraged to collect data themselves by using their vessels as data collection and fishing monitoring platforms, possibly through the onboard installation of simple real-time monitoring devices using a GPS/GPRS system; also notes that a highly significant amount of fishing data is obtained through research projects;
5. Emphasises the usefulness of making available charts of the spatial distribution of fishing fleets, fishing effort and catch composition and volume, as this would enable potential users to access information on areas with more intensive fishing activity and on species fished and catch volumes in specific areas, among other information; points in particular, within the overall volume of fishing data which should be included in this type of plotting, to certain information relating to type of fleet (e.g. nationality, port, age, length and tonnage, power, crew), fishing effort (e.g. number of sailings or fishing days, number and features of fishing gear), catches (e.g. target species, secondary species, discards, weight, value); also points out that the availability of VMS data would make it possible to identify the spatial distribution of fleets and that the spatial distribution of catches could be calculated by correlating this information with data from fishing logbooks;
6. Believes that the separate mapping of data according to type of fishing activity, such as small-scale fishing, traditional fishing or industrial fishing, would provide a more realistic picture of the diversity of fisheries; further emphasises that if socio-economic indicators relating to fishing (e.g. age and training of crew members) were made available, they could help provide a more detailed description of the sector;

#### ***How to promote the obtainability and availability of data***

7. Recognises that numerous parties have a legitimate interest in accessing information on fishing activity and the state of conservation and exploitation of stocks; therefore advocates the creation of mechanisms to provide easy access to relevant data on fishing, under conditions to be established and with different levels of access, and ensuring adequate levels of confidentiality of information and commercial interests;
8. Points out that data collection and fishery resource management are financed by the EU and the Member States and that the data collected must therefore be available for consultation by potential users and the general public; maintains that other fisheries data obtained using public financing or cofinancing (from the EU or the Member States) should also be accessible and publicly available, whereas access to fisheries data that are obtained using private financing and do not contain commercially sensitive information should be subject to authorisation by the organisations holding the data;
9. Points out that the section of the Regulation establishing a Community control system for ensuring compliance with the rules of the CFP which deals with fisheries data and information contains articles geared specifically to the protection of personal data and the confidentiality of professional and commercial secrecy; stresses further that the above Regulation explicitly states that fisheries data whose collection, exchange and disclosure would undermine the protection of the privacy and integrity of the individual or the commercial interests of a natural or legal person, including intellectual property, are subject to the applicable rules on confidentiality and professional and commercial secrecy;

Wednesday 23 October 2013

10. Maintains that the position is similar as regards fisheries data resulting from research projects, the expectation being that data obtained in scientific projects financed or co financed from public sources (EU or Member States) should be accessible and available to potential users and the general public, subject to compliance with conditions applying specifically to project data; points out that some types of fisheries data are produced specifically when models, prototypes, or experimental devices are designed and put to use, and that the dissemination of such data is therefore a particularly sensitive matter;

11. Highlights the existence of Commission communications and recommendations on access to and dissemination and preservation of scientific information, which state that the disclosure of research data must comply with European and national rules on data protection; points out, further, that these documents refer to the need to safeguard the conditions governing the disclosure of data and the restrictions necessary in order to comply with the rules on the protection of personal data, privacy, commercial secrecy, legitimate commercial interests and intellectual property rights;

12. Maintains that, irrespective of whether data are held by public or private bodies or have been obtained using public or private financing, the body responsible for collecting, processing, and communicating the information should invariably be mentioned; also affirms that when the release of information might have implications in terms of competitiveness and competition, or for the revenue of organisations holding information, all that should be publicly available is data products and not raw or processed data; takes the view regarding such cases that if reference had to be made to the data source, stakeholders would be able to approach those holding the original information and ask to be given access to more detailed data or even the raw data;

13. Maintains that when mapping is carried out and data are made available on fishing fleet movements and operations, especially information obtained from VMS reports, fishing logbooks, and logbooks kept by on-board observers, measures must be taken to protect data confidentiality and safeguard commercial interests in compliance with the legal provisions applicable in this context; stresses that this can be achieved by omitting individual information, such as vessel names and registration marks, disseminating aggregated data, possibly grouped by area, fleet segment or type of fishing gear, and allowing a time-lag between data collection and the point when the fishing map is made available; points out, however, that if data are aggregated on too broad a basis and spatial scales and timescales are very long, the level of detail and the precision of the information will be weakened;

14. Maintains that when data are held by public authorities in Member States, the Commission should draw up a comprehensive set of standard guidelines for circulation, schedule collection, processing, and communication within a given time-frame, and should provide the encouragement needed for information to be made available for consultation by potential stakeholders; believes that a minimum set of guidelines needs to be laid down for mandatory communication and that similar data should be communicated and shared, so that all Member States have the same type of fisheries information available for their use;

15. Maintains that when fisheries data are obtained in research projects financed by the EU or Member States or subject to cofinancing, there should be a requirement to communicate the data according to a predetermined timetable once the projects have been completed;

16. Maintains that when data have been obtained from research projects the researchers concerned must be given reasonable time to publish their studies; takes the view that, following the approach advocated in the Horizon 2020 initiative, this constraint could be overcome by laying down a moratorium allowing time for publication; also maintains that data should be communicated within as short a time as possible and that the moratorium should therefore be no longer than three years, in order to ensure that data are not rendered obsolete and derive maximum benefit from their dissemination;

#### ***How to compile and pool data effectively***

17. Notes that if data are to be robust and reliable, their quality has to be standardised, verified, and checked, whether they come from Member States' databases or from fisheries research projects;

**Wednesday 23 October 2013**

18. Considers it imperative to establish common protocols/models, harmonised and tested in sampling strategies, and to lay down data collection and processing procedures and the format in which information is to be communicated, these being essential in order to make fisheries data comparable and interoperable; notes that the DCF model could be used for that purpose;

19. Notes that the form in which fisheries data are communicated may vary according to their complexity and that it is necessary to determine which types of data can be made available as raw data, in processed form, or as data products; points out that the most basic/simple parameters could be supplied in the form of raw data, whereas more complex/specific parameters requiring analysis and specialised interpretation should be supplied in the form of processed data or data products; notes that it is important to specify the type of fisheries information made available to potential users, distinguishing between raw data, processed data, and data products, and between parameters obtained by measurement and those resulting from models;

20. Points out that in certain cases, if the data communicated are highly detailed and the mapping resolution is too high, fishing effort could come to be concentrated to an undesirable extent on given resources and vulnerable marine habitats; considers, therefore, that when such information is communicated, steps must also be taken to protect and monitor the resources and habitats concerned; maintains in addition that sensitive information on the spatial distribution of rare or endangered marine species should be withheld in order to protect them;

21. Maintains that if data are to be compiled and communicated effectively, the Commission must provide the necessary coordination and Member States must seek to organise their activities and work together; maintains that coordination by the Commission is essential in order to determine priority objectives, improve the cost-effectiveness of data collection, processing, and communication, and develop synergies between Member States;

22. Maintains that, given the diversity of data collection systems and the volume and type of data collected by the numerous public and private bodies holding fisheries information, Member States need to coordinate their activities and work together so as to enable the variety, quantity, quality, and format of data to be harmonised; calls for the effectiveness of coordination and cooperation among Member States to be regularly assessed by the Commission;

23. Recommends that Member States designate a national authority to be responsible for data collection, compilation, processing, quality control, pooling, and transmission with a view to integration into a common fisheries information access platform; believes that one possibility might be to set up a specific body for the above purpose at Member State level, funded and coordinated by the Commission;

### ***How to benefit from the processing and interpretation of data***

24. Points out that if the maximum benefit is to be derived from this initiative, the governance and operating model has to allow for the necessary collection, processing, interpretation, and communication of fisheries data and secure the participation and genuine involvement of Member States, the scientific world, and local communities;

25. Maintains, as regards governance and operation, that the European Marine Observation and Data Network (EMODnet) should be given permanent status; takes the view, as regards incorporating data and making them available in this platform, that it would be desirable to draw on the experience acquired as the EMODnet concept has been developed, encompassing the specialist groups set up and operating for that purpose and the marine-related thematic portals (hydrography, geology, physics, chemistry, biology, habitats, and human activities);

26. Takes the view, given the importance of the fisheries sector, that fisheries data should preferably be made an additional specific group within the EMODnet platform or, alternatively, integrated into the newly created 'human activities' thematic portal, thus making it possible to access wider-ranging general content;

27. Maintains that the EMODnet platform should be coordinated with the Marine Service of the European earth monitoring programme (Global Monitoring for Environment and Security — GMES), so as to provide as much information as possible and enable fisheries data to be linked to the GMES satellite monitoring data focusing on environmental parameters;

Wednesday 23 October 2013

28. Considers that an initiative as ambitious as 'Marine Knowledge 2020', immense in scope and based on a multidisciplinary approach with input in the desired form provided by fisheries information, implies a need for a specific action plan setting out medium- and long-term goals, based on a concerted effort by the EU and the Member States;

29. Maintains that the implementation and success of projects of this kind depends on substantial funding making for continuity and predictability over the long term; calls for the provision of fisheries data suitable for inclusion in the multi-resolution digital seabed map to receive the necessary encouragement and support from the EU; points out that, in order to produce fisheries information, all sources of funding available at EU and national level will need to be pooled, and notes that the EMFF fully encompasses the support required for every technical means employed to set up and operate EMODnet;

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30. Instructs its President to forward this resolution to the Council and Commission, the governments and parliaments of the Member States, the Committee of the Regions, the Advisory Committee on Fisheries and Aquaculture, the regional advisory councils, and the Scientific, Technical and Economic Committee for Fisheries.

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Wednesday 23 October 2013

P7\_TA(2013)0443

## Climate change conference

### European Parliament resolution of 23 October 2013 on the climate change conference in Warsaw, Poland (COP 19) (2013/2666(RSP))

(2016/C 208/08)

*The European Parliament,*

- having regard to the United Nations Framework Convention on Climate Change (UNFCCC) and to the Kyoto Protocol thereto,
- having regard to the results of the United Nations Climate Change Conference held in Bali in 2007 and to the Bali Action Plan (Decision 1/COP 13),
- having regard to the 15th Conference of the Parties (COP 15) to the UNFCCC and the 5th Conference of the Parties serving as the Meeting of the Parties to the Kyoto Protocol (CMP5) held in Copenhagen, Denmark, from 7 to 18 December 2009 and to the Copenhagen Accord,
- having regard to the 16th Conference of the Parties (COP 16) to the UNFCCC and the 6th Conference of the Parties serving as the meeting of the Parties to the Kyoto Protocol (CMP6), held in Cancún, Mexico, from 29 November to 10 December 2010 and to the Cancún Agreements,
- having regard to the 17th Conference of the Parties (COP 17) to the UNFCCC and the 7th Conference of the Parties serving as the Meeting of the Parties to the Kyoto Protocol (CMP7) held in Durban, South Africa, from 28 November to 9 December 2011 and in particular the decisions encompassing the Durban Platform for Enhanced Action,
- having regard to the 18th Conference of the Parties (COP 18) to the UNFCCC and the 8th Conference of the Parties serving as the Meeting of the Parties to the Kyoto Protocol (CMP8) held in Doha, Qatar, from 26 November to 8 December 2012 and to the adoption of the Doha Climate Gateway,
- having regard to the 19th Conference of the Parties (COP 19) to the UNFCCC and the 9th Conference of the Parties serving as the Meeting of the Parties to the Kyoto Protocol (CMP9) to be held in Warsaw, Poland, from 11 to 23 November 2013,
- having regard to the EU climate and energy package of December 2008,
- having regard to Directive 2008/101/EC of the European Parliament and of the Council of 19 November 2008 amending Directive 2003/87/EC so as to include aviation activities in the scheme for greenhouse gas emission allowance trading within the Community <sup>(1)</sup>,
- having regard to its resolution of 4 February 2009 entitled ‘2050: The future begins today — Recommendations for the EU’s future integrated policy on climate change’ <sup>(2)</sup>,
- having regard to its resolutions of 25 November 2009 on the EU strategy for the Copenhagen Conference on Climate Change (COP 15) <sup>(3)</sup>, of 10 February 2010 on the outcome of the Copenhagen Conference on Climate Change (COP 15) <sup>(4)</sup>, of 25 November 2010 on the Climate Change Conference in Cancun (COP 16) <sup>(5)</sup>, of 16 November 2011 on the Climate Change Conference in Durban (COP 17) <sup>(6)</sup>, and of 22 November 2012 on the Climate Change Conference in Doha, Qatar (COP 18) <sup>(7)</sup>,

<sup>(1)</sup> OJ L 8, 13.1.2009, p. 3.

<sup>(2)</sup> OJ C 67 E, 18.3.2010, p. 44.

<sup>(3)</sup> OJ C 285 E, 21.10.2010, p. 1.

<sup>(4)</sup> OJ C 341 E, 16.12.2010, p. 25.

<sup>(5)</sup> OJ C 99 E, 3.4.2012, p. 77.

<sup>(6)</sup> OJ C 153 E, 31.5.2013, p. 83.

<sup>(7)</sup> Texts adopted, P7\_TA(2012)0452.

Wednesday 23 October 2013

- having regard to its resolution of 15 March 2012 on a Roadmap for moving to a competitive low carbon economy in 2050 <sup>(1)</sup>,
  - having regard to the Consultative Communication from the Commission of 26 March 2013 entitled 'The 2015 International Climate Change Agreement: Shaping international climate policy beyond 2020' (SWD(2013)0097),
  - having regard to the Council conclusions of 9 March 2012 on the follow-up to the 17th Conference of the Parties (COP 17) to the UNFCCC and the 7th session of the Meeting of the Parties to the Kyoto Protocol (CMP 7) (Durban, South Africa, 28 November — 9 December 2011),
  - having regard to the Council conclusions of 15 May 2012 on 'climate finance — fast-start finance',
  - having regard to the Council conclusions of 18 July 2011 and of 24 June 2013 on EU Climate Diplomacy,
  - having regard to the United Nations Environment Programme (UNEP) Synthesis Report of November 2012 entitled 'The Emissions Gap Report 2012',
  - having regard to the World Bank report entitled 'Turn Down the Heat. Why a 4 °C Warmer World Must be Avoided',
  - having regard to the questions to the Council and to the Commission on the climate change conference in Warsaw (COP 19) (O-000095/2013 — B7-0517/2013 and O-000096/2013 — B7-0518/2013),
  - having regard to Rules 115(5) and 110(2) of its Rules of Procedure,
- A. whereas climate change represents an urgent and potentially irreversible threat to human societies, biodiversity and the planet and must thus be addressed at international level by all Parties;
- B. whereas the Doha Climate Gateway notes with grave concern the significant gap between the aggregate effect of the Parties' current mitigation pledges in terms of global annual emissions of greenhouse gases by 2020 and aggregate emission pathways consistent with having a likely chance of holding the annual mean surface temperature increase to 2 °C (the 2 °C objective);
- C. whereas, according to scientific evidence presented by the Intergovernmental Panel on Climate Change (IPCC), the 2 °C objective requires that global emissions peak by 2015, be reduced by at least 50 % by 2050 as compared with 1990 and continue to decline thereafter; whereas the EU should therefore push for concrete actions and their effective implementation at a global level before 2020;
- D. whereas according to the World Bank's 'Turn Down the Heat' report, current emissions trajectories will lead to warming of 2 °C above pre-industrial times within 20 to 30 years and to 4 °C warming by 2100; whereas the path to a 4 °C increase could result in substantially higher temperature rises in particularly sensitive tropical regions;
- E. whereas recent scientific results also underline the dangers of 2 °C warming and there is broad consensus that the warming so far produced (amounting at global level to approximately 0,8 °C above pre-industrial temperatures) is one of the factors behind some humanitarian and food crises already witnessed, in particular the most severe crises in Africa and especially in the Horn of Africa and the Sahel;
- F. whereas the broadly recognised risks and costs that the current emission pathway entails for the world necessitate not only commitments but also the political will of all parties to fulfil them;

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<sup>(1)</sup> OJ C 251 E, 31.8.2013, p. 75.

**Wednesday 23 October 2013**

- G. whereas for many regions warming of 2 °C is already extremely dangerous; whereas 112 countries, including the most vulnerable countries, the small island states and the least developed countries, have called for a reduction in CO<sub>2</sub> in the atmosphere below 350 parts per million and for stabilisation of the global temperature rise at below 1,5 °C;
- H. whereas the Warsaw Conference (COP 19) will be crucial for ensuring the necessary progress in advancing the Durban Platform to pave the way for the preparation of commitments and the conclusion of a global legally binding agreement by 2015;
- I. whereas such a global legally binding agreement must be consistent with a 2 °C-coherent carbon budget, equity and the principle of 'common but differentiated responsibilities and respective capabilities' (CBDRRC) and must recognise the need for all major emitters to adopt ambitious and sufficient targets and corresponding policy measures for the reduction of greenhouse gas emissions, reflecting evolving responsibilities and capabilities; reiterates that 90 % of the global emissions growth takes place in developing countries which have no reduction obligations under the current Kyoto Protocol;
- J. whereas, at COP 16 in Cancún (2010), developed countries committed themselves to providing USD 30 billion for the 2010-2012 period and, by 2020, USD 100 billion in 'new and additional' financing annually in order to address climate change needs in developing countries; whereas this funding was to ensure a balanced allocation between adaptation and mitigation; whereas there is so far no internationally agreed definition of what 'new and additional' actually means;
- K. whereas, despite the commitment endorsed by the Parties in Copenhagen to provide USD 30 billion over three years as fast-start finance, there is still no certainty as to how much climate finance will be delivered in order to secure the reliability of such a commitment;
- L. whereas there is growing recognition of the need to be vigilant concerning efforts by economic actors that emit significant amounts of greenhouse gases or benefit from burning fossil fuels, to undermine or subvert climate protection efforts;
- M. whereas, according to a study by the Potsdam Institute for Climate Impact Research and the University of Madrid, the frequency of extreme heatwaves will double by 2020 and quadruple by 2040; whereas the study also concludes that this development could be prevented in the second half of the century if global emissions are fundamentally reduced; whereas events seems to corroborate what scientists tell us, with natural disasters such as floods or extreme storms also occurring more often in Europe;
- N. whereas a study by the European Centre for the Development of Vocational Training (CEDEFOP) comes to the conclusion that it is possible to achieve a sustainable and energy-efficient economy, while at the same time securing job growth;
- O. whereas a study by the Potsdam Institute for Climate Impact Research concludes that if global action on a comprehensive international climate policy is delayed until after 2030, global economic growth could be reduced by up to 7 % within the first decade after climate policy implementation — compared with only 2 % if an agreement is already concluded in 2015;
- P. whereas the EU Covenant of Mayors initiative continues to be a great success, with almost 5 000 local authorities now committed to going beyond the EU's climate and energy targets by 2020; whereas this enthusiasm and engagement shown by European local authorities should be used as an example for also setting ambitious climate and energy policies at international level;
- Q. whereas developed and developing countries have agreed to the principle of CBDRRC; whereas efforts to limit greenhouse gas emissions are nonetheless wholly insufficient and the weak outcome that has emerged from previous COPs results from a lack of political will on the part of certain countries; whereas addressing this shortcoming is necessary in the light of recent extreme natural disasters;

Wednesday 23 October 2013

- R. whereas governments bear collective responsibility for ensuring an adequate response to the climate challenge facing mankind and the planet; whereas they should receive support from all relevant actors, including citizens and businesses in their respective countries;
- S. whereas the international community is seeking a new global development framework through two parallel tracks: the Millennium Development Goals review and the Sustainable Development Goals (SDG) process launched by the Rio+20 conference; whereas there are important overlaps between these tracks;
- T. whereas the climate challenge by no means reduces the development challenge, but compounds it; whereas official development assistance (ODA) funds must not be redirected to climate financing, but whereas the principle that climate financing should be additional to ODA levels and commitments must continuously be upheld;
- U. whereas climate change represents an enormous threat to a whole host of human rights, including the right to food, the right to water and sanitation and, more generally, the right to development;
- V. whereas globally around 20 % of greenhouse gas emissions come from deforestation and other forms of land use and land use change; whereas agro-forestry enhances CO<sub>2</sub>-mitigation effects through increased carbon storage and reduces poverty by diversifying the incomes of local communities;
- W. whereas, according to the International Energy Outlook 2013, global energy demand is projected to increase by 56 % between 2010 and 2040 <sup>(1)</sup> and meeting this demand would result in a significant increase in CO<sub>2</sub> emissions; whereas the major part of the incremental demand and emissions will occur in emerging economies; whereas worldwide fossil fuel subsidies have amounted to USD 1,9 trillion, according to figures provided by the International Monetary Fund (IMF), with the highest subsidies coming from the US, China and Russia (which together account for around half of these subsidies <sup>(2)</sup>);
- X. whereas many countries are taking steps towards greening the economy in the industry and energy sectors for various reasons, including climate protection, resource scarcity and efficiency, energy security, innovation and competitiveness; whereas, according to the International Energy Agency (IEA), global CO<sub>2</sub> emissions nevertheless rose to a record high in 2012;
- Y. whereas applying climate-related innovation in the energy and industry sectors would be an advantage for the EU as an early mover in the growing global market for energy-related goods and services;
- Z. whereas worldwide innovation in the sustainable energy sector (at both production and user levels) creates jobs, stimulates economic growth, increases energy independence and will result in a cleaner world in which climate change is mitigated and sufficient energy supplies ensured;

### ***Advancing the Durban Platform***

1. Is of the opinion that the post-2020 agreement will have to bring together the current 'patchwork' of binding and non-binding arrangements under the UN climate convention and the Kyoto Protocol into a single, comprehensive and coherent regime that binds all Parties; emphasises that the post-2020 agreement should no longer divide the world into categories of 'developing' or 'industrialised' countries, but should require each country to contribute according to the principle of CBDRRC; believes, in that connection, that emissions reductions calculated on the basis of a set of indicators, including GDP per capita, access to technology, the quality of life index and others may be a valid tool;
2. Emphasises the significant work that needs to be undertaken in the Ad Hoc Working Group on the Durban Platform for Enhanced Action on the principles and framework applicable to the new global climate agreement and the pathway towards achieving this by the time COP 21 is held in Paris in 2015; notes further that its work must be informed by the

<sup>(1)</sup> <http://www.eia.gov/forecasts/ieo/?src=Analysis-b2>

<sup>(2)</sup> <http://www.imf.org/external/pubs/ft/survey/so/2013/int032713a.htm>

**Wednesday 23 October 2013**

Fifth Assessment report of the IPCC, which is due by 2014; stresses that the 2015 agreement needs to meet the goal of reducing global emissions to below 1990 levels by 2030 and should aim at phasing out global carbon emissions by 2050;

3. Notes that the failure to develop an equitable approach to sharing mitigation and adaptation effort among countries has been a barrier to reaching an adequate agreement; emphasises that equity, including a dynamic approach to CDBRRRC, must be at the heart of the new agreement for it to deliver an adequate climate response;

4. Considers that the internationally legally binding protocol now under negotiation in the Durban Platform should build on, develop and improve the rules already agreed under the UNFCCC and the Kyoto Protocol; believes, therefore, that a process of exploring a number of equity principles and indicators, such as adequacy, responsibility, capability, and development and adaptation should be included;

5. Considers that the EU is in a position to play a constructive role in facilitating an agreement on the equitable sharing of efforts; calls for the Commission to put forward an EU proposal for global effort-sharing;

6. Welcomes the proposal by Ban-Ki Moon to hold a world leaders' climate summit in September 2014, as well as a people's pre-COP in 2014 in Venezuela; emphasises the importance of a well-prepared event with meaningful outcomes and engagement at the highest political level and with civil society, in order to secure and maintain the necessary political momentum ahead of the 2014 and 2015 Conferences; deems it necessary for a successful 2015 agreement that countries come forward with greenhouse gas reduction commitments before the world leaders' summit;

7. Calls for a COP Decision in Warsaw setting out the timetable and process for committing all Parties to formulate mitigation commitments in 2014, and subsequently to assess and revise them in 2015; considers that Warsaw COP Decisions should also set out requirements for information accompanying proposed mitigation commitments and ensure criteria for transparency, quantification, comparability, verifiability and adequacy;

8. Considers that the mitigation commitments proposed by the Parties must be underpinned by the principle of CDBRRRC, must be measureable, reportable and verifiable and must be sufficient to achieve the 2 °C objective (and must therefore 'close the mitigation gap' in terms of bringing greenhouse gas emission limits and reduction targets for 2020 in line with what is required to stay within the 2 °C objective); reiterates that, as a result, existing commitments should be collectively reviewed and scaled up in ambition in order to achieve the 2 °C objective; underlines that the EU must put pressure on Parties that are not on a trajectory compliant with the 2 °C objective;

9. Points to the importance of science-based policymaking and the imperative need to maintain and more strongly pursue the 2 °C objective; believes that rather than being an open-ended exercise, efforts to strengthen mitigation pledges and their implementation must be linked to more formalised, regular and rigorous progress reviews with scientific input, aimed at ensuring that the mitigation gap will be closed;

10. Notes the significant links between the aim of global poverty eradication underlying the Millennium Development Goals — currently under review — and the Sustainable Development Goals process launched by the Rio+20 conference; calls for these two processes to be integrated into a single, comprehensive and overarching framework, and for a set of goals to eradicate poverty and promote sustainable development after 2015;

11. Emphasises that a stable and long-term policy framework including ambitious long-term targets is the most important challenge, along with facilitating investments;

12. Reiterates that the current 'pledge and review' system will not bring about the fundamental changes needed in order to fight climate change in the long run and therefore urges all parties to consider other approaches as well;

13. Recalls that, according to the IEA, EU emissions represent about 11 % of global emissions and will represent an even lower share in the decades to come; underlines the fact that higher ambition and acceptance of ambitious climate change policies could be achieved by industrial actors and energy sectors if a higher level of ambition were shown through similar efforts on the part of other global economies;

Wednesday 23 October 2013

***Kyoto Protocol***

14. Welcomes the decision by the EU, Switzerland, Norway, Liechtenstein, Iceland and Australia to join a second commitment period of the Kyoto Protocol beginning on 1 January 2013, as a transition to a new international regime involving all Parties to be in place by 2020, and calls for its swift ratification as agreed in Doha; notes that these Parties currently account for less than 14 % of global emissions;

15. Clarifies that, although the second commitment period of the Kyoto Protocol will be limited in its extent, it should be seen as a very important interim step, constituting a bridge towards a more effective and comprehensive post-2020 international agreement binding all Parties;

16. Reiterates that many countries lead by example already, showing that it is possible to pursue low-carbon development strategies and to provide a high standard of living for a larger share of the current generation without jeopardising the ability of future generations to meet their own needs, while at the same time creating new jobs and ensuring less dependence on energy imports; clarifies that negative repercussions need not be feared if climate protection is included within a general sustainable development and industrial policy strategy;

***Mitigation gap***

17. Recalls that according to the findings of the Fourth IPCC Assessment Report, the industrialised countries need to reduce their emissions by 25 % to 40 % below 1990 levels by 2020, while the developing countries as a group should look to achieve a substantial reduction from the currently predicted emissions growth rate, in the order of 15 % to 30 %, by 2020;

18. Reiterates, therefore, the urgent need to raise the level of global ambition between now and 2020, in order to stay within the 2 °C objective; places particular emphasis on the urgent need for progress in closing the gigatonne gap which exists between the scientific findings and the current Parties' pledges; emphasises the important role of other policy measures, including energy efficiency, substantial energy savings, community renewable energy and the phase-down of HFCs, in contributing to closing the gigatonne gap;

19. Notes that the EU is on track to achieve emissions reductions well beyond the current 20 % target, and reiterates that the EU has offered to increase its emission reduction target to 30 % by 2020 if other major emitting countries commit to comparable reduction targets, thus creating sustainable growth and additional jobs and reducing dependence on energy imports;;

20. Notes that a global HFC phase-down could prevent the release of 2,2 gigatonnes of CO<sub>2</sub> equivalent by 2020 and almost 100 gigatonnes of CO<sub>2</sub> equivalent by 2050; calls for the EU to step up efforts to regulate a global HFC phase-down under the Montreal Protocol;

21. Notes that the EU could fulfil its vital role in reducing emissions through policies to stop the development of highly greenhouse-gas-intensive unconventional fossil fuels such as tar sands; takes the view, as already expressed in its resolution on stopping public subsidies for fossil fuels, that public subsidies supporting the development of unconventional fossil fuels should be phased out;

22. Is of the opinion that the EU Emissions Trading System (ETS) should be linked up with other ETS mechanisms already found across the world; recommends that the original spirit of the flexible mechanism be revived, in the sense that it should return to being a market mechanism as well as being a development tool, with a drastically simplified, but more transparent, procedure;

***Climate finance***

23. Emphasises that concrete commitments and work towards scaling up climate finance to USD 100 billion per year by 2020 are critical to securing progress in Warsaw and achieving the necessary mitigation commitments overall; takes note of the post-2015 development agenda and calls for the creation of real synergies between the two processes, with positive results for both development and climate policy; deplores the fact that the majority of Member States have still not made any pledges for climate financing post-2013 and calls on the Member States to commit to new and additional climate financing for the 2013-2015 period;

**Wednesday 23 October 2013**

24. Deplores the fact that the current average ODA level of 0,29 % of GDP is far from the 0,7 % commitment; reiterates that climate financing should be additional to ODA; stresses, however, the need to reconcile development and climate change goals; stresses, accordingly, that ensuring policy coherence and mainstreaming the environment into development projects must be at the core of an EU strategy for effective climate change mitigation and adaptation;

25. Calls on all Parties present at the COP to explain how they intend to scale up climate finance on a year-by-year basis in order to deliver their commitment made in Copenhagen in 2009 to mobilise USD 100 billion per year by 2020, in a way that is additional to the commitment to pay 0,7 % of GNI as ODA;

26. Notes with concern that the Green Climate Fund announced in Copenhagen in 2009 and set up in Cancún in 2010 is still not operational and calls on all Parties to finalise procedures as soon as possible; calls for the EU and other developed countries to make finance available over the course of 2014 to the Green Climate Fund, to be announced at the Warsaw COP, as well as to the Adaptation Fund and other UN climate funds;

27. Welcomes the progress on the operationalisation of the Technology Mechanism and stresses the need to enhance technology development, deployment and transfer by striking the right balance between adaptation and mitigation and intellectual property rights protection;

28. Calls on the Member States to phase out environmentally harmful subsidies, especially fossil fuel subsidies, by 2020 and to redirect this money to sustainable energy production; calls, in addition, for swift and internationally coordinated implementation of the Pittsburgh G-20 Summit objective of phasing out inefficient fossil fuels subsidies over the medium term, as this would make an important contribution to climate protection and would also be relevant within the current context of public deficit in many countries; notes that leaders at the G-20 Summit in Los Cabos reconfirmed this ambition and that the EU called for progress on that matter ahead of the Saint Petersburg G-20 Summit <sup>(1)</sup>; deplores the lack of proposals on concrete measures for the implementation of this objective;

29. Notes that in the future the Green Climate Fund should be financed not only by industrialised countries, but also by emerging economies with an increasing per capita GDP; clarifies, in this connection, that 32 countries considered as 'developing countries' under the Convention already have a higher per capita GDP than those EU Member States with the lowest per capita GDP;

### ***Adaptation; loss and damage***

30. Acknowledges the focus in Doha on the need to address loss and damage associated with climate change impacts in developing countries that are particularly vulnerable to the adverse effects of climate change; notes the decision to establish, during the Warsaw Conference, the institutional arrangements necessary to tackle this issue;

31. Recalls that, while poor countries have contributed the least to the increasing concentration of greenhouse gases in the atmosphere, they are the most vulnerable to the impacts of climate change and have the least capacity to adapt; calls for the EU to seek agreements on climate financing, technology transfer and capacity building;

32. Calls on governments to seek agreement on principles for effort-sharing and, if possible, the formulation of one or more effort-sharing formulas; believes that historic, current and potential future greenhouse gas emissions, as well as current and potential future capacity levels in relation to mitigation, adaptation and the provision of assistance, must be reflected in such principles and formulas; considers that the right to development must also be taken into account;

33. Recalls the willingness of the EU and other developed countries to support countries with low resilience, especially through capacity building and the exchange of best practice, but also through financial help;

34. Calls for greater awareness of the possible impact of climate change on the duration of droughts, on water stress affecting particular regions and on the reduced accessibility of water resources needed in everyday life;

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<sup>(1)</sup> [http://europa.eu/rapid/press-release\\_MEMO-13-717\\_en.html](http://europa.eu/rapid/press-release_MEMO-13-717_en.html)

Wednesday 23 October 2013

35. Acknowledges that adaptation is indeed a local issue, but insists on cooperation at a regional, national and international level to secure a coherent approach;

***Land use, land-use change and forestry (LULUCF) and reducing emissions from deforestation and forest degradation (REDD+)***

36. Notes the vital role played by LULUCF and REDD+ in reducing emissions and in particular in closing the mitigation gap by 2020; notes that further work is needed on comprehensive accounting to ensure the environmental integrity of the sector's contributions to emission reductions;

37. Notes that significant amounts of public finance will be directed towards REDD+ projects; stresses the urgent need to develop early performance indicators for the effective monitoring, reporting and verification (MRV) of REDD+ activities; welcomes, in this connection, the ongoing efforts to prioritise the selection of REDD+ projects in roadless areas;

38. Notes the positive contribution made by the Voluntary Partnership Agreements between timber-exporting countries and the EU under the EU Forest Law Enforcement, Government and Trade (FLEGT) Action Plan in the fight against global deforestation; emphasises that further action is needed to address the drivers of deforestation at international level through legally binding environmental and trade agreements;

39. Recalls that climate change threatens the ability of entire regions to feed themselves; urges the EU to address the impact of its agricultural policy on climate change; highlights once more that, as pointed out by the UN Special Rapporteur on the right to food, Olivier De Schutter, low-carbon and resource-preserving methods of agriculture, also known as agro-ecological approaches, offer an alternative pathway that can both mitigate climate change by limiting greenhouse gas emissions and improve the livelihoods of poor rural communities by reducing their dependence on expensive fossil fuel-based inputs for agriculture, while increasing levels of production; accordingly, urges the EU to promote rural development, sustainable development and the productivity of agricultural systems and food security, particularly in developing countries;

***Community energy***

40. Notes that vital reductions in emissions could be achieved through a significant shift towards clean and safe energy systems, with high acceptance of renewable energy through investment in small-scale energy production, also known as microgeneration; believes that public finance needs to be redirected and mobilised to ensure a shift to public and community/decentralised renewable energy;

41. Warns that the production of agro-fuels from, inter alia, oil seeds, palm oil, soybean, rapeseed, sunflower seeds, sugar cane, sugar beet and wheat could potentially lead to huge demand for land and put at risk people in poor countries whose livelihood depends on their access to land and natural resources;

***International aviation and maritime transport***

42. Emphasises that, even though the EU recently agreed to 'stop the clock' in relation to the inclusion of international aviation flights in its ETS, this derogation is limited to one year only and is conditional on the international negotiations producing tangible decisions on a global market-based measure on emissions from international aviation;

43. Emphasises that a price on carbon emissions from international aviation and maritime transport is needed and, in addition to reducing emissions, may also serve to generate income;

44. Reiterates its call for an international instrument with global emission reduction targets to curb the climate impact of maritime transport;

***Industry and competitiveness***

45. Is concerned about the increase in global CO<sub>2</sub> emissions in 2012, according to IEA data, despite falling emissions in Europe and the United States; suggests, therefore, that differentiated responsibilities be considered so that each country contributes to global efforts in the field of industrial and energy policy;

**Wednesday 23 October 2013**

46. Underlines the fact that Europe should promote innovation and the dissemination of environment-friendly technologies in its industrial policy, including in the fields of ICT, renewable energy, innovative and efficient fossil fuels technologies and, in particular, energy-efficiency technologies; emphasises that framework agreements to help encourage and incentivise the faster dissemination of new technologies internationally need to be developed, since research and the development of new technologies are at the core of a sustainable future;

47. Reiterates, in addition, that ambitious EU industrial, innovation, climate and energy policies for 2030 would allow the EU to remain in its position as first mover and could thus have a positive impact on the international negotiations and encourage international partners to raise their ambitions accordingly;

48. Welcomes any positive developments and reiterates that internationally coordinated action would help to address the carbon leakage and competitiveness concerns of certain sectors and in particular the energy-intensive sectors;

### ***Research and innovation***

49. Stresses that the development and deployment of sustainable breakthrough technologies hold the key to fighting climate change and, at the same time, convincing the EU's partners worldwide that emissions reductions are feasible without losing competitiveness and jobs;

50. Calls for an international commitment to increase research and development (R&D) investment in sustainable breakthrough technologies in the relevant sectors; considers it essential that the EU lead by example by directing expenditure devoted to research to demonstrating innovative climate-friendly and energy-efficient technologies, and that the EU develop close scientific cooperation in this field with international partners, such as the BRIC countries and the USA;

### ***Energy policy***

51. Welcomes recent signals from the US Government regarding climate action and its willingness to play a greater role in global efforts to address climate change;

52. Notes that the prices of different energy sources play a major role in determining the behaviour of market actors, including industry and consumers, and notes that the inability of the current international policy framework to fully internalise external costs perpetuates unsustainable consumption patterns; further reiterates that a global carbon market would be a sound basis for achieving both substantial emission abatements and a level playing field for industry; calls for the EU and its partners to find, in the immediate future, the most effective way of promoting links between the EU ETS and other trading schemes with the aim of achieving a global carbon market, ensuring greater diversity of abatement options, improved market size and liquidity, transparency and, ultimately, the more efficient allocation of resources for the energy sector and industry;

53. Calls for closer coordination between the Council, the Commission and the European External Action Service (EEAS) so as to enable the EU to speak with one coherent voice in international organisations such as the IEA, the International Renewable Energy Agency (IRENA), the International Partnership for Energy Efficiency Cooperation (IPEEC) and the International Atomic Energy Agency (IAEA), and thus to play a more active and influential role, particularly in pushing for sustainable energy policies and energy safety policies;

54. Regrets the fact that energy savings potential is not adequately tackled internationally and in the EU; underlines the fact that energy savings allow job creation, economic savings, energy security, competitiveness and emission cuts and can also contribute to reversing the trend in energy prices and costs; calls for the EU to pay more attention to energy savings in international negotiations, whether it be in discussing technology transfer, development plans for developing countries or financial assistance; highlights the fact that, in order to be credible, the EU and its Member States must meet their own targets;

55. Points out that across the globe an estimated 1,3 billion people do not have access to electricity and 2,6 billion people continue to rely on traditional use of biomass for cooking <sup>(1)</sup>; stresses the need to address the energy poverty issue in accordance with climate policy objectives; notes that energy technologies are available to address both global environmental protection and local development needs;

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<sup>(1)</sup> IEA World Energy Outlook Special Report, 'Redrawing the Energy Climate Map'.

Wednesday 23 October 2013

*Climate diplomacy*

56. Stresses, in this context, the importance of the EU as a major player, (in particular this year, with the holder of the COP 19 presidency and host nation being a Member State), speaking with 'one voice' at the Conference in seeking progress towards an international agreement and staying united in that regard;

57. Stresses the vital position of Poland as the 'host nation' and hopes that Poland, as a country which is still heavily dependent on fossil energy sources, but which is experienced in UNFCCC negotiations, will be able to invigorate the process, lead by example and help in building new alliances; welcomes the statement by the President-Designate that, by being creative, it is possible to reduce greenhouse gas emissions while creating jobs, promoting economic growth and ensuring better living standards; hopes that Poland will bring forward concrete proposals in that regard;

58. Emphasises that a new 'Climate Pact', applicable to all and involving industrialised as well as developing countries, should be the main objective; emphasises also that one of the EU's most important tasks is to ensure a coordinated and step-by-step approach to climate protection, ensuring action at all levels of government, including local and regional authorities;

59. Stresses that these current times of economic crisis demonstrate vividly that only a sustainable economy can provide prosperity in the long term and that climate protection is one of the main pillars of such a sustainable economy; highlights the fact that it is more important than ever before to clarify the reason for political action in the field of climate protection, which is to allow more people access to a high standard of living, while also securing resources and room for development for future generations;

60. Reiterates that the challenge of climate change cannot be viewed in isolation, but always needs to be addressed within the context of sustainable development, industrial policy and resource policy; emphasises, in this connection, that explaining climate policies to citizens and securing a change of consciousness is crucial; underlines the fact that any future agreement should also accommodate bottom-up initiatives, for example in the field of energy efficiency, since these are an important tool as regards acceptance by citizens;

61. Reiterates that in any legally binding climate change agreement, a robust system of compliance and enforcement is key in order to ensure that all countries taking part in the climate change agreement comply with their commitments, receive support where necessary and are held accountable for non-compliance;

62. Is of the view that the UNFCCC process has to become more effective and efficient, ensuring that it more adequately reflects changed realities; believes, in this context, that the consensus rule should be abolished in order to avoid results based on the lowest common denominator;

63. Shares the view that, rather than rotating annually, Conference presidencies could either be shared by several countries over several years or held by one country for two years to ensure a more coherent approach;

64. Draws attention to the positive developments during the MOP 25 negotiations on the Montreal Protocol and urges all Parties to strive to learn from this successful international agreement; invites the Parties to look in particular at the voting and decision mechanisms of the Montreal Protocol, its different approach to responsibilities, and its enforcement and sanction mechanisms and financing, as an example which might be also used under the UNFCCC;

65. Stresses the importance for the general progress of international climate negotiations of the EU being proactive in them; notes that the EU's ability to play a leadership role and the prospects for achieving general progress are influenced by the climate action taken by the EU itself; points to the need to reinforce the EU's climate action, including by adopting an ambitious climate and energy framework for 2030, and to dispel doubts raised by the limited effectiveness of the EU's ETS in providing incentives for greenhouse gas emission reductions and by the postponement of the inclusion of the aviation sector in the ETS;

66. Stresses also the role that developed countries should play in helping developing countries to curb their emissions; notes the vast potential for renewable energy and energy efficiency in many developing countries; encourages the developed and emerging economies to promote and implement renewable energy projects in developing countries, and to make available technology, expertise and investment in this field;

Wednesday 23 October 2013

***European Parliament delegation***

67. Believes that the EU delegation plays a vital role in the climate change negotiations, and therefore finds it unacceptable that Members of the European Parliament have been unable to attend the EU coordination meetings at previous Conferences of the Parties; expects at least the Chair of the European Parliament delegation to be allowed to attend EU coordination meetings in Warsaw;

68. Notes that, in accordance with the Framework Agreement concluded between the Commission and Parliament in November 2010, the Commission must facilitate the inclusion of Members of Parliament as observers in Union delegations negotiating multilateral agreements; recalls that, pursuant to the Lisbon Treaty (Article 218 of the Treaty on the Functioning of the European Union), Parliament must give its consent to agreements between the Union and third countries or international organisations;

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69. Instructs its President to forward this resolution to the Council, the Commission, the Governments and Parliaments of the Member States and the Secretariat of the UNFCCC, with the request that it be circulated to all non-EU Contracting Parties.

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Wednesday 23 October 2013

P7\_TA(2013)0444

**Organised crime, corruption, and money laundering****European Parliament resolution of 23 October 2013 on organised crime, corruption and money laundering: recommendations on action and initiatives to be taken (final report) (2013/2107(INI))**

(2016/C 208/09)

*The European Parliament,*

- having regard to its decision of 14 March 2012 on setting up a special committee on organised crime, corruption and money laundering, and its powers, numerical composition and term of office <sup>(1)</sup>, adopted under Rule 184 of its Rules of Procedure,
- having regard to its decision of 11 December 2012 whereby the term of office of the Special Committee on Organised Crime, Corruption and Money Laundering is to be extended until 30 September 2013,
- having regard to Article 3 of the Treaty on European Union, to Article 67 and Part Three, Title V, Chapter 4 (Articles 82-86) and Chapter 5 (Articles 87-89) of the Treaty on the Functioning of the European Union, and to the European Union Charter of Fundamental Rights, in particular Articles 5, 6, 8, 17, 32, 38, and 41, Title VI (Articles 47-50), and Article 52 thereof,
- having regard to the Stockholm Programme on freedom, security and justice <sup>(2)</sup>, the Commission communication 'Delivering an area of freedom, security and justice for Europe's citizens — Action Plan Implementing the Stockholm Programme' (COM(2010)0171) and the Commission communication 'The EU internal security strategy in action: Five steps towards a more secure Europe' (COM(2010)0673),
- having regard to the conclusions of the European Council of 22 May 2013, with special reference to those concerning the need to combat tax fraud, tax evasion and money laundering,
- having regard to the conclusions of the JHA Council of 8 and 9 November 2010 on the creation and implementation of an EU policy cycle for organised and serious international crime, the conclusions of the JHA Council of 9 and 10 June 2011, which set out the EU priorities in the fight against organised crime over the period 2011-2013, and the conclusions of the JHA Council of 6 and 7 June 2013 setting out the priorities for 2014 to 2017,
- having regard to the Council Conclusions of 28 May 2010 on Confiscation and Asset Recovery (07769/3/2010),
- having regard to the 2005-2012 and the 2013-2020 EU drugs strategies and the EU Action Plan on Drugs (2009-2012),
- having regard to the UN Convention against illicit traffic in narcotic drugs and psychotropic substances, adopted by the General Assembly on 20 December 1988 (resolution 1988/8) and opened for signature in Vienna, from 20 December 1988 to 28 February 1989, and thereafter in New York, until 20 December 1989,
- having regard to the UN Convention against Transnational Organised Crime, adopted by the General Assembly on 15 November 2000 (resolution 55/25), opened for signature in Palermo on 12 December 2000, the protocols thereto and the UNODC Digest of organised crime cases (2012),
- having regard to the UN Convention against Corruption (UNCAC), opened for signature in Merida on 9 December 2003,
- having regard to the Council of Europe criminal and civil law conventions on corruption, opened for signature in Strasbourg on 27 January 1999 and 4 November 1999 respectively, and to resolutions (98) 7 and (99) 5, adopted by the Council of Europe Committee of Ministers on 5 May 1998 and 1 May 1999 respectively, establishing the Group of States against Corruption (GRECO),

<sup>(1)</sup> OJ C 251 E, 31.8.2013, p. 120.

<sup>(2)</sup> OJ C 115, 4.5.2010, p. 1.

**Wednesday 23 October 2013**

- having regard to the Council Act of 26 May 1997 drawing up, on the basis of Article K.3(2)(c) of the Treaty on European Union, the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union <sup>(1)</sup>,
- having regard to the OECD Convention on Combating the Bribery of Foreign Public Officials in International Business Transactions, opened for signature in Paris on 17 December 1997, and to the recommendations supplementing it,
- having regard to the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime and on the Financing of Terrorism, opened for signature in Warsaw on 16 May 2005, and to the Council of Europe Committee of Ministers' Resolution CM/Res(2010)12 of 13 October 2010 on the Statute of the Committee of Experts on the Evaluation of Anti-Money Laundering Measures and the Financing of Terrorism (MONEYVAL),
- having regard to the Council of Europe Convention on Cybercrime, opened for signature in Budapest on 23 November 2001,
- having regard to the Strategic Concept for the Defence and Security of the Members of the North Atlantic Treaty Organisation 'Active Engagement, Modern Defence', adopted by NATO heads of state and government in Lisbon on 19—20 November 2010,
- having regard to the 40 recommendations and 9 special recommendations of the Financial Action Task Force (FATF) on combating money laundering,
- having regard to the work of the Basel Committee on Banking Supervision (BCBS),
- having regard to the reports by the United Nations Office on Drugs and Crime (UNODC) entitled 'The Globalisation of Crime — a transnational organised crime threat assessment' (2010), 'Estimating illicit financial flows resulting from drug trafficking and other transnational organised crime' (2011) and 'A comprehensive study on cybercrime' (2013),
- having regard to Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime <sup>(2)</sup>,
- having regard to Council Framework Decision 2001/500/JHA of 26 June 2001 on money laundering, the identification, tracing, freezing, seizing and confiscation of instrumentalities and the proceeds of crime <sup>(3)</sup>, Council Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence <sup>(4)</sup>, Council Framework Decision 2005/212/JHA of 24 February 2005 on Confiscation of Crime-Related Proceeds, Instrumentalities and Property <sup>(5)</sup>, and Council Framework Decision 2006/783/JHA of 6 October 2006 on the application of the principle of mutual recognition to confiscation orders <sup>(6)</sup>,
- having regard to Council Decision 2007/845/JHA of 6 December 2007 concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing and identification of proceeds from, or other property related to, crime <sup>(7)</sup> and having regard to the Commission report based on Article 8 of that decision (COM(2011)0176),

<sup>(1)</sup> OJ C 195, 25.6.1997, p. 1.

<sup>(2)</sup> OJ L 300, 11.11.2008, p. 42.

<sup>(3)</sup> OJ L 182, 5.7.2001, p. 1.

<sup>(4)</sup> OJ L 196, 2.8.2003, p. 45.

<sup>(5)</sup> OJ L 68, 15.3.2005, p. 49.

<sup>(6)</sup> OJ L 328, 24.11.2006, p. 59.

<sup>(7)</sup> OJ L 332, 18.12.2007, p. 103.

Wednesday 23 October 2013

- having regard to Council Decision 2009/426/JHA of 16 December 2008 on the strengthening of Eurojust and amending Decision 2002/187/JHA setting up Eurojust with a view to reinforcing the fight against serious crime <sup>(1)</sup>,
- having regard to Council Decision 2009/371/JHA of 6 April 2009, establishing the European Police Office (Europol) <sup>(2)</sup>,
- having regard to Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters <sup>(3)</sup>,
- having regard to Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States <sup>(4)</sup>, and the subsequent amending acts,
- having regard to Council Framework Decision 2002/465/JHA of 13 June 2002 on joint investigation teams <sup>(5)</sup> and to the Commission report on national measures taken to comply with that framework decision (COM(2004)0858),
- having regard to Council Decision 2009/902/JHA of 30 November 2009 setting up a European crime prevention network (EUCPN) <sup>(6)</sup>,
- having regard to Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA <sup>(7)</sup> and to the communication from the Commission ‘The EU Strategy towards the Eradication of Trafficking in Human Beings 2012-2016’ (COM(2012)0286),
- having regard to Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing <sup>(8)</sup>, and to the Commission report to Parliament and the Council on the application of that directive (COM(2012)0168),
- having regard to Regulation (EC) No 1889/2005 of the European Parliament and of the Council of 26 October 2005 on controls of cash entering or leaving the Community <sup>(9)</sup>,
- having regard to Regulation (EC) No 1781/2006 of the European Parliament and of the Council of 15 November 2006 on information on the payer accompanying transfers of funds <sup>(10)</sup>,
- having regard to Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC <sup>(11)</sup>,
- having regard to Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC <sup>(12)</sup>,

<sup>(1)</sup> OJ L 138, 4.6.2009, p. 14.

<sup>(2)</sup> OJ L 121, 15.5.2009, p. 37.

<sup>(3)</sup> OJ L 350, 30.12.2008, p. 60.

<sup>(4)</sup> OJ L 190, 18.7.2002, p. 1.

<sup>(5)</sup> OJ L 162, 20.6.2002, p. 1.

<sup>(6)</sup> OJ L 321, 8.12.2009, p. 44.

<sup>(7)</sup> OJ L 101, 15.4.2011, p. 1.

<sup>(8)</sup> OJ L 309, 25.11.2005, p. 15.

<sup>(9)</sup> OJ L 309, 25.11.2005, p. 9.

<sup>(10)</sup> OJ L 345, 8.12.2006, p. 1.

<sup>(11)</sup> OJ L 267, 10.10.2009, p. 7.

<sup>(12)</sup> OJ L 319, 5.12.2007, p. 1.

**Wednesday 23 October 2013**

- having regard to Council Framework Decision 2003/568/JHA of 22 July 2003 on combating corruption in the private sector<sup>(1)</sup> and to the Commission report to the Council based on Article 9 of that framework decision (COM(2007) 0328),
- having regard to Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal service sectors<sup>(2)</sup>, Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, and the amendments thereto<sup>(3)</sup>,
- having regard to Directive 2012/29/EU of the European Parliament and of the Council of 25 October 2012 establishing minimum standards on the rights, support and protection of victims of crime, and replacing Council Framework Decision 2001/220/JHA<sup>(4)</sup>,
- having regard to Directive 2011/93/EU of the European Parliament and of the Council of 13 December 2011, on combating the sexual abuse and sexual exploitation of children and child pornography, and replacing Council Framework Decision 2004/68/JHA<sup>(5)</sup>,
- having regard to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors<sup>(6)</sup>,
- having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>(7)</sup>,
- having regard to the Commission Decision of 28 September 2011 setting up an expert group on corruption<sup>(8)</sup>; having regard to the Commission communication of 6 June 2011 to the European Parliament, the Council, and the European Economic and Social Committee entitled 'Fighting Corruption in the EU' (COM(2011)0308) and to the Commission Decision of 6 June 2011 establishing an EU anti-corruption reporting mechanism for periodic assessment ('EU Anti-Corruption Report') (C(2011)3673),
- having regard to the Commission Decision of 14 February 2012 setting up the Commission expert group on policy needs for data on crime and repealing Decision 2006/581/EC<sup>(9)</sup>,
- having regard to Commission Recommendation 2007/425/EC of 13 June 2007, identifying a set of actions for the enforcement of Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein<sup>(10)</sup>,
- having regard to the initiative of the Kingdom of Belgium, the Republic of Bulgaria, the Republic of Estonia, the Kingdom of Spain, the Republic of Austria, the Republic of Slovenia and the Kingdom of Sweden for a Directive of the European Parliament and of the Council regarding the European Investigation Order in criminal matters (2010/0817 (COD)),
- having regard to the Proposal for a directive of the European Parliament and of the Council of 12 March 2012 on the freezing and confiscation of the proceeds from crime in the European Union (COM(2012)0085),

<sup>(1)</sup> OJ L 192, 31.7.2003, p. 54.

<sup>(2)</sup> OJ L 134, 30.4.2004, p. 1.

<sup>(3)</sup> OJ L 134, 30.4.2004, p. 114.

<sup>(4)</sup> OJ L 315, 14.11.2012, p. 57.

<sup>(5)</sup> OJ L 335, 17.12.2011, p. 1.

<sup>(6)</sup> OJ L 47, 18.2.2004, p. 1.

<sup>(7)</sup> OJ L 281, 23.11.1995, p. 31.

<sup>(8)</sup> OJ C 286, 30.9.2011, p. 4.

<sup>(9)</sup> OJ C 42, 15.2.2012, p. 2.

<sup>(10)</sup> OJ L 159, 20.6.2007, p. 45.

Wednesday 23 October 2013

- having regard to the proposal for a directive of the European Parliament and of the Council of 20 December 2011 on procurement by entities operating in the water, energy, transport and postal services sectors (COM(2011)0895) and the proposal for a Directive of the European Parliament and of the Council of 20 December 2011 on public procurement (COM(2011)0896),
- having regard to the proposal for a directive of the European Parliament and of the Council of 5 February 2013 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (COM(2013) 0045),
- having regard to the proposal for a regulation of the European Parliament and of the Council of 5 February 2013 on information accompanying transfers of funds (COM(2013)0044),
- having regard to the proposal for a regulation of the European Parliament and of the Council of 12 September 2012 on the statute and funding of European political parties and European political foundations (COM(2012)0499),
- having regard to the proposal for a regulation of the European Parliament and the Council of 29 November 2012, amending Regulation (EU, Euratom) No 966/2012 as regards the financing of European political parties (COM(2012) 0712),
- having regard to the proposal for a directive of the European Parliament and of the Council on the protection of the euro and other currencies against counterfeiting by criminal law, and replacing Council Framework Decision 2000/383/JHA (COM(2013)0042),
- having regard to the proposal for a directive of the European Parliament and of the Council on attacks against information systems and repealing Council Framework Decision 2005/222/JHA (COM(2010)0517),
- having regard to the proposal for a directive of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data (COM(2012)0010),
- having regard to the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011),
- having regard to the proposal for a directive of the European Parliament and of the Council on the fight against fraud to the Union's financial interests by means of criminal law (COM(2012)0363),
- having regard to the proposal for a Council regulation on the establishment of the European Public Prosecutor's Office (COM(2013)0534) and to the proposal for a regulation of the European Parliament and of the Council on the European Union Agency for Criminal Justice Cooperation (Eurojust) (COM(2013)0535),
- having regard to the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions entitled 'Better protection of the Union's financial interests: setting up the European Public Prosecutor's Office and reforming Eurojust' (COM(2013)0532),
- having regard to the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions entitled 'Improving OLAF's governance and reinforcing procedural safeguards in investigations: a step-by-step approach to accompany the establishment of the European Public Prosecutor's Office' (COM(2013)0533),
- having regard to the joint communication from the Commission and the High Representative of the European Union for Foreign Affairs and Security Policy to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions entitled 'Cybersecurity Strategy of the European Union: An Open, Safe and Secure Cyberspace' (JOIN(2013)0001),
- having regard to the Commission communication to the European Parliament and the Council entitled 'An Action Plan to strengthen the fight against tax fraud and tax evasion' (COM(2012)0722),
- having regard to the Commission communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entitled 'Building an open and secure Europe: the home affairs budget 2014- 2020' (COM(2011)0749),

**Wednesday 23 October 2013**

- having regard to the Commission communication to the European Parliament and the Council entitled 'First Annual Report on the implementation of the EU Internal Security Strategy' (COM(2011)0790),
- having regard to the Commission's Green Paper on shadow banking (COM(2012)0102),
- having regard to the Commission communication to the Council and the European Parliament entitled 'Tackling Crime in our Digital Age: Establishing a European Cybercrime Centre' (COM(2012)0140),
- having regard to the Commission communication to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions entitled 'Towards a comprehensive European framework for online gambling' (COM(2012)0596),
- having regard to the Commission communication to the European Parliament and the Council entitled 'Measuring Crime in the EU: Statistics Action Plan 2011-2015' (COM(2011)0713),
- having regard to the report from the Commission to the Council 'Evaluation report on the European Union Crime Prevention Network' (COM(2012)0717),
- having regard to the Commission report to the European Parliament and the Council on the implementation of Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime ('Prüm Decision') (COM(2012)0732),
- having regard to the Commission Green Paper — Towards an integrated European market for card, Internet and mobile payment (COM(2011)0941),
- having regard to the Commission communication to the European Parliament and the Council on concrete ways to reinforce the fight against tax fraud and tax evasion including in relation to third countries (COM(2012)0351),
- having regard to the Commission communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entitled 'Towards an EU Criminal Policy: Ensuring the effective implementation of EU policies through criminal law' (COM(2011)0573),
- having regard to the Commission report of 6 June 2011 to the Council on the modalities of European Union participation in the Council of Europe Group of States against Corruption (GRECO) (COM(2011)0307),
- having regard to the Commission communication to the European Parliament and the Council entitled 'Proceeds of organised crime: ensuring that "crime does not pay"' (COM(2008)0766),
- having regard to the communication from the Commission to the Council and the European Parliament on the role of Eurojust and the European Judicial Network in the fight against organised crime and terrorism in the European Union (COM(2007)0644),
- having regard to the Commission communication to the Council and the European Parliament on the prevention of and fight against organised crime in the financial sector (COM(2004)0262),
- having regard to the Commission working document on the feasibility of EU legislation in the area of protection of witnesses and collaborators with justice (COM(2007)0693),
- having regard to its recommendation of 7 June 2005 to the Council on combating the financing of terrorism <sup>(1)</sup>,

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<sup>(1)</sup> OJ C 124 E, 25.5.2006, p. 254.

Wednesday 23 October 2013

- having regard to its resolution of 8 March 2011 on ‘Tax and development — Cooperating with developing countries on promoting good governance in tax matters’ <sup>(1)</sup>,
- having regard to its resolutions of 15 September 2011 on the EU’s efforts to combat corruption <sup>(2)</sup>, of 25 October 2011 on organised crime in the European Union <sup>(3)</sup>, of 22 May 2012 on an EU approach to criminal law <sup>(4)</sup>, and of 14 March 2013 on match-fixing and corruption in sport <sup>(5)</sup>,
- having regard to its resolution of 15 January 2013 with recommendations to the Commission on a Law of Administrative Procedure of the European Union <sup>(6)</sup>,
- having regard to its resolution of 21 May 2013 on the fight against tax fraud, tax evasion and tax havens <sup>(7)</sup>,
- having regard to its resolution of 11 June 2013 on organised crime, corruption, and money laundering: recommendations on action and initiatives to be taken (CRIM interim report) <sup>(8)</sup>,
- having regard to its declaration of 18 May 2010 on the Union’s efforts in combating corruption <sup>(9)</sup>,
- having regard to the Joint Report by Europol, Eurojust and Frontex on the state of internal security in the EU (2010),
- having regard to the Eurojust Multi-annual Strategic Plan 2012-2014 and its annual report for 2011,
- having regard to the Europol SOCTA report (Serious and Organised Crime Threat Assessment) of March 2013,
- having regard to the Europol 2012 situation report on payment card fraud in the European Union,
- having regard to the joint report by the European Monitoring Centre for Drugs and Drug Addiction and Europol entitled ‘EU Drug Markets Report — A Strategic Analysis’, of January 2013,
- having regard to Opinion 14/2011 of 13 June 2011 on data protection issues related to the prevention of money laundering and terrorist financing, adopted by the Working Party established under Article 29 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data <sup>(10)</sup>,
- having regard to the conclusions which have emerged from the public hearings, discussions on the working documents, mid-term report and exchanges of views with eminent figures, as well as from the delegation visits made by Parliament’s Special Committee on Organised crime, Corruption and Money Laundering,
- having regard to the contributions of high-level experts specifically called for by its Special Committee on Organised Crime, Corruption and Money Laundering,

<sup>(1)</sup> OJ C 199 E, 7.7.2012, p. 37.

<sup>(2)</sup> OJ C 51 E, 22.2.2013, p. 121.

<sup>(3)</sup> OJ C 131 E, 8.5.2013, p. 66.

<sup>(4)</sup> Texts adopted, P7\_TA(2012)0208.

<sup>(5)</sup> Texts adopted, P7\_TA(2013)0098.

<sup>(6)</sup> Texts adopted, P7\_TA(2013)0004.

<sup>(7)</sup> Texts adopted, P7\_TA(2013)0205.

<sup>(8)</sup> Texts adopted, P7\_TA(2013)0245.

<sup>(9)</sup> OJ C 161 E, 31.5.2011, p. 62.

<sup>(10)</sup> [http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2011/wp186\\_en.pdf](http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2011/wp186_en.pdf).

Wednesday 23 October 2013

- having regard to the responses to the questionnaire sent to the national parliaments on their role and experiences in the fight against organised crime, corruption and money laundering, and the outcome of the interparliamentary meeting on that same subject held in Brussels on 7 May 2013,
- having regard to Rule 48 of its Rules of Procedure,
- having regard to the report of the Special Committee on Organised Crime, Corruption and Money Laundering (A7-0307/2013),

***Organised crime, corruption, and money laundering***

- A. whereas the Special Committee on Organised Crime, Corruption and Money Laundering (CRIM) was mandated to investigate the extent of organised crime, corruption and money laundering supported by the best available threat assessments and to propose appropriate measures for the EU to prevent and address these threats and to counter them, including at the international, European and national level;
- B. whereas criminal organisations have gradually extended their operating range on an international scale, exploiting economic globalisation and new technologies, and entering into alliances with criminal groups in other countries (examples being the South American drug cartels and Russian-speaking organised crime) in order to carve up markets and spheres of influence; whereas increasingly criminal groups are diversifying in their operations, with links growing between drug trafficking, the trafficking of human beings, the facilitation of illegal immigration, weapons trafficking, and money laundering;
- C. whereas corruption and organised crime are serious threats in terms of costs to the EU economy; whereas the proceeds and infiltration capacity of criminal organisations have grown considerably due to the fact that they are operating in many sectors, most of which are subject to the control of government departments; whereas organised crime is increasingly resembling an economic global player with a strong business orientation, enabling it to supply different kinds of illegal — but also, to an increasing extent, legal — goods and services at the same time, and is having an increasing impact on the European and global economy, significantly affecting tax revenues of the Member States and the EU as a whole, and at a cost to business estimated at more than EUR 670 billion annually;
- D. whereas organised crime is a major cross-border internal security threat in the EU in terms of the number of victims; whereas organised crime makes huge profits from trafficking in human beings, illegal trafficking in and smuggling of organs, arms, drugs and their precursors, nuclear, radiological, biological and chemical substances, prescription drugs, counterfeiting of everyday consumer goods such as foodstuffs, protected animal and plant species and parts of them, tobacco in all its forms, works of art and various other — often counterfeit — products; whereas the above-mentioned trafficking entails losses to the revenue of the European Union and the Member States, damages consumers, public health and manufacturing companies and can also facilitate the spread of other forms of organised crime;
- E. whereas Mafia-type organised crime relating to the environment — involving various forms of illegal waste trafficking and disposal and the destruction of environmental, landscape, artistic, and cultural heritage — has now assumed an international dimension requiring all European countries to pool their efforts with a view to taking more effective joint action to prevent and combat ‘ecomafias’;
- F. whereas numerous criminal organisations have a network structure characterised by high levels of flexibility, mobility, connectivity and inter-ethnicity, as well as a heightened capacity for infiltration and camouflage; whereas criminal organisations have been tending increasingly to rely on mutual assistance enabling them — also through their new international structures and the diversification of their activities — to overcome their differences in terms of language and commercial interests and engage in joint trafficking, thereby reducing costs and maximising profits at a time of world economic crisis;
- G. whereas the 2013 Europol SOCTA report estimates that 3 600 international criminal organisations are operating in the EU and that, of those, 70 % have a geographically heterogeneous composition and range of action and more than 30 % are poly-crime groups;

Wednesday 23 October 2013

- H. whereas it is necessary for Europol, based on proper information provided by the Member States, to evaluate the extent to which certain organised crime groups operate across the EU's internal and external borders and which particularly serious crimes with a cross border dimension as listed in article 83 TFEU they commit focusing on a different specific domain every time, and for this evaluation to be closely scrutinised by the European Parliament, national parliaments and other relevant actors to better target, and ensure the added value of, EU action and collaboration between police and judicial authorities among Member States, with third countries and international organisations;
- I. whereas criminal organisations can take advantage of a grey area of collusion with other parties, merging for the purpose of carrying out certain activities with white-collar perpetrators (entrepreneurs, public officials at all levels of decision-making, politicians, banks, professionals, etc.), who, while not actually belonging to criminal organisations, have mutually lucrative business relations with them;
- J. whereas, according to UNODC, the financial flows generated by the international drug traffic operated by Mafia-type organisations have, in a good many cases, been handled by banks in several parts of the world and whereas, therefore, investigations need to be coordinated at international level in order to thread a way through the banking circuits and trace the financial operators implicated in international drug trafficking;
- K. whereas the economic crisis of recent years has resulted in significant changes in the areas of interest of organised crime, which has been able quickly to identify the new opportunities being offered, and whereas this crisis, in prompting new waves of migrants to seek better living and working conditions, can sometimes provide it with new victims in terms of exploitation and labour;
- L. whereas entrepreneurship is one of the main traits of modern criminal organisations, which engage in forms of action geared strongly towards meeting market demand for goods and services and involving intensive cooperation with other operators, criminals or otherwise, and alternate constantly between the apparently lawful dimension of their business and methods of intimidation and corruption and illegal ends (pursued through money laundering, for example);
- M. whereas the transnational dimension of organised crime has been heightened by the ease with which criminal groups use every means of transport, tried and tested routes, and existing infrastructure, extending outside the European Union; whereas, in particular, the expansion in communications and transport infrastructure now under way in Africa is in danger of being exploited by organised criminals to facilitate their illicit trafficking operations;
- N. whereas European routes, in particular those crossing the Western Balkans, remain at the centre of trafficking in human beings, arms and drugs (and their precursors), in addition to money laundering, by most criminal groups operating in Europe; whereas the routes followed by the heroin destined for the European Union are constantly changing;
- O. whereas the victims of the trafficking in human beings are recruited, transported or harboured by force, coercion or fraud with the purpose of sexual exploitation, forced labour or services, including begging, slavery, servitude, criminal activities, domestic service, adoption or forced marriage, or the removal of organs; whereas these victims are exploited and completely subjugate to their traffickers or exploiters, obliged to pay them back huge debts, often deprived of their identity papers, locked-in, isolated and threatened, living in fear and retaliation, with no money and having been made fearful of the local authorities, they lose all hope;
- P. whereas operations involving trafficking in human beings and human organs, forced prostitution or enslavement and the establishment of labour camps are often run by transnational criminal organisations; whereas, in particular, trafficking in human beings generates an estimated profit of EUR 25 billion each year and this crime concerns all EU countries; whereas the revenues generated by the trafficking in wildlife species and body parts are estimated at EUR 18 to 26 billion per year, with the EU being the foremost destination market in the world;
- Q. whereas while trafficking in human beings evolves with changing socio-economic circumstances, the victims come mainly from countries and regions which are subject to economic and social hardship, and whereas the vulnerability factors have not changed for years; whereas other causes of trafficking in human beings include a booming sex industry and demand for cheap labour and products, and whereas a common factor among those who become victims of trafficking is, in general terms, the promise of a better quality of life and existence for themselves and/or their families;

Wednesday 23 October 2013

- R. whereas, although the exact levels of human trafficking in the EU are still not easy to identify because they are often hidden within other forms of criminality or are not properly recorded or investigated, the total number of forced labourers in the EU Member States is estimated at 880 000, of which 270 000 are victims of sexual exploitation, with women constituting the majority of them; whereas trafficking in human beings and enslavement are very lucrative forms of crime often run by transnational criminal organisations; whereas all EU countries are affected, but not all of them have ratified all relevant international instruments, which would make the fight against trafficking in human beings more effective; whereas, in particular, only nine Member States have fully transposed and implemented Directive 2011/36/EU on the preventing and combating of trafficking in human beings and the Commission is still to fully implement its EU strategy towards the eradication of trafficking in human beings 2012-2016;
- S. whereas illegal trafficking in cigarettes results in an annual tax loss of approximately EUR 10 billion; whereas the estimated turnover generated by global small arms trafficking ranges between approximately EUR 130 million and 250 million a year and there are more than 10 million illegal weapons in circulation in Europe, posing a serious threat to the safety of citizens as well as to law enforcement; whereas false medicines, some health- or life-threatening, are offered to Europeans at bargain prices on 30 000 attractive websites, 97 % of which are illegitimate, with the estimated impact on European public health at up to 3 billion per year with the majority of fake pharmaceuticals originating from China and India;
- T. whereas the recent report from the UN Special Rapporteur on the Human Rights of Migrants in the EU has produced evidence to suggest that many Frontex detention centres treat migrants in a way that is inconsistent with their fundamental rights;
- U. whereas a fraudulent use of the internet enables organised crime to expand its illicit trafficking in psychoactive substances, firearms, materials used in the production of explosives, counterfeit money, counterfeit and other IPR infringing products and services and endangered animal and plant species, to evade excise and other taxes on sales of genuine goods, as well as to experiment with growing success in new criminal activities, thereby revealing a fearsome ability to adapt to modern technology;
- V. whereas cybercrime is creating increasingly significant economic and social damage affecting millions of consumers and is causing annual losses estimated at EUR 290 billion <sup>(1)</sup>;
- W. whereas, in many cases, for organised crime, the bribery of public officials aids its illegal trafficking in that, amongst other things, it provides access to confidential information, enables false documents to be obtained, public procurement procedures to be guided, proceeds to be recycled and law enforcement actions by the police and courts to be evaded;
- X. whereas cocaine from Central and South America is sold in Europe through ports in north-eastern Europe, the Iberian peninsula and the Black Sea;
- Y. whereas in 2012 more than 70 new psychoactive substances came onto the EU market; whereas organised crime increasingly uses clandestine laboratories located in various parts of the EU to convert lawful chemicals into precursors of synthetic drugs and subsequently to produce the latter;
- Z. whereas Member States and the EU need to identify and combat relatively new areas of organised crime, including the trade of rare minerals, stolen metals, and the disposal of toxic waste, which are having a negative effect on legitimate markets;
- AA. whereas opportunities for contact and forms of integration between the public and private sectors are now frequent and, therefore, situations presenting a potential risk of conflict of interest are increasingly common;

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<sup>(1)</sup> According to the Norton Cybercrime Report 2012.

Wednesday 23 October 2013

- AB. whereas amongst the enemies of the euro area is the divergence of productivity gains among the Member States; whereas this creates, in the medium and long term, a divergence in terms of competitiveness that cannot be dealt with by monetary devaluation and leads to harsh and politically unsustainable austerity programmes aimed at internal devaluation; whereas systemic corruption in the public sector, which is one of the main impediments to efficiency, foreign direct investment and innovation, is thus preventing the proper functioning of the monetary union;
- AC. whereas, according to the World Bank, corruption represents 5 % of global GDP (US\$ 2,6 trillion) with over US\$ 1 trillion paid in bribes each year; whereas corruption adds up to 10 % of the total cost of doing business on a global basis and 25 % to the cost of procurement contracts in developing countries <sup>(1)</sup>;
- AD. whereas there are at least 20 million cases of petty corruption in the EU public sectors and it is obvious that the phenomenon also has a spillover effect in the government departments of the Member States (and relevant politicians) which are responsible for managing European Union funds and other financial interests;
- AE. whereas flows of dirty money through transfers of funds can damage the stability and reputation of the financial sector and threaten the internal market of the Union; whereas the full traceability of funds can be an important and highly valuable tool in the prevention, investigation and detection of money laundering or terrorist financing;
- AF. whereas although advances in new technology and payment methods should give rise to a more secure and a relatively cashless society, the use of cash remains commonplace, as indicated by ECB figures on the issuance of banknotes, which show that since 2002 the volume of euro banknotes has increased steadily (in particular as regards high denominations); whereas movements of vast amounts of cash from illicit sources remain a matter of concern for law enforcement and this is still one of the most favoured methods to repatriate criminal proceeds;

***In defence of citizens and of the lawful economy***

- AG. whereas the safety of citizens and consumers, freedom of movement, the protection of businesses, free and fair competition, the need to prevent stockpiles of illicit financial assets and funds from distorting the lawful business cycle, and the fundamental democratic principles on which the EU and its Member States are based are being seriously threatened by the spread of organised crime, corruption and money laundering; whereas the eradication of such phenomena requires a resolute political will at all levels;
- AH. whereas, in addition to acts of intimidation and violence, organised criminals are implicated in increasingly more sophisticated and lucrative forms of fraud which are draining substantial resources away from the lawful economy and damaging the prospects for growth, especially in difficult times such as the present; whereas, given the vast scale of their infiltration into the lawful economy, organised crime, corruption, and money laundering are having a devastating impact on Member States;
- AI. whereas the United Nations Office on Drugs and Crime (UNODC) estimates that the proceeds from illegal activities worldwide account for about 3,6 % of global GDP and whereas the flow of laundered money in the world today amounts to approximately 2,7 % of global GDP; whereas the Commission estimates that, in the EU alone, corruption costs roughly EUR 120 billion a year, that is to say, 1,1 % of EU GDP; whereas substantial resources are thus being stolen from economic and social development, public finances and citizens' welfare;
- AJ. whereas there are increasingly close links between criminal groups and terrorist groups; whereas, in addition to real structural links, these include the mutual supply of services, money, and of other forms of material assistance; whereas these links are a serious threat to the integrity of the European Union and the safety of its citizens;

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<sup>(1)</sup> International Chamber of Commerce, Transparency International, UN Global Compact, World Economic Forum, Clean Business is Good Business, 2009.

Wednesday 23 October 2013

- AK. whereas excessive red tape can discourage legitimate economic activity and provide incentives for bribing public officials; whereas high levels of corruption are a serious threat to democracy, the rule of law and the equal treatment of all citizens by the State in addition to being an unnecessary cost to businesses, preventing them from competing fairly; whereas corruption can undermine economic development through improper allocations of resources, especially at the expense of public services, in particular of social and welfare services;
- AL. whereas corruption is perceived by 74 % of European citizens to be a major national and supranational problem <sup>(1)</sup>, while cases of corruption apparently occur within all sectors of society; whereas corruption undermines citizens' confidence in democratic institutions and the effectiveness of elected governments in preserving the rule of law, since it creates privileges and hence social injustice; whereas distrust of politicians is heightened in times of dire economic crisis;
- AM. whereas the Member States do not all have a system to standardise citizens' access to information and fully protect it and to that extent fall short of the requirements of monitoring and awareness raising and hence of a genuine EU-wide freedom of information act;
- AN. whereas, also due to the economic crisis, credit is more difficult to obtain for 'clean' companies, given the higher costs and the more stringent guarantees that banks require; whereas businesses in economic difficulty sometimes turn to criminal organisations in order to obtain funds for investments, which enables criminal groups to take money earned through criminal activities and invest it in legal economic activities;
- AO. whereas money laundering is becoming increasingly sophisticated and now includes, for example, illegal, and sometimes even legal, betting, in particular in relation to sporting events; whereas the gambling industry can be used for the purposes of money laundering; whereas organised crime is also often at the heart of match-fixing as a profitable form of criminal activity;
- AP. whereas organised crime often makes use of personal data obtained fraudulently, also online, to create false documents or alter genuine documents and thus commit other crimes; whereas, according to research by the Commission <sup>(2)</sup>, 1,8 % of Internet users in the European Union have been victims of identity theft or have at least had some experience of it, and 12 % have been victims of some form of online fraud; whereas the protection of personal data online is an essential precondition for combating online crime and is an important tool for restoring citizens' trust in online services;
- AQ. whereas money laundering is linked not only to activities typically associated with organised crime, but also to corruption, tax fraud and tax evasion; whereas an estimated and scandalous EUR 1 trillion of potential tax revenue is lost to tax fraud, tax evasion, tax avoidance and aggressive tax planning every year in the EU, representing an approximate cost of EUR 2 000 for every European citizen each year, without appropriate measures being taken in response;
- AR. whereas money laundering is becoming increasingly sophisticated and now includes, for example, illegal, and sometimes even legal, betting, in particular in relation to sporting events; whereas organised crime is also often at the heart of match-fixing as a profitable form of criminal activity;
- AS. whereas the activities of organised crime increasingly include the counterfeiting of all kinds of products, from luxury goods to everyday items; whereas this poses a serious risk to the health of consumers, endangers job security, damages the businesses concerned and causes huge losses in revenue; whereas counterfeiting is sometimes seen as socially acceptable because it is perceived as not having any actual victims and this reduces the risk of detection for the criminal organisations involved;
- AT. whereas the increasing number of crimes being perpetrated against the agri-food sector are not only seriously endangering the health of European citizens but also causing considerable damage to those countries that have made food excellence their major asset;

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<sup>(1)</sup> Special Eurobarometer 374 on Corruption, February 2012.

<sup>(2)</sup> See Eurobarometer, Special Report No 390 on Cybercrime, July 2012.

Wednesday 23 October 2013

- AU. whereas an estimated EUR 193 billion in VAT revenues (1,5 % of GDP) was lost due to non-compliance or non-collection in 2011, according to the Commission; whereas the scale of tax fraud and tax avoidance undermines citizens' trust and confidence in the fairness and legitimacy of tax collection and the fiscal system as a whole; whereas the EU's VAT gap has almost doubled since 2006, with an estimated one-third being attributed to VAT fraud; whereas increasing OLAF's operational powers in the fight against VAT fraud could help to drastically reduce the incidence of this crime;
- AV. whereas the cost of corruption in public procurement in 2010 amounted to between EUR 1,4 and 2,2 billion in eight Member States alone;

***Need for a common Europe-wide approach***

- AW. whereas Mafia-type criminal organisations have been singled out for attention within the priorities laid down by the JHA Council of 6—7 June 2013 for the 2014-2017 policy cycle focusing on cross-border organised crime, a fact which demonstrates the soundness of the work of the CRIM Committee — which has devoted many of its hearings to the above subject — and of Parliament as a whole and amounts to a recognition that the European institutions need to follow an unwavering joint policy approach in order to counteract the threat posed by Mafia-type crime and criminal systems;
- AX. whereas, as Europol has noted in 2013, one of the biggest dangers, when it comes to fighting mafias, lies in the possibility of underestimating the complexity of organised crime and the extraordinary organisational skills of the criminals, who can adapt to different geographical and social environments and sometimes eschew 'military control' of the territory concerned in favour of an 'underground' strategy, enabling them to make huge profits while remaining invisible;
- AY. whereas criminal organisations are equipped to exploit to their advantage the free movement of persons, goods, services and capital in the European Union in addition to the differences in the legislation and legal traditions of the Member States; whereas tax havens and countries that pursue non-transparent or harmful tax practices play a vital role in money laundering; whereas the persistence of distortions caused by tax havens can lead to artificial flows and negative effects within the EU internal market; whereas harmful tax competition within European Union is clearly against the logic of the single market; whereas more efforts are needed to harmonise tax bases within an ever-closer economic, fiscal and budgetary Union;
- AZ. whereas some work has already been done at European level to provide a balanced legislative and regulatory framework as regards organised crime, corruption, and money laundering; whereas certain objectives in the fight against organised crime, corruption and money laundering cannot be achieved by the Member States acting on their own; whereas, nonetheless, new law enforcement measures and harmonisation of national laws to combat such multifaceted phenomena are necessary;
- BA. whereas, in order to tackle organised crime, legislators in the Member States must be able to react promptly and effectively to changing structures and new forms of crime, and even more so since, under the Treaty of Lisbon, all Member States are obliged to facilitate a Union of freedom, security and justice;
- BB. whereas the protection of the Union's financial interests and of the euro must be a priority; whereas, to that end, the growing phenomenon by which criminal organisations are misappropriating European funds (so-called Community fraud) and counterfeiting the euro needs to be stemmed; whereas programmes such as Hercule, Fiscalis, Customs and Pericles have been developed at the European level to protect the EU's financial interests and fight against transnational and cross-border criminal and illicit activities;
- BC. whereas mutual recognition is recognised as a fundamental principle underpinning judicial cooperation in civil and criminal matters between the EU's Member States;

Wednesday 23 October 2013

- BD. whereas, as is stated in the 2012 UNODC Digest of organised crime cases, 'Special investigative techniques are often irreplaceable for the successful investigation and prosecution of organised crime. They are at the root of the successful results achieved in the most serious and complicated investigations illustrated by the cases'; whereas Article 20(1) of the UN Palermo Convention calls on States Parties to use special investigative techniques 'for the purpose of effectively combating organised crime'; whereas such techniques must be regulated by law, proportionate and necessary in a democratic society, subject to scrutiny by judicial authorities and other independent bodies through prior authorisation and supervision during the investigation or ex post facto review, so as to ensure their full conformity with human rights, as required by Recommendation (2005)10 of the Committee of Ministers on 'special investigation techniques' in relation to serious crimes including acts of terrorism;
- BE. whereas the judicial independence is vital to the idea of separation of powers, furthermore an efficient, independent and impartial judicial system is important for the rule of law, protection of human rights and civil liberties of our citizens; whereas courts shall not be subjected to any influence or interests;
- BF. whereas this resolution is intended to provide political direction with regard to future legislation of the European Commission and the Member States;

***In support of a coherent uniform regulatory framework — protection and assistance for victims***

1. Reiterates the substance of its interim report, adopted by resolution of 11 June 2013, which this resolution seeks to confirm — also with regard to the provisions that are not explicitly mentioned herein — and supplement;
2. Calls on the Commission to launch a European action plan against organised crime, corruption and money laundering, which should include legislative measures and positive action designed to combat these criminal activities effectively;
3. Urges all Member States to promptly and correctly transpose into their national legislation all existing EU and international legal instruments concerning organised crime, corruption and money laundering; urges Member States and the Commission to complete the Roadmap on the rights of suspects and accused persons in criminal proceedings, including a directive on pre-trial detention;
4. Endorses the current (2011-2013) policy cycle for transnational organised crime and the cycle to be implemented in the next period (2014-2017), and calls on the Member States and European agencies to do their utmost to ensure that this initiative yields tangible results; believes that the policy cycle should be encompassed within a wider European action plan to combat organised crime and criminal systems; considers that once the policy cycle has been reviewed, as is due to happen in October 2015, corruption should be included among its cross-cutting priorities;
5. Calls on the Council, in due course, to revise its conclusions of 8 and 9 November 2010 on the creation and implementation of an EU policy cycle for organised and serious international crime in order to enable Parliament, in keeping with the spirit of the Treaty of Lisbon, to be involved in determining the priorities, discussing the strategic objectives, and assessing the results of the policy cycle; asks to be briefed by the Council on the outcome of the first (2011-2013) policy cycle and to hear COSI annually in order to obtain a detailed progress report on the annual plans for achieving the strategic objectives;
6. Reiterates its call to the Commission to propose common judicial standards to strengthen integration and cooperation among Member States; calls on the Commission, in particular, on the basis of an evaluation report on the implementation of the Framework Decision on the fight against organised crime and building on Member States' most advanced legislation, to submit, by the end of 2013, a legislative proposal setting out a common definition of organised crime, which should include, *inter alia*, the offence of participation in a transnational criminal organisation, emphasising the fact that criminal groups of this kind are business oriented, highly organised, technologically sophisticated, and often act through intimidation and blackmail; calls on the Commission, moreover, to take into account Article 2(a) of the UN Convention against Transnational Organised Crime;
7. Reiterates that the EU proposals concerning substantive criminal law provisions must respect fundamental rights and the principles of subsidiarity and proportionality, as well as the substance of Parliament's resolution of 22 May 2012 on an EU approach to criminal law;

Wednesday 23 October 2013

8. Calls on the Commission to criminalise the abuse and exploitation of the victims of human being trafficking, and urgently to develop an EU comparable and reliable data collection system, based on common and agreed solid indicators, together with Member States and the relevant international institutions; calls on the Commission to implement, as soon as possible, all measures and instruments presented in the communication entitled 'EU Strategy towards the Eradication of Trafficking in Human Beings 2012-2016', and to establish an EU Anti-trafficking Observatory, open to governments, law enforcement agencies and NGOs; calls on the Commission and the EEAS to strengthen the external dimension and the preventive scope of measures and programmes, in particular through bilateral agreements with the countries of origin and transit and with special attention to unaccompanied minors; calls on the Commission and the Member States to make human being trafficking socially unacceptable through strong and sustained awareness-raising campaigns to be evaluated annually as part of the European Anti-Trafficking Day;

9. Calls on the Commission to develop a consistent global policy against corruption; recommends that, when drawing up its report on action taken by Member States and EU institutions against corruption, the Commission should propose and include a list of concrete recommendations for each Member State and EU institution, highlighting best practice examples in combating it to foster and encourage Member States and EU institutions to undertake peer-learning exercises in the longer term; recommends also that the Commission include a comprehensive overview of vulnerable areas of corruption on a national basis; calls on the Commission to ensure the publication of the next report in 2015 to track progress of the efforts in Member States and EU institutions to fight corruption over time; calls on the Commission to report regularly to Parliament on actions taken by Member States and to update existing European legislation where necessary;

10. Takes the view that defamation/libel laws dissuade possible reporting of corruption; urges therefore that all Member States to de-penalise defamation/libel laws in their legal systems, at least for cases when allegations of organised crime, corruption and money laundering in Member States and abroad are in question;

11. Calls on the Commission to report regularly to the European Parliament on actions taken by Member States against organised crime, corruption and money laundering;

12. Calls on the Commission to submit, by the end of 2013, a proposal to harmonise criminal law on money laundering, providing a common definition of the offence of self-laundering based on Member States' best practices;

13. Takes notes of the recent legislative proposals on the establishment of the European Public Prosecutor's Office (EPPO) and on the European Union Agency for Criminal Justice Cooperation (Eurojust) and calls for their prompt adoption; considers it crucial that the EPPO is supported by a clear procedural rights framework and that the offences over which it will have authority are clearly defined;

14. Calls on the Commission, by the end of 2013, to submit a legislative proposal establishing an effective and comprehensive European whistleblower protection programme in the public and in the private sector to protect those who detect inefficient management and irregularities and report cases of national and cross-border corruption relating to EU financial interests and to protect witnesses, informers, and those who cooperate with the courts, and in particular witnesses testifying against mafia-type and other criminal organisations, with a view to resolving the difficult conditions under which they have to live (from risks of retaliation to the breakdown of family ties or from being uprooted from their home territory to social and professional exclusion); calls also on the Member States to put in place appropriate and effective protection for whistleblowers;

15. Stresses that an effective regulatory framework should duly take into account the interaction between provisions to fight organised crime, corruption and money laundering and the fundamental right to the protection of personal data, in order to combat these without lowering established data protection and fundamental rights standards; in this regard, welcomes the data protection system used by Europol, as well as the Commission's proposal on the Fourth Anti-Money Laundering Directive;

16. Recommends that the European Parliament, the Member States, and the Commission, with the support of Europol, Eurojust and the EU Fundamental Rights Agency, devise indicators, on the basis of recognised systems and common criteria which should be as uniform and consistent as possible, to measure, at least, the extent and economic costs of, and social

**Wednesday 23 October 2013**

harm caused by, organised crime, corruption and money laundering at EU level; calls on the Commission and the Member States to investigate the social harm caused by environmental, economic and corporate crimes;

17. Points to the need for the full application, and the strengthening, of the existing mutual recognition instruments and for European legislation providing for the immediate enforceability of all judicial measures, with particular reference to convictions, arrest warrants and confiscation orders in Member States other than those in which they were issued, whilst fully respecting the principle of proportionality; calls on the Commission, as a matter of priority, to produce the concrete legislative proposal required in order to give effect to mutual recognition of seizure and confiscation orders, including those issued for civil purposes; considers that mutual legal assistance and the mutual admissibility of evidence between Member States should be improved; stresses the importance of updating and improving the mechanisms of letters rogatory; calls for requests to extradite members of criminal organisations to be treated as a priority by the recipient authorities;

18. Calls on the Member States and the Commission to continue common efforts to conclude the negotiations on the draft directive regarding the European Investigation Order in criminal matters with a view to simplifying evidence gathering in cross-border cases and bringing about smooth, effective judicial cooperation to combat transnational crime;

19. Considers it vitally important that the directive on the confiscation of proceeds of crime be rapidly adopted, and recognises the prime importance of having clear and effective rules that will ensure proper Europe-wide harmonisation; invites the Member States to transpose that directive in a timely and effective manner;

20. Invites the Member States and the Commission to promote international cooperation and support a European programme to encourage the exchange and dissemination of good practices for the efficient management of confiscated assets;

21. Calls on the Commission and the Member States to step up the fight against trafficking in human beings and forced labour; believes that the fight against forced labour should focus on the places where cheap forced labour is exploited; calls therefore on Member States to strengthen their labour inspections and to facilitate those organisations that can help in detecting forced labour such as trade unions;

22. Believes that chain responsibility for businesses is an important tool in the fight against forced labour; calls therefore on the Commission to come forward with a proposal for minimum standards for chain responsibility for businesses; encourages the Member States to ban subcontracts in connection with public contracts until an agreement on chain responsibility for business is in place;

23. Reminds the Commission that special treatment should be given to children who are victims of trafficking, as well as to improve the protection of unaccompanied minors or trafficked children by their own families (cases to be taken into account when proposing return to countries of origin, identification of guardians, etc.); urges that not only the gender-specific approach, but also the role of health problems and disabilities be taken into account;

24. Calls on the Commission to develop an EU Charter for Protection and Assistance of Victims of Trafficking in order to gather all existing indicators, measures, programmes and resources in a more coherent, efficient and useful way for all stakeholders involved with the objective to strengthen the protection of the victims; calls on the Commission to set up a helpline for victims of trafficking in human beings;

25. Calls on the Commission to increase the resources allocated to specialised NGOs, media and research in order to step up support, protection and assistance for victims so that their testimony in court becomes less necessary; calls on the Commission also to reinforce the aspects of visibility, awareness-raising and victims' needs, with the aim of reducing the demand for and abuse of victims of trafficking in human beings and promoting a 'zero vision' against sexual and labour exploitation;

Wednesday 23 October 2013

26. Underlines that the World Bank estimates that each year, US\$ 20 to US\$ 40 billion, corresponding to 20 % to 40 % of official development assistance, is stolen through high-level corruption from public budgets in developing countries and hidden overseas <sup>(1)</sup>; given the European Union's position as the world's leading donor, calls on the European Commission to consolidate the cooperation with other donors and the International Organisation of Supreme Audit Institutions to develop capacities of Supreme Audit Institutions in aid recipient countries, in order to implement the International Standards for Supreme Audit Institutions and ensure that the EU financial assistance serves its intended purposes instead of being diverted;

***Halting organised crime by striking at the proceeds and assets that it generates***

27. Calls on the Member States, on the basis of the most advanced national legislation, to introduce models of non-conviction based confiscation, in those cases where, based on the available evidence and subject to the decision of a court, it can be established that the assets in question result from criminal activities or are used to carry out criminal activities

28. Considers that, in compliance with constitutional national guarantees and without prejudice to the right of property and the right of defence, provision could be made for preventive models of confiscation, which should be applicable only following a court decision;

29. Calls on the Commission to bring forward a legislative proposal aimed at effectively ensuring the mutual recognition of seizure and confiscation orders linked to the asset-protection measures adopted by the Italian judicial authorities and to the civil law measures adopted in various EU countries; calls on the Member States to immediately adopt the operational measures needed to render those provisions effective;

30. Calls on the Member States to foster administrative, police and judicial cooperation enabling criminal assets to be traced anywhere in EU territory with a view to their seizure or confiscation, including through full activation of the network of asset recovery offices and rapid access to national data records such as, for example, those of the tax authorities, the public registry of motor vehicles, the land registry and the bank registry;

31. Calls on the Commission to enhance the role and responsibilities of the asset recovery offices (AROs) and to create the conditions for their having swifter and across-the-board access to information, in a manner fully consonant with data protection and fundamental rights; invites the Member States to support this raising of the profile of AROs, including by providing the appropriate resources, in view of the potential those offices have for recovering criminal assets; commends the work performed by the ARO platform so far, and encourages it to continue that work so that current best practices and the activities of those offices can be turned to full advantage across the EU;

32. Considers it of vital importance, with a view to effectively countering the power of criminal systems by targeting their finances, to call into play every tool that can help pinpoint criminal and mafia-type assets, such as, for example, the creation of centralised registers for current bank accounts;

33. Encourages the Member States to promote the reuse of seized criminal assets for social purposes such as redirecting these proceeds to victims and communities which have been devastated by drugs and organised crime, and to use them to fund crime-fighting locally as well as cross-border actions by law enforcement agencies, and suggests that funds be released to finance measures to keep those assets intact;

34. Recommends that the Member States introduce rules for the criminal prosecution both of persons who make others the fictitious owners or holders of goods, money or other assets with a view to preventing their seizure or confiscation and of third parties who agree to act as the fictitious owners or holders of such assets;

35. Recommends that an economic operator should be excluded for at least five years from participation in any public contract throughout the EU if that operator has been the subject of a conviction by final judgment for participation in a criminal organisation, money laundering or terrorist financing, exploitation of human beings or child labour, corruption or any other serious offence against the public interest wherever such offences undermine the fiscal capacity of the State or produce social harm, such as, for example, tax evasion and other tax-related offences, or for any other particularly serious

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<sup>(1)</sup> International Chamber of Commerce, Transparency International, UN Global Compact, World Economic Forum, Clean Business is Good Business, 2009.

**Wednesday 23 October 2013**

crimes with a cross-border dimension, as referred to in Article 83(1) TFEU (so-called Eurocrimes), whilst fully respecting the rights of defence in accordance with the ECHR, the EU Charter and secondary EU legislation pertaining to the rights of suspects and accused persons in criminal matters, and that the above provision should apply even when the grounds for exclusion arise in the course of the award procedure; recommends further that economic operators registered in tax havens recognised as such by international organisations be excluded from participating in a public contract;

36. Considers that public procurement procedures must be based on the principle of legality and that, in this regard, the criterion of the economically most advantageous tender should be pursued while ensuring full transparency in the selection procedure (to be achieved not least through e-procurement) so as to prevent fraud, corruption and other serious irregularities;

37. Calls on the Member States to prevent the risks of criminal infiltration and corruption in public procurement by introducing appropriate controls and objective and transparent procedures;

38. Considers that, in order to combat organised crime, corruption and money laundering, cooperation between the private sector and law enforcement agencies should be stepped up so as to encourage private actors to refuse, abstain from and report to the judicial and police authorities, including Eurojust and Europol where appropriate, any illegal or unfair practice related to or fostering organised crime, corruption and money laundering or other crimes, notably in the transport and logistics sectors, the chemical industry, Internet service providers, and banks and financial services, in both Member States and non-EU countries; calls for stronger protection schemes for private actors under threat because of their collaboration in denouncing organised crime, corruption and money laundering activities; furthermore, urges the Member States — in keeping with the solidarity principle — to make adequate resources and funding available for Europol, Eurojust, Frontex and the future EPPO, whose action is beneficial to Member States and citizens alike;

39. Calls on the Commission to submit a proposal for a directive by the end of 2014 on common investigative techniques to combat organised crime, pursuant to Article 87(2)(c) of the Treaty on the Functioning of the European Union;

40. Calls on the Commission, the Member States and businesses to improve the traceability of products — for example by indicating the country of origin for agri-food products, providing C.I.P. proof marks on firearms, or digital identification codes, also for tax purposes, on cigarettes, alcoholic drinks and prescription drugs — in order to prevent counterfeiting, deprive organised crime of an important source of income and protect consumers' health; regrets that Member States did not want to include traceability in the modernisation of the Union Customs Code;

41. Calls on the Commission and the Member States to strengthen their maritime cooperation with a view to stamping out trafficking in human beings, drugs and tobacco smuggling, and other illegal or counterfeit products; acknowledges that inconsistent border management, including sea borders, is a gateway for organised criminals into the EU, and is an issue which must continue to be looked at, and calls upon EUROPOL, FRONTEX and the European Commission to examine the trends with regard to the EU's external borders and its vulnerabilities;

42. Takes note of the existing links between organised crime and terrorism, as highlighted by the judicial authorities and the police in some circumstances in connection with the financing of the illegal activities of terrorist groups via the proceeds of illicit trafficking at international level and calls on the Member States to strengthen their measures to combat such activities;

43. Encourages the joint training of anti-crime and anti-terrorism experts, also with a view to the establishment of common task forces operating at least nationally, in addition to the creation and use of EU-wide joint investigation teams;

44. Emphasises the major results achieved so far thanks to the introduction of joint investigation teams, and recognises the fundamental importance of these in terms of disseminating a culture of cooperation in the combating of cross-border crime; calls on the Member States to suitably transpose Framework Decision 2002/465/JHA and to encourage their competent authorities, and in particular their judicial authorities, to expand on this tool; acknowledges the great added value of joint investigation teams and stresses the need to continue funding such a useful investigating tool;

Wednesday 23 October 2013

45. Notes with concern that organised crime is already managing to reach a vast number of potential victims through the fraudulent use of the Internet, by using, in particular, social networks, sending unsolicited emails (spamming) the facilitation of intellectual property theft, and using phishing websites and online auctions; in this regard encourages comprehensive national strategies, including education, public awareness campaigns, and best practice in businesses in order to create a better awareness of the dangers and consequences of online criminal activity;

46. Condemns the involvement of organised crime groups in the setting-up and running of illegal waste disposal areas and the illicit transportation of waste to third countries, particularly in Africa and Asia; calls on the Member States to severely punish criminal activities centring on the illicit disposal of waste, including toxic waste, and any involvement of corrupt public officials in such activities;

47. Underlines that independent investigative journalism plays a vital role in exposing fraud, corruption and organised crime schemes as demonstrated in April 2013 through 'Offshore leaks' that disclosed details of 130 000 offshore accounts following years-long investigations by the International Consortium of Investigative Journalists together with 36 international newspapers; is of the opinion that investigative journalism reports represent a valuable source of information to be considered by OLAF and law enforcement or other relevant authorities in Member States;

48. Calls for European funding to be made available for projects and measures aimed at stopping mafia-type organisations taking root in the European Union;

#### ***Strengthening judicial and police cooperation at European and international level***

49. Calls on the Member States to create national bodies for investigating and combating criminal and mafia-type organisations, with the possibility of developing — with Europol coordination and support from the Commission — a streamline and informal 'anti-mafia operational network' for exchanging information on the structural aspects of mafia activities, on criminal and financial projects, on the location of assets and on attempted infiltration of public procurement procedures;

50. Stresses the importance of stepping up cooperation by developing effective systematic communication and promoting information-sharing between judicial and law enforcement agencies among Member States, Europol, Eurojust, OLAF and ENISA, and with the corresponding authorities in non-EU countries, especially the EU's neighbouring countries, on the basis of proper data protection and procedural rights standards, with a view to improving systems for gathering evidence and to enabling data and information relevant to the investigation of offences, including those against the EU's financial interests, to be processed and exchanged effectively with increased accuracy and speed of exchange, in full compliance with the principles of subsidiarity and proportionality and with EU fundamental rights; reiterates that the collection, storing and processing of personal data in the course of addressing organised crime, corruption and money laundering must in all circumstances comply with the data protection principles laid down in the ECHR, the EU Charter and secondary EU legislation; furthermore, stresses the need to achieve a higher degree of democratic and fundamental rights accountability of the activities of Europol and Eurojust in their upcoming review;

51. Notes that often the lack of synergy between law enforcement and legislative bodies, delays in judicial response, and deficient legislation enable criminals to exploit loopholes and capitalise on demands for illicit commodities;

52. Considers that ensuring freedom of movement within the Schengen area and the effective combating of organised cross-border crime are closely related matters; welcomes, in this connection, the recent introduction of the second generation Schengen Information System, which will enable information to be exchanged more quickly and efficiently between the competent authorities of the Member States;

53. Calls on the Commission to commit itself to making full use of the synergies that exist between the European Judicial Network and Eurojust, with a view to achieving a very high level of intra-European judicial cooperation;

54. Stresses the importance of the EU facilitating good practice on how to combat organised crime and terrorism, and in identifying its root causes, both within the EU, but also with third countries, especially those where these problems often originate;

**Wednesday 23 October 2013**

55. Calls on the Commission to consider, in its association and trade agreements with third countries, specific cooperation clauses with reference to combating organised crime, corruption and money laundering; notes the lack of international cooperation, in particular with non-EU countries and especially with neighbouring countries of transit or origin; recognises the need for strong diplomatic action to urge those countries to contract cooperation agreements or to comply with the agreements that they have signed;

56. Calls on the Member States and the Commission to strengthen the role of judges, prosecutors and liaison officers and to encourage judicial training, as well as training in financial investigation, in order to enable those concerned to fight all forms of organised crime (including cybercrime), corruption and money laundering, in particular through the use of CEPOL and the European Judicial Training Network and by making full use of financial instruments such as the Internal Security Fund for police cooperation or the Hercules III Programme; encourages the teaching of foreign languages in the training of the judicial authorities and the police, in order to facilitate transnational cooperation, and calls for support for a European best practice exchange and training programme for judges, prosecutors and police forces;

57. Calls on the EU and the Member States to develop legal tools and specific strategies to ensure that their law enforcement and investigative authorities facilitate and increase, in a manner fully involving Europol and enhancing its role, the circulation of information among themselves and carry out the necessary analyses to identify and, where possible, prevent and counter emerging organised crime trends while at the same time respecting fundamental rights, and in particular the right to privacy and the right to personal data protection;

58. Believes that the globalisation of organised crime requires stronger cooperation among Member States, at EU and international level; encourages greater interaction between the EU, the UN, the OECD and the Council of Europe in the fight against organised crime, corruption and money laundering; supports the efforts made by the FATF to promote anti-money laundering policies; calls on the Commission to support Member States effectively in their efforts to combat organised crime and recommends that the EU join GRECO as a current member; also encourages the EU to not just look towards our most common allies and partners for cooperation, but to attempt to create a truly international and global response and solution to money laundering, corruption and the funding of terrorism;

59. Calls on the Commission and, in particular, the High Representative of the Union for Foreign Affairs and Security Policy, to take the necessary steps to ensure that the Union adopts a common approach in respect of third countries as regards links between organised crime and terrorism; calls on the Member States to police their own borders and exchange all necessary information in order to sever existing or potential links between organised crime groups and terrorist groups;

60. Strongly recommends the need to draw up, without further delay, a European action plan to combat cybercrime, with a view to achieving greater intra-European and international cooperation and with the support of the European Cybercrime Centre (EC3), with the aim of providing citizens (especially the most vulnerable, notably to prevent the exploitation of children), businesses and public authorities with a high level of security while fully guaranteeing the freedom of information and the right to the protection of personal data;

61. Supports the call by European leaders at the recent G8 summit to enhance the effectiveness of the fight against tax evasion and tax havens, with the aim of recovering taxes from avoiders and evaders;

62. Recommends that joint action be taken to prevent and combat illegal environment-related activities connected to or resulting from organised crime and mafia-type criminal activities, including by strengthening European bodies such as Europol and Eurojust, and international ones such as Interpol and the United Nations Interregional Crime and Justice Research Institute (UNICRI), as well as by sharing working methods and information held by the Member States that have been the most involved in combating this form of crime, with a view to developing a common action plan;

63. Points out that cross-border crime can only be tackled by cross-border judicial and police cooperation between Member States and that even if the EU needs more legal instruments in order to combat organised crime, there is already a toolbox for Member States to use; emphasises that the biggest obstacle to really fight organised crime on an EU level is the lack of political will in Member States; calls on the Member States, therefore, to use the instruments provided by the EU and its agencies;

Wednesday 23 October 2013

64. Proposes that all innocent victims of organised crime, especially mafia-type crime, be commemorated, and that special tribute be paid to those who have died fighting organised criminal groups, by establishing a 'European Day of Memory and Commitment in Remembrance of the Innocent Victims of Organised Crime' to be held each year, starting from 2014, on the day of the adoption of this resolution by Parliament;

***In support of an efficient and corruption-resistant public administration***

65. Considers that, in addition to potentially marring the effectiveness of administrative action and harming the well-being of citizens, a disorganised bureaucracy and complex procedures can undermine the transparency of decision-making and frustrate citizens and businesses in their legitimate expectations, thus providing a fertile breeding ground for corruption;

66. Is of the opinion that investigative journalists, as well as NGOs and academics, play a vital role in identifying instances of corruption, fraud and organised crime and that they can consequently be exposed to security threats; recalls that over a period of five years a total of 233 investigative reports have been published on cases of fraud related to the misuse of EU funds within the 27 Member States<sup>(1)</sup> and considers that investigative journalism should benefit from appropriate resources; in particular, supports the actions of the Commission aimed at recognising the role of investigative journalism in the discovery and reporting of facts relating to serious criminal offences;

67. Stresses that holders of high office should be subjected to adequate controls, *inter alia* by the tax authorities; recommends, in particular, that holders of public office submit declarations concerning their activities, income, responsibilities and interests;

68. Calls on the Council and the Member States to ratify and fully implement the Organisation for Economic Cooperation and Development (OECD) Convention on combating bribery of foreign public officials in international business transactions; stresses the negative impact that bribery of foreign officials has on the Union's fundamental rights, environment and development policies;

69. Stresses that the fight against corruption is an integral part of capacity building for tax administration; calls on the full implementation of the Merida Convention against Corruption (2003);

70. Recommends that stronger systems be put in place to bring transparency and integrity to, and eliminate 'red tape' from, government departments and other public bodies, with this meaning that there must be full access to information on every aspect of administrative organisation and activity, the performance of institutional duties and the use of public resources, including by guaranteeing the right of citizens to access documents (starting with the very sensitive area of public procurement); encourages the promotion of a culture of legality and integrity in the public and the private sector alike, not least by means of an effective protection scheme for whistleblowers;

71. Encourages, to enable official corruption to be uncovered more effectively, the use of the resources available for covert operations, within the boundaries of the principle of the rule of law and subject to democratic control mechanisms and the application of national law;

72. Calls for the introduction of clear, proportionate rules and the relevant enforcement and monitoring mechanisms, to be specified in a code of conduct to prevent the phenomena of 'revolving doors' or 'pantouflage', by prohibiting public officials who have certain managerial or financial responsibilities from moving to the private sector until a defined time has elapsed since their departure from service, if there is a risk of a conflict of interest with their preceding public function; considers, moreover, that whenever there is a risk of a conflict of interest, similar restrictions should apply to employees moving from the private to the public sector; calls for the harmonisation of conflict of interest rules and monitoring systems across the EU for the various supervisory bodies;

73. Calls on the Member States to develop a comprehensive system for protecting people who report cases of corruption and to extend the scope for reporting corruption anonymously; proposes that confidential channels for the reporting of corruption be created; calls for an extension of the scope for challenging the outcome of public procurement procedures;

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<sup>(1)</sup> European Parliament, Study on the deterrence of fraud with EU funds through investigative journalism in EU-27, October 2012

Wednesday 23 October 2013

74. Points out that much-needed investments in alternative energy solutions are linked to generous grants and tax subsidies from Member States and the EU; calls on both national and Union authorities to ensure that such grants do not benefit criminal organisations;

***In support of more accountable politics***

75. Reminds political parties of their responsibility in putting forward candidates and, in particular, in the drawing-up of election lists at all levels; stresses that they have the duty of gauging the calibre of candidates, not least by requiring them to comply with a strict code of ethics, including — in addition to rules relating to conduct — clear and transparent rules on donations to political parties;

76. Maintains that persons should be ineligible for membership of the European Parliament or service for other EU institutions and bodies, with due regard for the principle of proportionality, if they have been convicted by final judgment of participation in organised crime, money laundering, corruption, or other serious offences, including of an economic and financial nature; calls for similar restrictions to be laid down with due regard for the principles of subsidiarity and proportionality, for all elective offices, starting with that of member of a national parliament;

77. Recommends that Member States provide, in their respective penalty systems, that those convicted by final judgement of participation in organised crime, money laundering, corruption, including those of an economic and financial nature, be deemed ineligible for inclusion on the election lists; is of the view that such a penalty should be applied for a period of at least five years and that the same period of disqualification should apply to government posts at every level;

78. Recommends that Member States should require people to forfeit political office or management and administrative positions once they have been convicted of organised crime, corruption or money laundering offences;

79. Calls for greater transparency in the budgets of political parties, *inter alia* by tightening up income and expenditure reporting requirements; in order to avoid abuse and waste, calls for greater control of public and private funding, in order to ensure the accountability of political parties and those who support them financially and insists that strict, comprehensive and timely control followed by dissuasive financial and criminal sanctions should be imposed for breaches of the laws on funding political parties and campaigns;

80. Calls on the Member States to punish vote buying, stipulating in particular that the benefit given for a promise to vote can take the form not only of money, but also of other advantages, including intangible advantages and those accorded to third parties not directly implicated in the illicit agreement; recommends that such a practice be prohibited as being illegal, in that it infringes the principle of democracy, regardless of evidence of any intimidation that might have taken place;

81. Believes that a lobby register is a useful transparency instrument; calls on Member States to adopt this tool where it does not already exist; further, encourages governments, parliaments, elected bodies and public administrations to make registration in a lobby register a condition for a meeting with a business organisation, interest organisation or lobby-agency;

***In support of more credible criminal justice***

82. Recommends that the Member States establish effective, efficient, accountable and balanced criminal justice systems which can also guarantee defence rights in accordance with the European Charter of Fundamental Rights; also recommends that a uniform monitoring mechanism on the efficiency of criminal justice systems in fighting corruption be created at the European level, carrying out regular evaluations on the basis of common, clear, transparent and objective criteria and standards and publishing recommendations;

83. Believes that approximation measures on corruption should address the differences in statutes of limitations among Member States, with a view to taking account of both defence needs and the need for certain punishment, and recommends that such statutes of limitations should be organised according to the stages of the proceedings or the instance involved, so that a crime would be statute-barred only if the stage or step in question had not been completed within a defined time-frame; considers, moreover, that, with due regard for the principles of proportionality and of the rule of law, a corruption offence should not be allowed to be statute-barred where the relevant criminal proceedings are being implemented;

Wednesday 23 October 2013

84. Is of the view that measures to combat organised crime should be based on a combination of effective, dissuasive systems for the confiscation of criminal assets, efforts to ensure that fugitives who deliberately elude police inquiries will be brought to justice, and measures to prevent imprisoned bosses of criminal groups, without prejudice to basic prisoners' rights, from continuing to run their organisation and give orders to members even though they themselves are in prison;

85. Encourages Member States to provide for both prison sentences and large fines for all types of serious offences that harm citizens' health and security; stresses, nonetheless, the importance of preventing organised crime; urges the Member States, therefore, to provide for punishments offering an alternative to imprisonment, such as fines or community service, in cases where this is permitted and taking account of all the circumstances, including the non-serious nature of the offence or the purely marginal role of the defendant, in order to give young offenders in particular a chance to create a life outside the criminal world;

86. Calls on Member States to introduce and apply penalties which will have a deterrent effect and which, in the case of money laundering, are proportionate to the sums involved;

87. Recommends the adoption of a legislative instrument facilitating the designation of those transnational criminal organisations which pose a significant threat to the security of the EU, in order to promote the adoption of administrative measures against them and their associates, promoters and supporters aimed at blocking their properties, assets and interests in the EU;

#### ***In support of more honest business practices***

88. Recalls the paramount role of private business actors and enterprises in refusing, abstaining from and denouncing illegal or unfair practices fostering organised crime, corruption and money laundering or other serious crimes; calls them to collaborate fully and report to law enforcement authorities any criminal activity they might be aware of; calls for law enforcement agencies to protect from threats those who abide by the law and report illegal activities;

89. Urges businesses to practise self-regulation and ensure transparency through codes of conduct, and to introduce oversight procedures, including internal or external auditing and the provision of public registers of lobbyists working within the institutions, in order to avoid, in particular, corruption, collusion and conflicts of interest between the public and private sectors and to prevent unfair competition;

90. Calls on the Commission to consider formulating an EU public list of companies which have been convicted of corrupt practices or whose company officials are being indicted for corrupt practices in Member States or third countries; is of the opinion that such listing should exclude the company from participation in any public contract throughout the EU if that economic operator has been the subject of a conviction by final judgment; highlights that 'blacklisting' does much to dissuade companies from engaging in corrupt activities and provides a good incentive for them to improve and enforce their internal integrity procedures;

91. Calls on Member States to strengthen the role of chambers of commerce in preventing, providing information on and combating the most frequent organised crime, corruption and money laundering risks in the business world and to fully implement the Action Plan to strengthen the fight against tax fraud and tax evasion; encourages the harmonisation of business taxes as a tool with which to combat tax fraud, tax evasion and money laundering and, in this regard, calls for uniform tax rules in all Member States; recommends that Member States use a fairer system of taxation in order to distribute wealth more effectively because high levels of inequality and poverty are exploited by criminal gangs and encourage organised crime;

92. Calls on Member States to introduce a requirement for country-by-country reporting on profit and taxes for all multinational companies, with a view to ending aggressive tax planning;

Wednesday 23 October 2013

***In support of greater transparency in the banking system and the professions***

93. Emphasises the importance of common EU rules to ensure effective and accountable instruments to protect the EU's financial interests; therefore welcomes the euro zone banking union with better supervision for the 6 000 banks in the euro area;

94. Calls for ever increasing cooperation with and greater transparency of the banking system and the professions, including the financial sector and the accounting professions, in all Member States and with non-EU countries, especially with a view to determining which IT tools and legislative, administrative and accounting measures would ensure the traceability of financial flows and ascertain criminal activity, and to laying down procedures for reporting such offences as might have occurred;

95. Calls on auditing firms and legal consultants to alert national tax authorities to any signs of aggressive tax planning of the audited or advised company;

96. Calls on the Commission and the other supervisory authorities having the necessary access to domestic and international cooperation channels to ensure provision of customer due diligence measures and related risk profiles by banks, insurance companies, and credit institutions in order to ensure that corporate or legal entities in the Member States obtain adequate, accurate and current information on their ultimate beneficial owners of companies, trusts, foundations and other similar legal structures, including from offshore tax havens, using intelligence tools to maximise incisiveness when identifying the beneficiaries of suspicious transactions, and that business registers are regularly updated and monitored for quality; considers that transparency of that information — also by means of publication of a country-by-country registry of real ownership and through cross-border cooperation — can contribute to combating phenomena such as money laundering, the financing of terrorism, tax evasion and tax avoidance;

97. Calls on the Commission to develop strong criteria concerning the substance of business to end the creation of shell companies or letterbox companies that aid the legal and illegal practises of tax avoidance and tax evasion;

98. Recommends that accurate assessment be brought to bear on the risks entailed in new banking and financial products where these allow anonymity or long-distance operations; calls, moreover, for a common definition and a clear set of criteria to identify tax havens, as proposed in the Parliament resolution on the fight against tax fraud, tax evasion and tax havens of 21 May 2013, since tax havens are often used by organised crime through companies or banks whose ownership is hard to ascertain;

99. Calls for common definitions and harmonisation of regulations concerning electronic (including prepaid cards, virtual currencies etc.) and mobile money products as regards their potential use for money laundering and terrorist financing purposes;

100. Considers that tax havens and impenetrable bank secrecy can hide the illicit profits of corruption, money laundering and organised and serious crime; recommends, therefore, that they be dispensed with; calls on the EU and the Member States, consequently, to urgently and definitively address this issue internally, as well as externally by raising it with third states and territories, notably those in Europe or with which Member States have very numerous or suspicious financial transactions, and to take appropriate measures to ensure that the fight against crime, corruption and money laundering is effective and efficacious;

***Ensuring that crime does not pay***

101. Calls on all stakeholders, public and private, to take resolute action to combat money laundering; calls for action to ensure full compliance with anti-money laundering requirements by professionals, for instance in the form of systems for reporting suspicious transactions and codes of conduct for professional bodies and trade associations;

102. Calls on non-EU countries, especially those which are members of the Council of Europe, or which, in any case, are on the European continent, to establish effective anti-money laundering systems;

Wednesday 23 October 2013

103. Points out the essential role of financial intelligence units (FIUs) in guaranteeing the effectiveness of the fight against money laundering and welcomes its close cooperation with Europol; calls for their powers to be increased and harmonised and for their technical integration into Europol to be continued;

104. Considers that, owing to the vital part played by international cooperation between financial intelligence units (FIUs) in combating money laundering and international terrorism, it is necessary for the new regulatory approach also to include updated rules on the role and organisation of the FIUs, as well as the arrangements governing international cooperation between them, including in cases of non-compliance with the Egmont standards in which international cooperation is refused or is inadequate;

105. Recommends that the use of anonymous means of payment to settle bets placed online be banned and, in general, that anonymity in online gambling be prevented by enabling host servers to be identified and developing information systems to ensure that any movements of money made through online and offline games are fully traceable;

106. Emphasises that cooperation and information exchange between Member States, their regulatory bodies, Europol and Eurojust should be reinforced to combat criminal activities in cross-border online gambling activities;

107. Calls on the Commission to propose an appropriate legislative framework to combat money laundering linked to gambling and betting, in particular sports betting and betting on animals used in blood sports, by providing for new offences such as betting-related match fixing and laying down appropriate penalties and monitoring arrangements involving sports federations, associations, online and offline operators and, where necessary, national authorities;

108. Calls for more cooperation at European level — coordinated by the Commission — to identify and prohibit online gambling operators engaged in match-fixing activities and other illegal activities.

109. Urges sports organisations to establish a code of conduct for all staff with a clear prohibition on manipulating matches for betting or other purposes, a ban on gambling on own matches and an obligation to report awareness of match-fixing with an adequate whistleblower protection mechanism;

110. Recommends that, within the framework of their respective competencies, a Europe-wide supervisory role in money laundering matters be conferred on the European Banking Authority, the European Securities and Markets Authority, the European Insurance and Occupational Pensions Authority, as well as the Single Supervisory Mechanism, in cooperation with Europol and the other competent European bodies, not least with a view to establishing a genuine European banking union that helps to combat corruption and money laundering effectively; insists that in the meantime supervisory capacities, expertise and determination should be reinforced at national level, while enhanced cooperation between national authorities should be encouraged and facilitated;

111. Stresses that public and private partnerships are key in ensuring a collaborative and effective response which minimises vulnerabilities in legitimate markets, and that key players in online services and the financial sector should be identified and prioritised for information sharing and coordination in order to combat vulnerabilities in emerging technologies;

112. Calls for minimum standards of good governance in tax-related matters to be encouraged, in particular through joint initiatives by Member States regarding their relations with territories constituting tax havens, not least in order to obtain access to proprietary information relating to any shell companies that might be based there; calls for the swift and full implementation and follow up of the Commission communication of 6 December 2012 on an action plan to strengthen the fight against tax fraud and tax evasion (COM(2012)0722), including the revision of the parent-subsidiary and the royalties and interest payments directives;

113. Calls on the competent authorities in the Member States to consider that even activities that apparently have a purely local impact, such as car theft, theft of agricultural machinery and industrial vehicles, burglaries, armed robberies, or theft of copper and other metals for industrial use and of cargo from trucks, can actually be traced back to transnational organised crime and be aimed at committing further more serious crimes;

**Wednesday 23 October 2013**

114. Regrets the differences in the legislation — in particular on penalties — of the Member States are regards euro counterfeiting and hopes that the negotiation concerning the ‘proposal for a directive on the protection of the euro and other currencies against counterfeiting by criminal law’, submitted by the Commission in February 2013, will be concluded shortly; calls on all parties concerned, both public and private, at EU and Member State level, to make a concerted effort to curb this phenomenon effectively;

115. Considers that the origin of wealth principle makes it easier for tax authorities to tax effectively and to avoid tax evasion; considers that a fair tax system is indispensable, especially in times of crisis, where the tax burden is shifted unfairly to small business and households, and that tax evasion is in part created by tax heavens inside the EU;

116. Underlines that stepping up the fight against tax fraud and evasion is a vital key to promoting sustainable growth in the EU; stresses that reduced levels of fraud and evasion would strengthen the growth potential in the economy by making public finances healthier and by making enterprises compete on an honest and level playing field;

117. Stresses in particular the importance of identifying the banknote-handling phases in order to allow traceability along the cash-handling chain and therefore calls on the European Central Bank and national central banks to put in place a traceability system for euro banknotes; calls on the eurozone countries to stop printing bank notes in denominations of more than EUR 100;

#### ***New technologies to fight organised crime***

118. Believes that all satellite earth observation systems could help to identify the routes of vessels secretly transporting, unloading, or trans-shipping illegal goods; calls, therefore, for the judicial and law enforcement authorities to intensify the use of new technologies, including satellite observations, as a means of helping to combat the activities of organised crime;

119. Welcomes the recent establishment in Europol of the European Cybercrime Centre (EC3) and calls for it to be strengthened, in particular with a view to combating cross-border organised crime offences and to improving cooperation between stakeholders in the public, private and research sectors and stepping up cooperation with non-EU countries, especially those posing a specific threat to the EU in terms of cybercrime; regrets that financial resources and staff to set up the Centre have been taken from other operational fields; calls upon the Commission to reflect the new tasks of Europol in its financial statement and assign adequate funding to it in order to combat child pornography, VAT fraud and trafficking in human beings, etc.;

120. Considers that the European Border Surveillance System (EUROSUR) will be a major instrument in combating cross-border organised crime as a result of improved cooperation and exchanges of information between the Member State authorities and the use of new technologies for monitoring external borders and pre-frontier areas; urges the Member States, the Commission and Frontex to ensure that EUROSUR becomes fully functional by the end of 2014;

121. Welcomes the recent extension and enhancement of ENISA's mandate and considers that it has a key role to play in ensuring a high level of IT systems and network security within the European Union thanks to its technical and scientific expertise and its contribution to preventing and combating cyber incidents; urges ENISA to step up its efforts to improve the response and support capacities of computer emergency response teams (CERT) and help establish European security standards for electronic appliances, networks and services;

122. Recommends that a culture of prevention and cybersecurity be made more widespread, taking an integrated and multidisciplinary approach with the aim of raising public awareness and promoting research and technical and specialist training, cooperation between the public and private sectors and the exchange of information both nationally and internationally; welcomes the inclusion of cyber-attacks in the Strategic Concept for the Defence and Security of the Members of NATO; welcomes the establishment in some Member States of national coordination bodies to combat the cyber threat and calls on all EU Member States to follow suit;

Wednesday 23 October 2013

***Final recommendations for a European action plan to combat organised crime, corruption and money laundering***

123. Calls on the Commission, through OLAF, to introduce an adequate percentage of own-initiative investigations by the anti-fraud EU investigative authorities, aimed at sectors, areas or cases where systemic and large-scale corruption affecting EU financial interests is suspected and there are reasons for initiating such investigations;

124. Calls, in order to combat financial fraud, for the swift reform of the Market Abuse Directive (MAD), which will, according to the IMF's 'European Union: Financial System Stability Assessment', be key to fostering the integrity of European financial markets;

125. Expresses concern over the fact that a whole range of so-called emerging crimes, such as illegal waste trafficking, illegal trafficking in works of art and protected species, and goods counterfeiting, are extremely profitable for criminal organisations;

126. Regrets the fact that the Commission has not published the first report on corruption in the EU as announced in its earlier statements, and hopes that this report will be adopted before the end of 2013.

127. Calls on the Commission and the Council to develop a European action plan against wildlife trafficking;

128. Urges the Member States to transpose, as soon as possible, Directive 2012/29/EU establishing minimum standards on the rights, support and protection of victims of crime; calls on the Commission to ensure that the transposition into national law is completed correctly; urges Member States and the Commission to complete the Roadmap on the rights of suspects and persons accused of offences, including a directive on pre-trial detention;

129. Stresses the need to promote a culture of legality and to increase citizens' knowledge of the mafia phenomenon; recognises in this regard the fundamental role played by cultural, recreational and sports associations in raising public awareness of the fight against organised crime and the promotion of lawfulness and justice;

130. Asks the Commission to publish a scoreboard that demonstrates the implementation by each Member State into their own national law books of EU legislation for fighting organised crime;

131. Urges that this resolution be implemented by means of a European action plan for the period 2014-2019 to eradicate organised crime, corruption and money laundering, which shall provide a roadmap and adequate resources and, with due respect for the principles of subsidiarity and proportionality, include as priorities — on an indicative and non-exclusive basis — the following positive actions already set out in the previous paragraphs and hereby confirmed:

- (i) decide on a definition of organised crime (to include, *inter alia*, the crime of involvement in a mafia-type organisation), corruption and money laundering (including self-laundering) to be based, *inter alia*, on a report on the implementation of the relevant European legislation;
- (ii) abolish banking secrecy;
- (iii) eliminate tax havens throughout the European Union and put an end to tax evasion and tax avoidance by adopting the 'origin of wealth' principle recommended by the OECD;
- (iv) guarantee full access to information on the actual owners of companies, foundations and trusts ('beneficial ownership'), also by adapting and interconnecting Member States' business registries accordingly;
- (v) introduce the principle of the legal liability of legal entities — in particular of holdings and parent companies for their subsidiaries — in cases of financial crime;
- (vi) eradicate trafficking in human beings and forced labour, especially as regards minors and women, through tougher sanctions, and make sure that the victims of trafficking are duly protected and supported;

**Wednesday 23 October 2013**

- (vii) make sports-rigging a criminal offence in order to strengthen the fight against illegal sports betting;
- (viii) call on Member States to make vote buying a criminal offence, even where its benefits are intangible and accrue to third parties;
- (ix) introduce Europe-wide corporate taxation that is as uniform, equal and homogeneous as possible;
- (x) strengthen the agreements on judicial and police cooperation between the Member States and between the EU and third countries;
- (xi) promote instruments for the seizure and confiscation of criminal assets, including additional confiscation methods such as civil law asset forfeiture, and the reuse of confiscated assets for social purposes, in compliance with the subsidiarity principle;
- (xii) strengthen the fight against environmental crimes and drug trafficking;
- (xiii) ensure swift mutual recognition, whilst fully respecting the principle of proportionality, of all judiciary measures, with particular reference to criminal judgments, confiscation orders and European arrest warrants;
- (xiv) provide for economic players convicted by final judgement of organised crime, corruption or money laundering to be excluded from public procurement procedures anywhere in the European Union;
- (xv) establish and launch the European Public Prosecutor's Office, equipping it with the necessary human and financial resources; at the same time support European Agencies, such as Europol and Eurojust, as well as JITs and AROs;
- (xvi) fully comply at both Member State and EU level with the obligations laid down in the international instruments dealing with organised crime, corruption and money laundering;
- (xvii) recognise the relevant role of investigative journalism in identifying serious crimes;
- (xviii) introduce standard pan-European rules on the protection of witnesses, informers and those who cooperate with the courts;
- (xix) bar persons who have been sentenced by final judgement for organised crime, corruption or money laundering or other serious crimes from standing for or to hold public office, or have them removed from office;
- (xx) define and introduce, also on the basis of a uniform reporting system, appropriate penalties for standard types of cybercrime;
- (xxi) prevent corruption in the public sector through better public access to documents, specific rules on conflicts of interests and transparency registers;

132. Insists that Parliament continue to pay special attention to the issues dealt with by its Special Committee on Organised Crime, Corruption and Money Laundering and, to this end, instructs its Committee on Civil Liberties, Justice and Home Affairs, where necessary in cooperation with any other relevant parliamentary committee, to make sure that the recommendations included in this resolution have been duly implemented at political and institutional level and, where appropriate, to hear experts, set up working groups and adopt follow-up reports;

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133. Instructs its President to forward this resolution to the Council, the Commission, the governments and parliaments of the Member States, Eurojust, Europol, Frontex CEPOL, OLAF, COSI, the European Investment Bank, the Council of Europe, the OECD, Interpol, UNODC, the World Bank and the FATF and the European Supervisory Authorities (EBA, ESMA, EIOPA).

Wednesday 23 October 2013

P7\_TA(2013)0445

**e-justice Action Plan 2014-2018**

**European Parliament resolution of 23 October 2013 on the e-Justice Action Plan 2014-2018 (2013/2852(RSP))**  
(2016/C 208/10)

*The European Parliament,*

- having regard to the European e-Justice Action Plan 2009-2013,
  - having regard to the question to the Council on the e-Justice Action Plan 2014-2018 (O-000111/2013 — B7-0521/2013),
  - having regard to Rules 115(5) and 110(2) of its Rules of Procedure,
- A. whereas the first multiannual European e-Justice Action Plan covered the 2009-2013 period and sought to make justice and the legal system more accessible to citizens, and to improve the mutual understanding of practitioners and administrations by providing electronic tools for information and cooperation;
- B. whereas the e-Justice Portal was launched in 2010;
- C. whereas the time has now come to decide on the e-Justice Action Plan for 2014-2018;
- D. whereas the e-Justice Action Plan should be developed on an open-access basis and all Member States should be encouraged to participate;
- E. whereas awareness of EU civil justice instruments and cross-border procedures is relatively low, and whereas 73 % of citizens believe that additional measures are needed to help them access civil justice in other Member States <sup>(1)</sup>;
1. Considers that e-Justice is a means of enabling greater access to legal and judicial information, and to judicial and administrative proceedings, for both citizens and practitioners;
  2. Considers that e-Justice has an important role to play in enhancing mutual trust and understanding and thus in underpinning the mutual recognition of judicial and administrative decisions, which is a major principle of the EU's legal system;
  3. Points out that e-Justice systems, by their very nature, tend to decrease the costs of judicial and administrative proceedings, in particular through automation of the exchange of information, the service of documents and the translation of certain procedural acts; considers that this is in the interest of all stakeholders in the judicial system; believes that, in view of cost-efficiency considerations, projects should remain voluntary;
  4. Welcomes the development of e-Justice tools to facilitate the use of certain EU instruments, such as the European Payment Order and the Small Claims Procedure, as well as information systems in the area of Justice and Home Affairs, notably the European Criminal Records Information System (ECRIS) and the Schengen Information System (SIS) II;
  5. Notes the importance of e-Justice for the provision of multilingual standard forms and thus for the reduction of cross-border red tape;
  6. Calls for the use of electronic applications, the electronic provision of documents, the use of video-conferencing and the interconnection of judicial and administrative registers to be increased in order to further reduce the cost of judicial and quasi-judicial proceedings;

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<sup>(1)</sup> European Commission, *Special Eurobarometer 351* (Civil Justice), October 2010, Question 3.

**Wednesday 23 October 2013**

7. Calls on the Member States and the Commission to continue working on electronic cooperation in the justice area, in particular by extending the applications available on the e-Justice Portal; considers that the necessary attention should be given to developing e-learning tools for the judiciary;
  8. Points out that the EU's Justice Programme 2014-2020 should allow for the funding of successful European and national e-Justice projects, which should have real European added value for citizens; believes that legislative work, e-Justice projects and financial programme planning should be streamlined;
  9. Emphasises the importance of the e-Justice portal for the aim of building a true European judicial culture by hosting online tools for judicial training and serving as a knowledge management and interconnection instrument;
  10. Instructs its President to forward this resolution to the Council and the Commission.
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Wednesday 23 October 2013

P7\_TA(2013)0446

## European Neighbourhood Policy, working towards a stronger partnership: EP's position on the 2012 progress reports

**European Parliament resolution of 23 October 2013 on the European Neighbourhood Policy: towards a strengthening of the partnership. Position of the European Parliament on the 2012 reports (2013/2621(RSP))**

(2016/C 208/11)

*The European Parliament,*

- having regard to the Commission Communications of 11 March 2003 on 'Wider Europe — Neighbourhood: A New Framework for Relations with our Eastern and Southern Neighbours' (COM(2003)0104), of 12 May 2004 entitled 'European Neighbourhood Policy — Strategy Paper' (COM(2004)0373), of 4 December 2006 on 'Strengthening the European Neighbourhood Policy' (COM(2006)0726), of 5 December 2007 on 'A Strong European Neighbourhood Policy' (COM(2007)0774), of 3 December 2008 on 'Eastern Partnership' (COM(2008)0823), of 20 May 2008 entitled 'Barcelona Process: Union for the Mediterranean' (COM(2008)0319), of 12 May 2010 on 'Taking Stock of the European Neighbourhood Policy' (COM(2010)0207) and of 24 May 2011 on 'A dialogue for migration, mobility and security with the southern Mediterranean countries' (COM(2011)0292),
- having regard to the Joint Communications of the European Commission and of the High Representative of the European Union for Foreign Affairs and Security Policy of 20 March 2013 on 'European Neighbourhood Policy: Working towards a Stronger Partnership' (JOIN(2013)0004), of 25 May 2011 on 'A new response to a changing Neighbourhood' (COM(2011)0303) and of 8 March 2011 on 'A partnership for democracy and shared prosperity with the Southern Mediterranean' (COM(2011)0200),
- having regard to the conclusions of the Foreign Affairs Council of the European Union of 26 July 2010, 20 June 2011 and 22 July 2013 on the European Neighbourhood Policy (ENP) and to the conclusions of the Foreign Affairs/Trade Council of the European Union of 26 September 2011 and of the European Council of 7 February 2013,
- having regard to the Joint Communications of the European Commission and of the High Representative of the European Union for Foreign Affairs and Security Policy of 15 May 2012, entitled 'Eastern Partnership: A Roadmap to the autumn 2013 Summit' (JOIN(2012)0013) and 'Delivering a new European Neighbourhood Policy' (JOIN(2012)0014) and their accompanying joint staff working documents of 20 March 2013 ('Regional reports', SWD(2013)0085 and 0086),
- having regard to Regulation (EC) No 1638/2006 of the European Parliament and of the Council of 24 October 2006 laying down general provisions establishing a European Neighbourhood and Partnership Instrument <sup>(1)</sup>,
- having regard to the Barcelona Declaration adopted at the Euro-Mediterranean Conference of Ministers of Foreign Affairs, held in Barcelona on 27 and 28 November 1995, establishing a Euro-Mediterranean Partnership,
- having regard to the Declaration of the Paris Summit for the Mediterranean, held on 13 July 2008,
- having regard to its resolution of 20 May 2010 on the Union for the Mediterranean <sup>(2)</sup>,
- having regard to the Deauville Partnership launched by the G8 at the leaders' meeting in Deauville in May 2011, to which the EU is a party,

<sup>(1)</sup> OJ L 310, 9.11.2006, p. 1.

<sup>(2)</sup> OJ C 161 E, 31.5.2011, p. 126.

**Wednesday 23 October 2013**

- having regard to the Joint Declarations of the Prague Eastern Partnership Summit of 7 May 2009 and of the Warsaw Eastern Partnership summit of 29—30 September 2011,
- having regard to the Joint Statement of the Eastern Partnership Foreign Ministers meeting in Brussels, of 23 July 2012,
- having regard to Council Decision 2011/424/CFSP of 18 July 2011 appointing a European Union Special Representative for the Southern Mediterranean region <sup>(1)</sup> and Council Decision 2011/518/CFSP of 25 August 2011 appointing the European Union Special Representative for the South Caucasus and the crisis in Georgia <sup>(2)</sup>,
- having regard to its resolutions of 7 April 2011 on the review of the European Neighbourhood Policy — Eastern Dimension <sup>(3)</sup> and on the review of the European Neighbourhood Policy — Southern Dimension <sup>(4)</sup>,
- having regard to its resolution of 14 December 2011 on the review of the European Neighbourhood Policy <sup>(5)</sup>,
- having regard to its resolution of 23 May 2013 on asset recovery by the Arab Spring countries in transition <sup>(6)</sup>,
- having regard to its recommendation of 12 September 2013 on EU policy towards Belarus <sup>(7)</sup>,
- having regard to its Resolution of 13 June 2013 on freedom of the press and media in the world <sup>(8)</sup>,
- having regard to its Resolution of 11 December 2012 on a digital freedom strategy in EU foreign policy <sup>(9)</sup>,
- having regard to the Constituent Act of the Euronest Parliamentary Assembly of 3 May 2011 <sup>(10)</sup>,
- having regard to the conclusions of the Summit of Euro-Mediterranean Parliaments (Marseille, 6—7 April 2013) and to the conclusions of the Parliamentary Assembly of the Union for the Mediterranean and the Euronest Parliamentary Assembly,
- having regard to its resolutions containing Parliament's recommendations to the Council, the Commission and the European External Action Service on the negotiations of the EU-Armenia Association Agreement <sup>(11)</sup>, the EU-Azerbaijan Association Agreement <sup>(12)</sup>, the EU-Moldova Association Agreement <sup>(13)</sup>, the EU-Georgia Association Agreement <sup>(14)</sup> and the EU-Ukraine Association Agreement <sup>(15)</sup>,
- having regard to Decisions 2006/356/EC, 2005/690/EC, 2004/635/EC, 2002/357/EC, 2000/384/EC, 2000/204/EC and 98/238/EC concerning the conclusion of a Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and, respectively, the Republic of Lebanon, the People's Democratic Republic of Algeria, the Arab Republic of Egypt, the Hashemite Kingdom of Jordan, the State of Israel, the Kingdom of Morocco and the Republic of Tunisia,

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<sup>(1)</sup> OJ L 188, 19.7.2011, p. 24.

<sup>(2)</sup> OJ L 221, 27.8.2011, p. 5.

<sup>(3)</sup> OJ C 296 E, 2.10.2012, p. 105.

<sup>(4)</sup> OJ C 296 E, 2.10.2012, p. 114.

<sup>(5)</sup> OJ C 168 E, 14.6.2013, p. 26.

<sup>(6)</sup> Texts adopted, P7\_TA(2013)0224.

<sup>(7)</sup> Texts adopted, P7\_TA(2013)0382.

<sup>(8)</sup> Texts adopted, P7\_TA(2013)0274.

<sup>(9)</sup> Texts adopted, P7\_TA(2012)0470.

<sup>(10)</sup> OJ C 198, 6.7.2011, p. 4.

<sup>(11)</sup> OJ C 258 E, 7.9.2013, p. 44.

<sup>(12)</sup> OJ C 258 E, 7.9.2013, p. 36.

<sup>(13)</sup> OJ C 51 E, 22.2.2013, p. 108..

<sup>(14)</sup> OJ C 153 E, 31.5.2013, p. 137.

<sup>(15)</sup> OJ C 165 E, 11.6.2013, p. 48.

Wednesday 23 October 2013

- having regard to the Joint Statement on the Eastern Partnership of the Foreign Ministers of the Visegrad Group, Ireland and Lithuania, issued in Krakow on 17 May 2013,
  - having regard to the EU's long-standing relations with the countries of Europe's Southern Neighbourhood and the historical, economic, political and social links that many EU Member States have with the countries of this region, and of the EU's commitment to maintaining the closest possible ties and providing the necessary support, in coherence with the broader ENP,
  - having regard to the fact that the decisions at the Vilnius Eastern Partnership Summit may be crucial for the future of the Eastern Partnership, which is why it is important to keep a long-term perspective in mind, extending beyond the Summit and ensuring an ambitious follow-up policy for the region,
  - having regard to Rule 110(2) of its Rules of Procedure,
- A. whereas Association Agreements (AAs) are not a goal in themselves but an instrument for promoting profound and sustainable reform, systemic transformation and closer alignment with the Union and its founding values and standards; whereas their due and timely implementation is therefore an overriding criterion in assessing the situation in the relevant countries;
- B. whereas the European Neighbourhood Policy should strengthen the partnership between the EU and the countries and societies of the neighbourhood, in order to build and consolidate healthy democracies, pursue sustainable economic growth and manage cross-border links;
- C. whereas the privileged relationship with Europe's neighbours within the ENP is built on a mutual commitment to common values (democracy and human rights, the rule of law, good governance, market economy principles and sustainable development); whereas following the revision of the ENP, there should be a strong focus on the promotion of deep and sustainable democracy, accompanied by inclusive economic development;
- D. whereas a functioning democracy, respect for human rights and the rule of law are fundamental pillars of the EU's partnership with its neighbours; whereas building deep and sustainable democracy requires a strong and lasting commitment on the part of governments in favour of free and fair elections, freedom of association, expression and assembly and a free press and media, the rule of law administered by an independent judiciary and the right to a fair trial, efforts to combat corruption, reform of the security and law enforcement sector (including the police), and the establishment of democratic control over armed and security forces;
- E. whereas the Union's external policy has to be consistent, especially with its internal policies, by avoiding double standards; whereas the economic and financial crisis cannot justify any reduction in the Union's engagement with its Neighbourhood;
- F. whereas the mass movements in the Arab world constitute a milestone in the modern history of the countries of Europe's Southern Neighbourhood and of their relations with the EU, and the ongoing implementation of a differentiated approach based on the principle of assistance in line with performance and progress ('more for more' and 'less for less') in the partner countries should be regularly assessed in progress reports according to specific and estimable criteria and on the basis of their needs; whereas the inconsistent or non-existent application of the 'more-for-more' principle may be self-defeating and may undermine the whole process, as well as the Union's leverage and credibility;
- G. whereas the peaceful popular demonstrations seen in the Arab world in 2011 were a call for dignity, expressed legitimate democratic aspirations and made strong demands for institutional, political and social reforms aimed at achieving genuine democracy, fighting corruption and nepotism, ensuring respect for the rule of law, human rights and fundamental freedoms, reducing social inequalities and creating better economic and social conditions; whereas, two years later, the citizens of several Mediterranean countries still encounter violations of their basic human rights and fundamental freedoms, economic hardship and unrest;
- H. whereas the assessment of progress made by partner countries in respecting human rights, fundamental freedoms and the democratic process and implementing the rule of law, as well as sustainable economic and public sector reforms, must be based on common general principles and country-tailored specific requirements, using effective, clear, transparent, objective and measurable indicators and benchmarks and taking into account overall progress and the level of commitment to reform;

Wednesday 23 October 2013

- I. whereas respect for and promotion of democracy and human rights (particularly children's, women's and minority rights), justice and the rule of law, fundamental freedoms (including freedom of speech, conscience, religion or belief and association), free and independent media (including unrestricted access to information, communication and the internet), the strengthening of civil society, security (including peaceful conflict resolution and good neighbourly relations), democratic stability, prosperity, the fair distribution of income, wealth and opportunities, social cohesion, the fight against corruption and the promotion of good governance and sustainable development are all founding principles and aims of the EU which must always constitute common values at the core of the ENP;
- J. whereas respect for the fundamentals of democracy is a red line which must not be crossed and is a basic condition for closer association by the Eastern Partnership countries with the EU; whereas depriving citizens of their legitimate right to a choice of government, by applying selective justice, pre-trial detention, imprisoning political opponents and failing to conduct free and fair elections, jeopardises those fundamental principles;
- K. whereas the goal of the ENP is to establish an area of prosperity and good neighbourliness, founded on the values of the Union and characterised by close and peaceful regional relations, promoting deep and sustainable democracy, the rule of law, political and economic reforms, a sustainable social market economy in the EU's neighbouring countries and creating a circle of friends of the Union and friends' relations with each other; whereas, therefore, the ultimate guiding principle for assessing progress should be the contribution made to each side's security, solidarity and prosperity; condemns, in this regard, the negative effects of closed borders policies within the EU Neighbourhood area, and in particular among Eastern Partnership and EU candidate countries;
- L. whereas the multilateral dimension of the ENP offers a unique opportunity to bring together all countries and stakeholders in the region to achieve tangible progress and understanding by working on concrete projects on a technical level; whereas the Euronest and Euromed parliamentary assemblies offer a further opportunity on a political level to create and deepen mutual understanding by helping to develop the fledgling democracies in these regions; whereas the Conference of the Regional and Local Authorities for the Eastern Partnership (CORLEAP) and the Euro-Mediterranean Regional and Local Assembly (ARLEM) both play an important role in strengthening democracy through economic, social and territorial cooperation;
- M. whereas press and media freedom, as well as digital freedoms, are under constant pressure in many of the ENP countries; whereas the right to freedom of expression is a universal human right which lies at the basis of democracy and is essential for the attainment of other rights; whereas universal rights and freedoms require protection both online and offline;
- N. whereas the EU revised its European Neighbourhood Policy in 2011 in order to provide more support to partner countries engaged in building deep and sustainable democracy and to support inclusive economic development; whereas the EU external financial instruments, and especially European Neighbourhood Instrument, should support the objectives of the Neighbourhood Policy; whereas it is necessary to establish strong and clear links between the policy framework and the support provided under these instruments;
- O. whereas the unsatisfactory progress made by several Eastern Partnership (EaP) countries may result from the slow or non-existent dynamics of political and social change in the partner countries, from the Union's fatigue with the ENP and a failure to show European partners a sufficiently motivating European perspective, from the economic and financial crisis, and also from pressure by Russia and its competing offer of integration into the Eurasian Union;
- P. whereas the Vilnius summit is a milestone in the evolution of the Eastern Partnership and a major test of the ability of the EU's neighbourhood policy to deliver tangible results;
- Q. whereas, while the Association Agreements (AAs) are the result of the EaP's bilateral track, the multilateral track remains a crucial dimension in developing good regional cooperation based on good-neighbourly relations; whereas, in this respect, it is deplorable that the EaP harbours a number of unsettled territorial disputes, which should be resolved; whereas Parliament fully subscribes to the principles of sovereignty, territorial integrity and the right to self-determination of nations;

Wednesday 23 October 2013

- R. whereas, in this regard, the EU should play a more active role in the peaceful resolution of conflicts, including frozen conflicts, which currently constitute an insurmountable obstacle to the full development of good-neighbourly relations and regional cooperation in Eastern and Southern partnership countries;
- S. whereas the Parliamentary Assembly of the Eastern Partnership (Euronest) remains a key player in developing the democratic and parliamentary dimension of the EaP, allowing for the sharing of best practices in parliamentary work methods and constituting a crucial platform for bringing Eastern partners closer to the EU and reaching out to citizens;
1. Welcomes the publication of the 2012 progress reports for the ENP South and East countries, but regrets that, in most cases, the reports, as well as the events that followed, present a mixed picture of progress, stagnation and regression and describe the national situation without evaluating the programmes carried out by the Union or making concrete recommendations regarding the allocation of funds under the EU external instruments or development cooperation assistance and its influence on policy-making in the partner countries; takes the view that those reports should also assess trends by containing data for previous years;
  2. Stresses that according to Articles 8 and 49 of the Treaty on European Union (TEU), all European countries, including those covered by the EaP, have the long-term possibility of applying for membership of the European Union;
  3. Strongly believes that Parliament should be fully involved in implementing the new ENP and in adjusting EU financial support, notably through delegated acts, and should be kept regularly informed about progress in the implementation of reforms in the partner countries and resulting adjustments; deplores the fact that it is not always consulted when action plans are drawn up or informed about the tenor of discussions; considers that its resolutions constitute an integral part of the ENP policy framework and calls for the status of observer to be accorded to MEPs to take part in meetings of policy and human rights subcommittees;
  4. Regrets that progress made by partner countries has not always matched the goals set in common with the EU; calls for a concrete evaluation of the effectiveness of the revised ENP; calls for greater efforts to use all instruments and policies at the disposal of the Union in a coherent way under the umbrella of the ENP; calls for the consistent implementation of the incentive-based and differentiated approaches and of the principle of 'more for more' as the cornerstone of the revised ENP; calls, if necessary, for 'less for less' for those ENP countries making insufficient efforts to build a deep and sustainable democracy and to undertake the agreed reforms; underlines that the Union's baseline support shall also reflect partners' needs in terms of development;
  5. Emphasises the important role played by civil society in transition and reform processes and political dialogue in the Neighbourhood countries; calls on the EU to strengthen cooperation with civil society in the Neighbourhood countries and provide it with support through a range of different funding instruments;
  6. Considers that support for democratic transition processes should focus on developing the institutional capacity of democratic institutions, on supporting all democratic political parties and civil society and women's and minority rights, and on enshrining in the societies of partner countries the rule of law, human rights and fundamental freedoms, in particular the freedom of association, expression, assembly and free press and media; calls on the Union and the Member States to enhance partnerships between various organisations and sectors in society in order to hand over ownership of the European neighbourhood process to them; reaffirms that this should be conducted, *inter alia*, by creating horizontal links between different societal actors on the basis of twinning partnerships between civil society organisations (NGOs, trade unions, business organisations, media, youth organisations, etc.) and twinning projects with national authorities and administrations (especially in the education sector);
  7. Considers that a proper gender analysis should be conducted throughout the progress reports; underlines the need for a greater focus on strengthening labour and trade union rights, mainstreaming gender equality and collaboration and dialogue with NGOs, trade unions and other civil society organisations in the revised ENP;
  8. Insists on respect for universal human rights and fundamental freedoms as the founding principle of EU external policy; considers that support for civil society is the keystone of the revised ENP and therefore recommends that assistance to civil society, including the social partners, be commensurate with the challenge faced and that close coordination with the European Endowment for Democracy be established for that purpose;

**Wednesday 23 October 2013**

9. Stresses that the main NGOs have set up common platforms for both the Union for the Mediterranean and the Eastern Partnership; takes the view that due and timely consultations should be held with these civil society fora when drawing up, implementing and monitoring ENP Action Plans;

10. Believes that the ENP's multilateral structures should be consolidated and developed along more strategic lines; contends that, given the centrality of 'effective multilateralism' in the Union's foreign policy, the Commission and the EEAS should consider the possibility of the ENP's multilateral track serving as a framework for organising political relations in the wider Europe;

11. Calls on the Union to enhance the visibility of ENP-funded or supported projects in the partner countries and to engage more actively with society in improving the image and acceptance of the Union among citizens in the ENP countries, namely by using media campaigns and demonstrating the added value of cooperation with the EU;

12. Regrets the substantial cuts made to Heading 4 in the 2014-2030 MFF compared to the original proposal from the Commission; underlines that ambitious funding of the Eastern Partnership is crucial for further progress in reforms, the sharing of best practices and achieving and/or maintaining fully-fledged functioning democracies in the EU's Eastern neighbourhood, these being of vital interest to the EU; believes also that the current balance between the Eastern and Southern parts of the ENP should be maintained, with full respect for the principles of differentiation and the tailor-made approach applied so far; insists that relevant budgetary authorities should be updated regularly on the indicators and guidelines that shape the decision-making process in relation to budget support, and that Parliament should be involved in the process of attributing or withdrawing allocations resulting from the application of the 'more-for-more' and 'less-for-less' principles;

13. Stresses that freedom of expression, pluralism and media independence are cornerstones of democracy; underlines therefore the importance of EU support for independent, sustainable and accountable public media services providing quality, pluralistic and diverse content, bearing in mind that free and independent public media always play a crucial role in deepening democracy, in maximising the involvement of civil society in public affairs and in empowering citizens on the path to democracy;

14. Recognises the crucial importance of free and fair elections for the transition to democracy and highlights the role of independent media, in particular public service media, in the transparent, credible and democratic conduct of the election process; calls on the Commission and the EEAS to continue and, wherever possible, to reinforce their support for the democratic conduct of upcoming elections in the partner countries, including the strengthening of media freedom and pluralism;

### ***Eastern Partnership***

15. Recommends that the Union should: (a) strengthen the application of the more-for-more principle and stimulate it by positive competition and cooperation among partner countries, expressing necessary support to EaP states facing pressure from third countries when implementing the *acquis communautaire*; (b) apply a two-track approach, by making demands of EaP governments whilst being open, generous and engaging towards the citizens of partner countries; (c) encourage those citizens to advance the values the EU is based upon — namely democracy, the rule of law and respect for human rights and fundamental freedoms — through their commitment to promote them, thus making them the main source of normative power transformation; (d) design a long-march strategy to promote European values encompassing internal change and the aspirations of these societies for freedom and prosperity; (e) decentralise the EaP by engaging with, and offering its ownership to, public actors on both sides through horizontal partnerships and twinning, accompanied by increased mobility, people-to-people contacts, visa facilitation and the prospect of a visa-free system, in which case the neighbours-first approach should apply; and (f) initial or sign the Association Agreements and aim for their prompt entry into force, initially on a provisional basis and then in full, before the end of the current term of the European Parliament and the European Commission, provided that the necessary conditions and requirements have been met; (g) refrain from using force or threats to use force in resolving disputes in the region, underlining that the only possible way to settle conflicts in the region is through negotiations within the internationally accepted formats, based on the principles of international law;

16. Recalls its position that the occupation by one country of the Eastern Partnership of the territory of another violates the fundamental principles and objectives of the Eastern Partnership and that the resolution of the Nagorno-Karabakh conflict should comply with UN Security Council resolutions 822, 853, 874 and 884 of 1993 and the Organisation for Security and Cooperation in Europe (OSCE) Minsk Group Basic Principles, enshrined in the L'Aquila joint statement of 10 July 2009;

Wednesday 23 October 2013

17. Deplores the fact that as the Vilnius Eastern Partnership Summit approaches, different types of pressure are escalating on Eastern Partnership countries; regards this pressure as unacceptable and calls on Russia to abstain from proceedings which are in clear violation of the Helsinki principles; strongly underlines that the free choices of the Eastern Partnership countries should not make them bear consequences such as trade measures, visa policy, the restricted mobility of workers, interference in frozen conflicts, and others; calls on the Commission and the European External Action Service (EEAS) to deal with the deplorable developments beyond a purely trade dimension, thereby acting and defending the Union's partners by sending a strong message of support for all Eastern Partnership countries in their European aspirations and choices; underlines however, that Association Agreements (AAs) and Deep and Comprehensive Free Trade Agreements (DCFTAs) are a blueprint for reforms that are beneficial for all;

18. Remains committed to further developing the Euronest Parliamentary Assembly as an important forum for multilateral interparliamentary cooperation with the Eastern Partnership countries; deplores the proposed cuts in the ENP budget lines for the 2014-2020 multiannual financial framework, as these budget lines aim at a closer support for actions and projects related to democracy-building, the rule of law and the promotion of human rights;

19. Stresses that lifting visa requirements would be a significant gesture towards the peoples of Eastern Partnership countries and would genuinely help them to move closer to EU Member States;

20. Considers the publication of the Eastern Partnership Roadmap 2012-2013 to be a first step towards developing better monitoring tools; calls on the Commission and the EEAS to further develop appropriate follow-up mechanisms capable of assessing the performance and achievements of the ENP countries and to set clear and measurable objectives;

21. Recommends that the Eastern Partnership countries: (a) rebalance and redouble their efforts towards the fulfilment of political, legal and economic criteria; (b) enshrine in their societies fundamental values of democracy, the rule of law, human rights and gender equality, and the fight against corruption; (c) further boost societal change, reform processes and the systemic upgrading of public standards and administration, considering European integration as a long-term strategic choice and not merely an economic and administrative endeavour; (d) close the gap between rhetoric and practical action; (e) pay greater attention to the multilateral structure of the Eastern Partnership and to learning through best practices; (f) apply to regional conflicts the spirit and lessons derived from the historical experience of European integration and enhance regional, political and economic cooperation among themselves, since bilateral issues must be resolved peacefully and good neighbourly relations and regional cooperation are fundamental elements of the Eastern Partnership; (g) involve citizens and engage public actors in horizontal partnerships and in twinning with counterparts from the Union, as well as engaging with civil societies and the younger generation as a factor for change; (h) refrain from using force or threats to use force in resolving disputes in the region, underlining that the only possible way to settle conflicts in the region is through negotiations within the internationally accepted formats, based on the principles of international law;

22. Is concerned by Russian actions designed to deter partner countries from political and economic association with the EU; reaffirms the sovereign right of each state to choose political and trade alliances; believes, furthermore, that progressive integration of partner countries with the EU is fully consistent with their pursuit of cordial relations with Russia; rejects the perception of a zero-sum game as a paradigm for the EU's and Russia's relations with partner countries;

23. Reaffirms the need to strive for the regional stability and security that are necessary to achieve the goals of the Eastern Partnership, also in the context of further integration with the EU; urges further efforts to progress towards the resolution of the territorial conflicts in Georgia, Azerbaijan, Armenia and Moldova;

24. Recalls that a commitment to the AAs and DCFTAs precludes any other simultaneous form of participation in a customs union;

25. Calls on the Member States and Eastern European partners to review their arms export policies in the region with a view to reaching agreements on the disarmament and demilitarisation of conflict areas; calls on Russia to respect the agreements in a constructive way, fully respecting the sovereignty of the countries of the region and refraining from any actions which would endanger regional stability;

26. Emphasises that the EU and Eastern European partners face common political challenges with regard to ensuring the reliable and safe supply of energy; recalls that energy security cooperation is clearly identified as a priority under the Eastern

**Wednesday 23 October 2013**

Partnership and the ENP for the period 2014-2020; expects the third Eastern Partnership Summit, to be held in Vilnius, to provide an impetus for enhanced cooperation in the energy field and to increase energy security on both sides;

27. Recalls that the Energy Community Treaty sets the basis for establishing a fully integrated regional energy market favouring growth, investment and a stable regulatory framework; recommends to this end extending the Energy Community Treaty beyond 2016, whilst adapting its decision-making to future challenges, including by setting up legal control mechanisms to deal with deficient *acquis* implementation as well as solidarity mechanisms; welcomes the application to join the Energy Community by Georgia, which would become the third Eastern Partnership country, after Ukraine and Moldova, to join; calls for further expansion of the Energy Community via the ENP in line with the objectives of the Energy Community on the basis of mutual interest; emphasises that regulatory integration should be in line with common investments in interconnection capacity and infrastructure as well as renewable energy, energy efficiency and new technologies; emphasises the key importance of the further diversification of supply and transit routes;

28. Calls for the insertion of an energy security clause in every agreement with the Eastern Partnership countries to guarantee full respect for EU internal energy market laws, as well as the inclusion of an Early Warning Mechanism in such agreements to guarantee an early evaluation of potential risks and problems relating to transit and supply of energy from third countries, as well as establishing a common framework for mutual assistance, solidarity and dispute settlement;

### **Armenia**

29. Recognises the progress made in democratic standards and in the fulfilment of Association Agreement requirements, but acknowledges that persistent deficiencies in the area of democracy still remain to be addressed; recognises that further progress should be made in the areas of governance reforms, including law enforcement, judicial sectors, and the fight against corruption; regrets the latest move by the President of Armenia in committing to the customs union; reminds the Armenian authorities that such a policy is not compatible with the Association Agreement; deplores, in this regard, the fact that this choice was made without fully-fledged parliamentary scrutiny or an open and transparent debate in Armenian society; hopes, in this regard, that Armenia will continue EU-related reforms, the implementation of which could lead to the country's economic prosperity and could help solve socio-economic and political problems which still persist within the country; calls for a pursuit of cooperation with the EU, to which the EU is open; condemns, furthermore, the attacks on civic activists demonstrating in favour of European integration, and calls for the perpetrators to be brought to justice;

30. Welcomes the implementation of sound macroeconomic policies and structural reforms in Armenia and further progress towards meeting the objectives of the Action Plan;

### **Azerbaijan**

31. Regrets that an unclear vision and hesitation persist on the issue of Azerbaijan's pursuit of the Association Agreements; stresses the economic potential of EU-Azerbaijan relations, but is concerned by deficiencies in the fields of democracy, the rule of law and human rights in Azerbaijan; insists therefore that Azerbaijan show its commitment by stepping up its relevant standards, including freedom of speech and association and allowing the democratic opposition to enjoy their rights; insists that the release of political prisoners and an end to the harassment of political activists, human rights defenders and journalists are the necessary preconditions for any agreement on a strategic modernisation partnership with Azerbaijan;

32. Regrets the fact that, according to the conclusions of the ODIHR long-term mission, the latest presidential election, held on 9 October 2013, once again failed to meet OSCE standards, with restrictions being placed on freedom of assembly and expression; calls, in view of this, on the Azerbaijani authorities to address and swiftly implement all the recommendations included in present and past ODIHR/OSCE reports; and calls for the immediate and unconditional release of the 14 Azerbaijani opposition politicians, journalists and human rights activists imprisoned during the past months, including Tofiq Yaqublu and Ilgar Mammadov <sup>(1)</sup>;

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<sup>(1)</sup> European Parliament resolution of 13 June 2013 on Azerbaijan: the case of Ilgar Mammadov (Texts adopted, P7\_TA(2013)0285).

Wednesday 23 October 2013

**Belarus**

33. Deplores the stagnant, unacceptable situation with regard to human rights, democracy and political prisoners, and the lack of progress in respecting the values and standards promoted by the Union; insists that critical engagement and strict conditionality are needed on the part of the Union, together with a more generous and open attitude towards civil society and NGOs, which should be supported to monitor and deliver reforms; urges the Belarusian authorities to participate in the Dialogue on Modernisation and start negotiations with the EU on visa facilitation and readmission agreements in order to promote people-to-people contacts;

34. Calls on the Belarusian authorities to take advantage of Lithuania's presidency and the Eastern Partnership Summit in Vilnius as a further opportunity to improve relations with the EU, as soon as all political prisoners have been released, in order to restart the political dialogue on, inter alia, democratic reforms, free and fair elections, respect for the rule of law, human rights and fundamental freedoms, and engagement with the opposition and civil society, provided that the Belarusian authorities demonstrate respect for these fundamental values;

35. Reiterates the EU's readiness to improve relations with the Belarusian Government as soon as its authorities commit to pursue a commonly defined agenda, including respect for democratic principles, human rights and fundamental freedoms through, inter alia, the unconditional release and rehabilitation of all political prisoners; stresses, however, that any engagement is subject to strict conditionality;

36. Stresses the particular need to strengthen even more financial support for independent Belarusian media;

**Georgia**

37. Recognises the progress achieved in the modernisation of the country and in meeting the requirements of the Association Agreement in recent years, as well as the authorities' effort to fight corruption; welcomes the exemplary peaceful transfer of power following the democratic parliamentary elections; notes with concern, however, the deficiencies that still persist in the application of democratic standards; highlights in this regard the need for further improvements and reforms aimed at achieving an independent and impartial judiciary and an effective criminal justice system, as well as a non-discriminatory electoral system and respect for minority rights; notes the ongoing judicial inquiries affecting leading opposition figures, including Vano Merabishvili, and calls for the full respect of European standards and norms; supports the efforts of the Georgian Government to lessen tensions with Russia while preserving the country's pro-European orientation; reiterates the EU's firm support for Georgia's territorial integrity;

38. Encourages the initialling of the Association Agreement, including DCFTA, at the Vilnius summit and the speedy conclusion of the Visa Liberalisation Action Plan; believes that the signing of the Association Agreement should be conditional on tangible progress by Georgia in the area of the rule of law and democracy and meeting European standards in the upcoming presidential elections; recognises the important impact the implementation of the Association Agreement, free trade and the introduction of visa-free travel will have on the reform process in Georgia;

39. Calls on the Commission to apply this rule of conditionality by setting a range of benchmarks according to which this progress will be measured;

40. Stresses that the presidential elections to be held on 27 October 2013, and thus concurrently with the closing of negotiations on the AA with the EU, will be a litmus test for Georgia's readiness to apply standards of democracy and the rule of law, with full freedom for the opposition to run in the elections and for free, independent media to cover the campaign without any interference by the authorities;

41. Stresses that Georgia should not abstain from European aspirations and that it should resist pressure to give up association with the EU;

**Moldova**

42. Welcomes the political determination to fulfil the requirements of the Association Agreement, including the DCFTA, as well as the Visa Liberalisation Action Plan and the progress with regard to the initialling of the Iasi-Ungheni pipeline project; praises the modernisation efforts undertaken in the country, in particular the increased expenditure on education; calls for the rapid signature and completion of all necessary steps in order to implement the Agreement as soon as possible; is aware, however, of the weakness of the democratic institutions and of the need for the steady reinforcement of those

**Wednesday 23 October 2013**

institutions; encourages the Government of Moldova to continue to work hard on the implementation of the necessary measures; believes that political stability and enduring consensus on reforms, especially as regards the rule of law and independence from state institutions, are of paramount importance to Moldova's European aspirations;

43. Encourages the initialisation of the Association Agreement, including the DCFTA, at the Vilnius summit, and hopes to see a speedy conclusion of the visa dialogue; recognises the important impact that the implementation of the Association Agreement, free trade and visa-free travel will have on the reform process in Moldova; notes, in this regard, that the most recent political crises have revealed the fragility of the democratisation process conducted so far, and stresses the need to work towards building truly credible independent democratic institutions;

44. Recommends proceeding swiftly with the signing, in the near future (post-Vilnius summit), of the Association Agreement, if the present compatibility with the requirements is sustained;

45. Welcomes the Commission proposal to fully liberalise wine imports from Moldova and hopes that swift implementation of the proposal will help offset the negative consequences of the Russian import ban on Moldovan wine;

46. Welcomes the launch of a new pipeline between Moldova and Romania and encourages the continuation of efforts and resistance to pressure from Russia to give up the Association Agreement;

***Ukraine***

47. Welcomes the ongoing dialogue between Ukraine and the EU and their common ambition to sign an Association Agreement at the Eastern Partnership Summit in Vilnius on 28 and 29 November 2013;

48. Encourages the Ukrainian authorities to advance further in fulfilling the requirements of the Association Agreement, as laid down in the Council conclusions of 10 December 2012 on Ukraine and in Parliament's resolution of 13 December 2012 on the situation in Ukraine <sup>(1)</sup>, and in addressing the pending issues of selective justice and electoral and judicial reform; welcomes, nevertheless, the recent commitments made by both President Yanukovich and the opposition leaders to proceed with the required legal acts through Verkhovna Rada, and awaits prompt delivery on those promises before the Vilnius summit; recognises the progress made so far, but underlines the need for reforms, notably of the Prosecutor's Office; commends the work of the European Parliament's Monitoring Mission for Ukraine and welcomes the extension of its mandate until 12 November 2013; expresses hope and confidence that it will soon lead to a mutually acceptable solution to the case of Yulia Tymoshenko, on the basis of the appeal by Pat Cox and Aleksander Kwaśniewski to the President of Ukraine;

49. Acknowledges Ukraine's European aspirations and reiterates its view that a deepening of relations between the EU and Ukraine and the fact of offering Ukraine a European perspective are of great significance, and are in the interests of both parties;

50. Recommends that the Council sign the Association Agreement between the EU and its Member States, on the one part, and Ukraine on the other part, if the required conditions, as formally defined by the Foreign Affairs Council of 10 December 2012 and supported by Parliament's resolution of 13 December 2012, are met; expresses its approval, conditional upon the above-mentioned requirements, of the Council decision on the provisional application of the EU-Ukraine Association Agreement immediately upon signature; states its intention, in the event of meeting all requirements and subsequent signing, to proceed with the full ratification of the EU-Ukraine Association Agreement within the present legislative term;

51. Condemns the recent trade sanctions imposed by Russia on Ukrainian exports, which are aimed at putting pressure on Ukraine not to sign the Association Agreement with the EU; calls on Russia not to impose these sanctions and to refrain from undue political interference and pressure;

***The Southern Neighbourhood***

52. Is concerned at the difficulties being encountered by the southern Mediterranean countries in overcoming the challenges of their democratic transitions;

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<sup>(1)</sup> Texts adopted, P7\_TA(2012)0507.

Wednesday 23 October 2013

53. Emphasises the vital role which the legal and technical assistance provided by the Union and its Member States to the authorities of the Arab Spring countries in transition has played in helping the latter to achieve concrete results in their efforts to recover assets;

54. Welcomes the success of its initiative of convening task forces for Tunisia, Jordan and Egypt, and stresses that these meetings between private stakeholders, public authorities and international organisations should ensure greater inclusion of civil society and NGOs and should produce tangible outcomes, provided the political situations allow increased economic cooperation and integration; suggests that the possibility of widening this initiative to other countries in the region should be explored;

55. Takes the view that a successful transition to sustainable democracy must be the Union's priority regarding its Southern Neighbourhood, and calls for the EU institutions and the Member States to increase their support to that effect;

56. Recommends that the Union maintain and, where appropriate, step up its engagement in supporting transitions in the Southern partner countries, focusing on democratic transformation, partnership with people and civil society, and sustainable and inclusive economic growth;

57. Points out that social justice and improving the quality of life are key elements of the transitions currently taking place in the Southern Neighbourhood countries; expresses deep concern at the employment situation, in particular among young people, and urges the Commission to support effective employment policies;

58. Notes that the number of students from the Southern Neighbourhood countries taking part in the Tempus and Erasmus Mundus programmes is very low, despite the additional funding allocated to those programmes in 2012; reiterates its call on the Commission to set up a Euro-Mediterranean Leonardo da Vinci programme with the aim of fostering mobility for young apprentices who want to acquire professional training abroad, thus contributing to the fight against youth unemployment, which is endemic in the Southern Mediterranean;

59. Calls for the Union and its Member States to implement a concrete and effective mobility policy with the countries of the Southern Neighbourhood, in particular by simultaneously signing visa liberalisation agreements and readmission agreements similar to those signed with most countries of the Eastern Partnership; underlines, in this context, the importance of increasing mobility and cooperation in the field of academic education and vocational training, broadening and increasing the existing programmes and mobility of students, graduates, teachers and academics, and promoting exchanges between higher education and training institutions, along with public-private partnerships in the field of research and enterprise; considers it essential to develop easier procedures for issuing visas to participants in such programmes; calls for the EU to develop a sensible and comprehensive strategy involving the EEAS, the Commission, Member States and partners in the Southern Neighbourhood to deal with migration and protect refugees and asylum seekers originating from the Southern Neighbourhood, especially in the light of the Arab Spring and continued instability in North Africa;

60. Reiterates how important it is that the EU institutions and the Member States demonstrate the genuine political will to play an active part in resolving conflicts in the region, in particular the Israeli-Palestinian conflict, so that they no longer pose an obstacle to the implementation of the ENP;

61. Considers it a priority to support partner countries in the development and financing of projects on regional policy and the inclusion of regional enclaves; recommends in this regard that steps be taken to build on the Union's experience in managing European regional funds for the development of competences both of partner countries and of the Secretariat of the Union for the Mediterranean;

62. Believes that there is an urgent need to promote projects for sustainable and inclusive socio-economic development and integration in the Maghreb in order to facilitate the circulation of goods, services, capital and persons; recalls that the conflict in Western Sahara is a major obstacle to the integration of the region; calls on Algeria and Morocco to create an active partnership capable of meeting the regional challenges, including the Western Sahara conflict; welcomes, in this context, the adoption of the Joint Communication of December 2012 from the High Representative and the Commission setting out proposals to support the five countries of the Maghreb in their efforts towards closer cooperation and deeper regional integration; welcomes the fact that the Union has assumed the Northern co-presidency of the Union for the Mediterranean, and expects it to promote policy coherence, overall coordination and effectiveness, with particular reference to projects which receive financing;

**Wednesday 23 October 2013**

63. Encourages all parties involved in the conflict to work with a view to achieving a just, peaceful, long-lasting and mutually acceptable political solution on Western Sahara, in accordance with the relevant United Nations resolutions, including those allowing self-determination; stresses the importance of guaranteeing human rights for the Saharawi people and the need to address these rights in Western Sahara and in the Tindouf camps, including those of Sahrawi political prisoners who have not had a fair trial and who should be released;

64. Highlights the importance of the Union for the Mediterranean as an instrument for the institutionalisation of relations with the Southern Neighbourhood; underlines the importance of the upcoming ministerial meetings in terms of invigorating the Euro-Mediterranean partnership and pushing forward common projects;

65. Reaffirms that, for the Southern partnership, the aim is to bring the two shores of the Mediterranean closer together with a view to establishing an area of peace, democracy, security and prosperity for their 800 million inhabitants, and to provide the EU and its partners with an effective bilateral and multilateral framework enabling them to overcome democratic, social and economic challenges, promote regional integration, in particular in relation to trade, and ensure their co-development for the benefit of all, as well as to assist partners in building democratic, pluralistic and secular states, especially through institutional-capacity building programmes, while also developing mutually beneficial, balanced and ambitious arrangements for trade in goods and services, preceded by the relevant impact assessments that can lead to DCFTAs; believes this will surely represent the first step towards a large 'Euro-Mediterranean Economic Area' that could also help to alleviate the economic problems of our neighbouring partners in the South and facilitate South-South integration;

66. Stresses the fact that supporting the process of returning the assets stolen by former dictators and their regimes constitutes a moral imperative for the EU; believes that asset recovery is a highly political issue due to its symbolic value and that there is a need to restore accountability in the spirit of democracy and the rule of law; notes that asset recovery must constitute a key political commitment of the EU in its partnership with the Southern Neighbourhood; reiterates the need to establish an EU mechanism with the aim of delivering legal support to countries of the Southern Neighbourhood in the process of asset recovery;

67. Calls on the Commission, the EEAS and the Member States to do more to encourage countries in the region to incorporate clear provisions into their laws and to implement programmes with a view to guaranteeing the rights of women, their involvement in political and economic decision-making, their access to education and their economic independence, and to eliminating all forms of violence against them;

68. Believes that the EU should provide assistance and knowledge to lawmakers in considering and drafting legislation related to the ICT sector, which should unlock the vast potential of digital technologies for both the democratic process and economic development and regional cooperation; considers the free flow of information and access to the internet to be essential for socio-economic improvements; stresses, in this regard, the importance of respect for digital freedoms;

69. Expresses grave concern over increasing religiously motivated violence in the region, especially towards Christians, and calls on the Union to act on this also within the ENP framework;

70. Reiterates its call on the Commission to raise the profile of Eastern Partnership and Union for the Mediterranean projects in the partner countries, and to make them more readily understandable to people in those countries by demonstrating the value added which cooperation with the EU generates;

## **Algeria**

71. Notes that Algeria has confirmed its intention to participate in the ENP, but that it has not yet adopted an action plan; welcomes the launching of the negotiations for an EU-Algeria action plan and strongly encourages Algeria to take advantage of this instrument for enhancing its relations with the EU; calls on the EU and Algeria to speed up their negotiations in the context of the ENP with a view to adopting an action plan quickly;

72. Welcomes the steps taken by the Algerian Parliament to improve cooperation with the European Parliament and the quality of the political dialogue established between the two parliaments;

73. Welcomes the signing on 7 July 2013 of the Memorandum of Understanding on the establishment of a Strategic Partnership between the European Union and Algeria in the field of energy, which will ultimately clear the way for the closer integration of markets, infrastructure development and technology transfers between the two sides;

Wednesday 23 October 2013

74. Stresses the need for a policy that enables human rights and fundamental freedoms, especially freedom of association and the freedom to demonstrate, to be fully upheld; hopes that the expected revision of the Algerian constitution takes place in the framework of an open and transparent process open to representatives of all political tendencies in the country, in such a way that it can contribute to the consolidation of democracy and the rule of law; notes the smooth running of the European Union Election Observation Mission (EU EOM) sent to Algeria for the general elections of 10 May 2012; recalls the recommendations made by the EOM, and urges the Algerian authorities to make the improvements required, in preparation for future elections; reiterates the Union's offer of support for that process;

75. Calls on the Union to reinforce and to step up even further its support to civil society organisations in Algeria and to programmes promoting female and youth employment, economic governance, improvement of the business environment and the strengthening of freedoms and fundamental rights;

76. Urges Algeria to facilitate the work of civil society organisations by promoting freedom of association and the freedom to demonstrate;

### **Egypt**

77. Is concerned about current political developments in Egypt after the military takeover of 3 July 2013, about the political polarisation, serious economic difficulties, and the situation regarding respect for human rights and fundamental freedoms in the country, and about security in the region, with special regard to Sinai; condemns in the clearest possible terms all acts of violence, including attacks on Coptic churches, and believes that the recent operations of the Egyptian security forces have been disproportionate and have resulted in an unacceptably large number of deaths and injuries; calls on the Egyptian Government to refrain from such action; urges all political parties to engage in a genuinely inclusive dialogue in order to restore a democratic process responding to the legitimate requests and aspirations of the Egyptian people; stresses the need for a national reconciliation of all political and social forces, including the moderate components of the Muslim Brotherhood, as a key element in order to move forward the democratic transition which entails the organisation of presidential and parliamentary elections; stresses that the EU, through the HR/VP, could be in a position to encourage a dialogue between the main political actors in the country conducive to the establishment of a government of national unity to prepare elections; in particular, recommends that the HR/VP send a clear message that the illegalisation of the Muslim Brotherhood would jeopardise democratic inclusion and compromise the prospects of returning to democracy;

78. Stresses that a prosperous future for Egypt is only possible on the basis of a democratic solution with fully functioning democratic institutions which will guarantee the safety of all citizens, and that the democratic transition should entail the right to a fair trial for all;

79. Calls on the Union, in its bilateral relations with and its financial assistance to Egypt, to take into consideration both the serious economic challenges the country is facing and their social consequences, on the one hand, and to apply the principle of 'conditionality' ('more for more'), on the other; believes that the Union should not commit to a full and detailed free trade agreement with Egypt until the conditions for political stability, such as the settled establishment of elected democratic bodies, the rule of law, and respect for human rights and fundamental rights, have been fulfilled; notes that the Foreign Affairs Council on 21 August 2013 tasked HR/VP Catherine Ashton to review the issue of EU assistance under the ENP and the Association Agreement on the basis of Egypt's commitment to the principles that underpin them and on the basis of the understanding that the assistance to the most vulnerable groups and to civil society will continue;

80. Considers that the Union should concentrate its support on respect for human rights and fundamental freedoms, particularly women's rights, minority rights and freedom of belief, as well as on the transition to democracy, the development of institutional capacities, judicial and security reforms, the development of all democratic political parties and NGOs, and the improvement of the business environment; is of the view that the EU should maintain current aid and assistance channelled to NGOs and civil society, as part of a strategy to engage with political actors in Egypt and to sponsor a genuine democratic transition process; welcomes the decision by the Foreign Affairs Council on 21 August 2013 to suspend export licenses to Egypt of any equipment used for internal repression and to reassess the export licences covered by the EU common position;

81. Appreciates the mediation efforts of the HR/VP and believes that the Union should capitalise on its unique position and networks of relationships among the key Egyptian players and continue to strive toward a political settlement in line with the basic parameters of a democratic transition;

**Wednesday 23 October 2013**

82. Notes the Court of Auditors' special report (No 4/2013) on cooperation with Egypt in the area of governance and the Commission's replies, and calls on the Commission and the EEAS to draw the requisite conclusions as regards the need to make Union support more effective;

### ***Israel***

83. Notes the positive implementation by Israel of the action plan, adopted in April 2005 for a period of three years and extended until the end of 2012; regrets the discriminatory policies pursued by the current Israeli Government, and calls for measures to enhance and advance the rights of minorities, especially those of the Arab-Israeli and Bedouin communities in the country; in addition, calls on the Commission and the EEAS to step up efforts and further develop projects to this end;

84. Welcomes the resumption of direct negotiations between Israelis and Palestinians; stresses its commitment to a two-state solution, based on the 1967 borders, with mutually agreed land swaps and Jerusalem being the capital city of both states; expresses its disapproval and repeated condemnation of the increasing number of illegal settlements in the occupied territories, and calls on the Government of Israel to cease settlement activity and cancel all planned projects for building new settlements; recalls vehemently that the building of settlements is a tangible obstacle to the success of both the peace talks between Israel and the Palestinians and the viability of the two-state solution; and draws attention to the guidelines which the EU has laid down concerning the eligibility for grants, prizes and EU-funded financial instruments, from 2014 onwards, of Israeli entities established in the territories occupied by Israel since June 1967 and the activities they carry on there;

85. Expresses concern at Israel's decision to end its involvement in the Human Rights Council and the universal periodic review conducted by the UN; calls on Israel to implement the UN Convention on the Rights of the Child, to recognise minors as a specific group and to uphold the rights of Palestinian minors without discrimination;

86. Calls on Israel, notwithstanding the fact that the number of Palestinian detainees under administrative detention decreased in 2012, to further address the issue of the use of administrative detention and to continue to ensure international rights standards for Palestinian prisoners, especially women and children;

### ***Jordan***

87. Recognises the improving cooperation between the Union and Jordan, specifically with the signature of the Protocol for the participation of Jordan in Union programmes, and the positive progress of political reforms, notably the establishment of the electoral commission and the constitutional court and the adoption of an electoral law;

88. Welcomes the implementation of political reforms in Jordan; deplores, however, the use of military tribunals to try cases involving freedom of expression, a practice which represents a breach of the country's constitution, as well as the amendment of the law on the press and publications concerning electronic publications and the delays in strengthening the independence of the legal system;

89. Calls on the Commission and the EEAS to give financial priority to projects supporting democratic and judicial reforms, the fight against corruption, and humanitarian assistance for refugees;

90. Welcomes Jordan's active role in the resolution of conflicts in the Middle East, as well as its considerable efforts to take in refugees from the Syrian conflict; notes that according to UNHCR, as of 8 October 2013 the number of Syrian refugees in Jordan, including unregistered refugees, stood at 538 839; would welcome the signature by Jordan of the UN Convention relating to the Status of Refugees;

91. Is deeply concerned about the implications for Jordan of the Syrian crisis and the dangerous saturation point that the country is approaching due to the influx of Syrian refugees, which could set off unprecedented regional instability in relation to its capability and resources in providing shelters and humanitarian aid to families fleeing the conflict; urges the Union to generously support Jordan in managing the growing refugee influx, as well as in facing the tremendous domestic challenges that include economic instability, inflation and unemployment;

Wednesday 23 October 2013

**Lebanon**

92. Calls for the rapid implementation of the action plan, and regrets the slow pace of reform, but is aware of the volatility of the context, especially due to the persistence of the conflict in Syria, which has effectively impacted inside Lebanon, especially through refugee inflow and imported political conflicts;

93. Considers that the Union's assistance should be focused on supporting institutions and the development of their capacities, on the humanitarian aid needed due to the ever-increasing number of Syrian refugees, on the reinforcement of the judicial sector and its independence, and on assistance at borders; calls on the Lebanese Parliament to resume its session as scheduled and to adopt the electoral law as soon as possible;

94. Notes the neutral stance taken by Lebanon in the Syrian conflict and welcomes its efforts to take in Syrian refugees;

95. Notes that, according to the UNHCR, the number of Syrian refugees in Lebanon, including unregistered refugees, is close to one million, and is deeply concerned at the implications for Lebanon of the Syrian crisis and the dangerous saturation point that the country is approaching due to the influx of Syrian refugees, which could set off unprecedented regional instability in relation to its capability and resources in providing shelters and humanitarian aid to families fleeing the conflict; urges the Union to generously support Lebanon in managing the growing refugee influx, as well as in facing the tremendous domestic challenges that include economic instability, inflation and unemployment;

96. Applauds Lebanon's commitment to take in and assist Syrian refugees, despite its limited capacity and the need to maintain a balance among its communities, as well as its efforts to limit the regional impact of the conflict, but deplores the fact that this situation has hampered implementation of the country's reform agenda; stresses the importance of a new, inclusive electoral law;

97. Welcomes Lebanon's role in providing shelter to over one million Syrian refugees who have been forced to leave their home and country; commends the resourcefulness of the Lebanese population in facilitating the taking-in of refugees, and reiterates its full support for the Lebanese authorities in continuing these efforts;

**Libya**

98. Encourages the Libyan authorities to step up democratic reforms and actions designed to stabilise the security and political situation; calls for the resumption of the negotiations on the signature of an association agreement between the Union and Libya at the earliest opportunity, as a means to assist the country in its efforts towards reform; invites Libya to draft and adopt its Action Plan;

99. Urges the Commission and the EEAS to cooperate with other international institutions operating in the region and complement their work, with the aim of supporting Libya in the process of constructing its democracy;

100. Stresses the importance of building a strong and independent judicial system, expresses concern at the human rights situation in Libya, and calls for action to fight racism and discrimination against minorities;

101. Calls on the Commission and the EEAS to focus their support on promoting civil society and institution-building in Libya, as well as on constitution drafting and capacity- building and on the training of Libyan senior officials and of effective security forces (armed forces and police forces) that can ensure peace and order in the country; stresses that the EU should also step up efforts in assisting the Libyan justice system to reform, as well as in other fields such as independent media, respect for human rights, national reconciliation and the fight against corruption, in order to meet the needs expressed by the Libyan authorities, including those relating to border management, in particular in southern Libya, and to ensure a migration policy respectful of fundamental rights;

**Wednesday 23 October 2013**

102. Welcomes the deployment of the CSDP-led EU Border Assistance Mission (EUBAM) in Libya to support the country in securing its borders, which entails short- and long- term goals that will contribute to state consolidation and will help in fighting terrorism and organised crime, especially arms and human trafficking, not only within Libya but also in the wider region; invites the HR/VP to review its mandate and dimension in order to adjust it to the huge needs on the ground; criticises the slowness of the procedures, in particular when set against the gravity of the situation;

### **Morocco**

103. Welcomes Morocco's commitment to deepening its relationship with the EU and taking full advantage of its advanced partnership status; considers that implementation of the constitution, reform of the legal system, reinforcement of the capacities of democratic institutions and support for civil society, including at local level, contributing to the human development of the Moroccan people, and the negotiation of an ambitious, balanced and mutually beneficial DCFTA, should constitute the main thrust of the Union's support to Morocco;

104. Welcomes the proposal for adoption of the Council decision on the implementation of the EU-Morocco action plan implementing the advanced status (2013-2017) <sup>(1)</sup>;

105. Welcomes Morocco's commitment to pursuing political reform; recommends the rapid implementation of the new constitution, accompanied by a calendar for the adoption of organic laws and the national Charter for the reform of the legal system, and stresses in this regard that this reform has been ongoing for at least three years, with significant financial support from the Union; recalls that the implementation of policy reforms, and particularly of the process for advanced regionalisation, while also respecting cultural, economic and social specificities, should contribute to Morocco's development and should help consolidate democratic processes at local level;

106. Welcomes the fact that parliamentary debate in Morocco has become more dynamic, but criticises the lack of any specific reference in the progress report to the work of the EU-Morocco Joint Parliamentary Committee;

107. Calls on Morocco to foster gender equality, to set up a gender equality and anti-discrimination authority, to ratify the United Nations Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) and to revise the provisions of its Family Code on polygamy and marriages involving underage girls;

108. Notes the work carried out by the Moroccan National Human Rights Council, and calls for its regional offices to be provided with the human and financial resources they need so that the Council can carry out its tasks properly and take on new ones;

### **Palestine**

109. Calls for the effective implementation of the new action plan; welcomes the progress made by the Palestinian authorities on the implementation of the current action plan despite the extremely difficult situation; welcomes the resumption of direct negotiations between Israelis and Palestinians; stresses that there is no alternative to direct negotiations between the parties to reach the two-state solution;

110. Insists once again on the need for an intra-Palestinian reconciliation process, which the EU, under the coordination of the HR/VP, should be in a position to sponsor and facilitate; calls on the Palestinian political actors to start negotiating a clear roadmap envisaging presidential and general elections in the nearest possible future; stresses that genuine Palestinian reconciliation is essential to the successful pursuit of Palestinian-Israeli peace talks and is vital to the stability and overall viability of a Palestinian state;

111. Calls on the Commission and the EEAS to support as a priority the moves to establish institutional empowerment and for reinforcement of the rule of law, good governance, the modernisation of public services, and projects aiming at the inclusion of women and young people in economic and political activities;

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<sup>(1)</sup> JOIN(2013)0006.

Wednesday 23 October 2013

**Syria**

112. Expresses its deepest concern at the further aggravating violent crisis in Syria and the use of chemical weapons in the country, and is alarmed at the continued violence of this ongoing civil war; expresses its solidarity with the victims and their families; takes the view that humanitarian law violations of such magnitude cannot go unpunished and require a strong reaction from the international community and the Union, and stresses in this context the responsibility to protect the civilian population; considers, in the light of the humanitarian catastrophe in Syria, that the immediate priority for the international community and for the Union must be to ensure that humanitarian aid reaches those in need of basic goods and services in Syria and the neighbouring countries affected by the crisis, notably Egypt, Iraq, Jordan, Lebanon and Turkey, and calls for special attention to the situation of Palestinians in Syria;

113. Calls on the EU to take appropriate, responsible measures regarding a possible influx of refugees into its Member States; calls on the Commission and the Member States to continue monitoring the current situation and to work on contingency planning, including the possibility of applying the Temporary Protection Directive if and when conditions demand it;

114. Expresses its deepest concern over further aggravation of the violent crisis in Syria, and condemns in the strongest terms the use of chemical weapons against civilians, which is a crime according to international law; calls again for an adequate response from the UN Security Council and for the EU and the international community to show a strong united front and to react strongly to this breach of international law, in order to fulfil their responsibility to protect civilians in Syria; calls on the Union to support mediation attempts such as the Geneva Conference II in order to find a solution that would respect the democratic aspirations of the Syrian people; believes that any deterrent action must have clear and attainable objectives and must be anchored in a wider political strategy aimed at containing the Syrian conflict;

115. Is convinced that a lasting solution to the crisis in Syria can only be achieved through a political process; supports, therefore, all efforts to implement Geneva II and the efforts of High Representative/Vice-President Ashton, Member States and UN Special Envoy Lakhdar Brahimi aimed at achieving progress in the Geneva II process and on the UN Security Council; stresses the importance of involving all key actors, in the region and beyond, in these efforts;

116. Expresses concern regarding the situation of the Kurdish population in the north and north-east of Syria, resulting in large numbers of refugees and threatening to further destabilise the region;

117. Expresses concern at the intolerable burden which refugees are imposing on the countries which have borders with Syria, what is more at a time when funding humanitarian aid is becoming problematical;

**Tunisia**

118. Expresses its concern at the increasing polarisation of political life in Tunisia; condemns in the strongest terms the brutal assassinations of prominent opposition figures; stresses that freedom of expression, freedom of association and freedom of the media must be guaranteed;

119. Welcomes the strengthened commitments on the part of the Union and Tunisia as illustrated in the action plan, and calls on both parts to adopt that plan; urges the National Constituent Assembly to finalise a democratic constitution that respects international human rights agreements; calls for the organisation of free and fair elections, and regrets the extension of the state of emergency; takes the view that the adoption of a constitution firmly grounded in democratic values and respect for human rights, corresponding to the wishes of the Tunisian people, a functional and independent judiciary and media, and the holding of new elections are key elements for pursuing Tunisia's political transition; is concerned about the increasing numbers of trials of journalists in Tunisia; welcomes the inclusion in the draft constitution of a specific article on children's rights in line with the UN Convention on the Rights of the Child, and recommends the establishment of an independent mechanism to monitor its implementation;

120. Urges Tunisia's Constituent Assembly to complete the process of adopting the constitution, and as soon as possible to call elections, to be supervised by the Independent Supreme Electoral Commission; takes the view that implementing the new constitution, reforming the legal system and the media, revising the press code and strengthening the capacity of democratic institutions and civil society should be the priorities guiding the provision of support by the Union;

121. Calls on Tunisia to deposit without delay the ratification instruments for and thus withdraw its last remaining reservations to the United Nations Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), and to enact laws which guarantee equal rights and non-discrimination, including by decriminalising homosexuality;

**Wednesday 23 October 2013**

122. Welcomes the fact that EU cooperation with Tunisia has been stepped up, through the doubling of the aid granted, and, more particularly, the fact that the aid has been used to boost the economy, develop less-favoured areas and strengthen civil society;

123. Calls on the Commission and the EEAS to increase their support for moves to open up regions by infrastructure development projects, for actions in favour of employment, especially of young people, for civil society at regional level, and for the reform of the judicial sector with a view to establishing the rule of law whilst respecting human rights and fundamental freedoms, as well as for reform of the social sectors (health, education and social protection), with special focus on gender, equity and vulnerable children;

124. Deplores the delays affecting the negotiations for the signing of a deep and comprehensive free trade agreement with Tunisia;

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125. Instructs its President to forward this resolution to the Council, the Commission, the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy, the European External Action Service, the governments and parliaments of the Member States and the ENP countries, the Euronest Parliamentary Assembly, the Parliamentary Assembly of the Union for the Mediterranean and the Secretary-General of the Union for the Mediterranean.

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Wednesday 23 October 2013

P7\_TA(2013)0447

**European Semester for economic policy coordination****European Parliament resolution of 23 October 2013 on the European Semester for economic policy coordination: implementation of 2013 priorities (2013/2134(INI))**

(2016/C 208/12)

*The European Parliament,*

- having regard to its resolution of 26 October 2012 on the European Semester for economic policy coordination: implementation of 2012 priorities <sup>(1)</sup>,
- having regard to the conclusions of the European Council of 14—15 March 2013,
- having regard to the Treaty on the Functioning of the European Union, and in particular Article 136 in combination with Article 121(2) thereof,
- having regard to the Treaty on Stability, Coordination and Governance (TSCG),
- having regard to Regulation (EU) No 1175/2011 of the European Parliament and of the Council of 16 November 2011 amending Council Regulation (EC) No 1466/97 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies <sup>(2)</sup>,
- having regard to Council Directive 2011/85/EU of 8 November 2011 on requirements for budgetary frameworks of the Member States <sup>(3)</sup>,
- having regard to Regulation (EU) No 1174/2011 of the European Parliament and of the Council of 16 November 2011 on enforcement measures to correct excessive macroeconomic imbalances in the euro area <sup>(4)</sup>,
- having regard to Council Regulation (EU) No 1177/2011 of 8 November 2011 amending Regulation (EC) No 1467/97 on speeding up and clarifying the implementation of the excessive deficit procedure <sup>(5)</sup>,
- having regard to Regulation (EU) No 1176/2011 of the European Parliament and of the Council of 16 November 2011 on the prevention and correction of macroeconomic imbalances <sup>(6)</sup>,
- having regard to Regulation (EU) No 1173/2011 of the European Parliament and of the Council of 16 November 2011 on the effective enforcement of budgetary surveillance in the euro area <sup>(7)</sup>,
- having regard to Regulation (EU) No 472/2013 of the European Parliament and of the Council of 21 May 2013 on the strengthening of economic and budgetary surveillance of Member States in the euro area experiencing or threatened with serious difficulties with respect to their financial stability <sup>(8)</sup>,
- having regard to Regulation (EU) No 473/2013 of the European Parliament and of the Council of 21 May 2013 on common provisions for monitoring and assessing draft budgetary plans and ensuring the correction of excessive deficit of the Member States in the euro area <sup>(9)</sup>,
- having regard to the Commission Communication of 28 November 2012 on the Annual Growth Survey 2013 (COM (2012)0750),
- having regard to its resolution of 7 February 2013 on the European Semester for Economic Policy Coordination: contribution to the Annual Growth Survey 2013 <sup>(10)</sup>,

<sup>(1)</sup> Texts adopted, P7\_TA(2012)0408

<sup>(2)</sup> OJ L 306, 23.11.2011, p. 12.

<sup>(3)</sup> OJ L 306, 23.11.2011, p. 41.

<sup>(4)</sup> OJ L 306, 23.11.2011, p. 8.

<sup>(5)</sup> OJ L 306, 23.11.2011, p. 33.

<sup>(6)</sup> OJ L 306, 23.11.2011, p. 25.

<sup>(7)</sup> OJ L 306, 23.11.2011, p. 1.

<sup>(8)</sup> OJ L 140, 27.5.2013, p. 1.

<sup>(9)</sup> OJ L 140, 27.5.2013, p. 11.

<sup>(10)</sup> Texts adopted, P7\_TA(2013)0052.

Wednesday 23 October 2013

- having regard to the Commission Communication of 27 March 2013 entitled ‘The EU Justice Scoreboard — A tool to promote effective justice and growth’ (COM(2013)0160),
  - having regard to the Commission Communication of 29 May 2013 accompanying the draft 2013 country-specific recommendations and entitled ‘2013 European Semester: country-specific recommendations — Moving Europe beyond the crisis’ (COM(2013)0350),
  - having regard to the Commission recommendation for a Council recommendation of 29 May 2013 on the implementation of the broad guidelines for the economic policies of the Member States whose currency is the euro (COM(2013)0379), as well as all the Commission proposals of 29 May 2013 for Council recommendations for individual Member States of the European Union,
  - having regard to the 2012 study entitled ‘Data for the evaluation of the European Semester process from a gender equality perspective’<sup>(1)</sup>,
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Budgets, the Committee on Employment and Social Affairs, the Committee on the Internal Market and Consumer Protection, the Committee on Regional Development and the Committee on Women’s Rights and Gender Equality (A7-0322/2013),
- A. whereas the economic, social, financial and sovereign debt crises have not yet abated and whereas a more balanced, robust, stable and integrated Economic and Monetary Union (EMU) is an objective still in the process of being realised;
- B. whereas the euro area sovereign debt crisis is having a significant impact on the euro money market and the Eurosystem’s extraordinary policy measures as well;
- C. whereas the Commission’s country-specific recommendations (CSRs) contain useful and detailed insights, but on the whole need to be more precisely defined and improved for some Member States, notably in terms of the balance of the policy prescriptions across policy areas; whereas there is also some margin for improvement as regards the methodology for assessing National Reform Programmes and following up country-specific recommendations;
- D. whereas SMEs remain the backbone of the euro area economy, representing about 98 % of all euro area firms, employing around three quarters of employees in the euro area and generating around 60 % of value added;
- E. whereas it is important to safeguard the role of the social partners and respect different national practices and institutions as regards wage formation when implementing the European Semester;
- F. whereas urgent action is required in many areas, inter alia in restoring lending to the real economy and SMEs, which involves developing alternative resources of financing, in making the business environment more competitive, in fighting tax fraud, tax evasion and aggressive tax planning, in restoring the sustainability of public finances and in seeking effective European solutions to unemployment and thus establishing a fully integrated labour market and also significantly enhancing the social dimension of EMU;
- G. whereas the democratic legitimacy of economic governance in the European Semester requires real and dedicated respect for parliamentary prerogatives at European and national level and for those of the Commission as laid down in the Treaties and EU law against the trend of an increasingly de-parliamentarised and intergovernmental culture of economic-policy making at EU and euro-area level;
- H. whereas the involvement of the social partners and civil society organisations is essential to carrying out social assessments of the impact of the crisis on the ground, and thus taking adequate measures;

<sup>(1)</sup> European Parliament, Directorate-General for Internal Policies, Policy Department C.

Wednesday 23 October 2013

- I. whereas, given that the new provisions introduced by the so-called '2-pack' have already entered into force, the CSRs have increased importance now that the national reform programmes and stability programmes have to be consistent with them;
  - J. whereas, although in the case of Member States under a financial assistance programme recommendations have been strictly enforced, the level of compliance by the rest of the Member States with previous CSRs is low;
  - K. whereas the 2-pack sets rules within the Community method in respect of Member States in the euro area experiencing, or threatened with, serious difficulties with respect to their financial stability;
  - L. whereas the single market and the EU's cohesion must be secured;
  - M. whereas new technology affords both employers and employees new opportunities for organising work in such a way as to strike a better work-life balance and thus make the labour market more inclusive for women;
  - N. whereas, on 17 September 2013, Parliament's Committee on Economic and Monetary Affairs held a meeting with national parliamentarians to discuss the implementation of the country-specific recommendations adopted by the Council with a view to take greater account of their effectiveness and of potential spill-over effects in the EU,
- 
- 1. Welcomes the Commission's country-specific recommendations, adopted by the Council; points out that there is room for improvement; welcomes the fact that these recommendations are more detailed than their previous editions and give more insight into the Member States' assiduity in carrying out the obligations they agreed to in the past; welcomes the Commission's statement that, 'to be successful, policies need not only to be well designed but to have political and social support', and that Europe and the Member States need, beyond fiscal consolidation, structural reforms leading to real, sustainable and socially balanced growth, sustainable employment and strengthened competitiveness while more specific and urgent measures should be taken to tackle the unacceptably high levels of unemployment, in particular youth unemployment; calls on the Commission, in this connection, to monitor the compliance of all Member States' reports with Europe 2020 targets, notably with regard to poverty reduction and employment, and to carefully look at the interconnections and interdependence between policies;
  - 2. Welcomes the achievements made in several Member States which allowed their deficit procedures to be closed;
  - 3. Welcomes the Commission's statement that 'deficit' countries need to boost their competitiveness and that 'surplus' countries need to boost, where possible, their demand in a proportionate and sustainable way in order to contribute to the stability and growth of the eurozone;
  - 4. Believes that the EU economy as a whole needs to boost its competitiveness in the global economy, particularly by increasing competition in the product and services markets to enhance productivity and to lower prices, and by keeping labour costs in line with productivity; stresses that the EU cannot compete on costs alone, but needs to invest more in research and development, education and skills, and resource efficiency;
  - 5. Welcomes the fact that the Commission and the Council aim to avoid a one-size-fits-all approach to the CSRs thus to ensure that recommendations are fine-tuned according to the national specificities and needs of the Member State concerned while remaining focused on growth-enhancing policies and fiscal stability; calls on the Member States to assess the social impact of economic and structural reform plans, and to ensure that a genuine evaluation is made of their implementation with a view to more efficient cross-policy coordination and fine-tuning;
  - 6. Points out that sovereigns and financial institutions show persistent vulnerabilities in a low-growth environment;
  - 7. Points out that the Commission has identified a significant degree of progress in comparison with previous years in only 15 % of the around 400 country-specific recommendations;
  - 8. Welcomes the fact that the Commission's recommendations are directed not only at Member States but also at the euro area as a whole; considers that the recommendations made to Member States need to take increasingly into account the strong interdependence between EU economies, particularly within the euro area, and all the relevant information contained in the Alert Mechanism Report;

**Wednesday 23 October 2013**

9. Emphasises the importance of the monitoring and implementation of the country-specific recommendations, multilateral surveillance, the exchange of experiences and best practices, and peer reviews;
10. Calls for deeper investigation of the reasons for the huge and visible increase in internal divergences in competitiveness, fiscal consolidation and economic performance across Member States that have resulted from the functioning of the single currency, and in particular of the asymmetric impact of common policies;
11. Calls for a prudent interpretation of the 'slow recovery' growth indicators and recommends a closer look into the sustainability of the improvements identified, in particular in trade and current account balances and public deficits and the progress of structural reforms; calls for a closer look into the quality of economic forecasts as previous Commission forecasts have more often than not been revised downwards; stresses the need to design assistance programmes under conservative rather than optimistic assumptions and scenarios, in order to avoid self-defeating and pro-cyclical effects;
12. Urges the Commission to introduce Europe 2020 national objectives into the recommendations issued to Member States under Economic Adjustment Programmes and to take proper account of the constraints created by these adjustment programmes in the delivery of such objectives; calls also for the democratic legitimacy of such programmes to be promoted and enhanced;
13. Welcomes the fact that some Member States have submitted Europe 2020 progress reports, in some cases outlining specific projects for achieving the targets; calls on all Member States to include such reports in their 2014 European Semester contributions; regrets that the Commission has not presented a Europe 2020 progress report; calls on the Commission to present such a report annually;
14. Deplores the fact that no CSRs address the challenge posed by the impact of the labour taxation regime on long-term investment and the outcome in terms of job creation;
15. Welcomes the Commission's statement that European competitiveness 'cannot and will not be based merely on costs'; points out, in addition, that it is essential to enhance productivity, including capital, resource and energy productivity, social inclusion, investment in education and life-long learning, research and innovation and resource efficiency, in line with Europe 2020 goals; encourages additional progress on the Europe 2020 targets, especially in the area of employment; calls for the above to be adequately reflected in the 'deficit' countries' CSRs as these are the Member States which are in critical need of boosting their competitiveness;
16. Welcomes the Commission's country-specific recommendations in the field of environmental taxation and its job-creation potential, and calls on the Commission to take this into account in the upcoming Annual Growth Survey; highlights the positive budgetary, employment, social, and environmental impact of shifting taxation from labour to environmental taxation;
17. Regrets delays in implementing the EUR 120 billion 'Compact for Growth and Jobs' agreed in June 2012, the Project Bond initiative launched in November 2012 and the EUR 180 billion additional investment by the EIB; calls on the Council and the Commission to investigate and quickly remove the obstacles preventing full delivery of these initiatives;
18. Calls on the Commission to submit as a matter of urgency legislative proposals with the aim of creating a genuine convergence process within the EU Semester, based on Europe 2020 objectives and including incentives supporting Member States in the implementation of structural reforms, such as a Competitiveness and Convergence Instrument (CCI), as well as provisions on ex-ante economic policy coordination based on the Community method;
19. Calls on the Commission to include within the scope of a CCI financial support to structural reforms in areas that block economic dynamism and efficiency;
20. Welcomes the use by the Commission of the flexibility offered by the revised SGP to extend the deadlines for the correction of excessive deficits in seven procedures; understands that this extension will make it easier for those countries to implement the structural reforms they need; calls on the Commission and the Council to ensure that the content and the calendar of the fiscal adjustment path are adapted to the specificity of each country and, particularly in 'deficit' countries, include the aforementioned flexibility and the full use of European structural and investment funds, sound and sustainable structural reforms and the identification of investments (notably in the CSR) essential to boost competitiveness; welcomes

Wednesday 23 October 2013

the Commission's statement that already in this year's budgetary execution assessment and in the analysis of the national budgets for 2014, the Commission will try to accommodate, in particular within the preventive arm of the SGP, under certain conditions, non-recurrent, public investment programmes with a proven impact on the sustainability of public finances, while fully respecting the EU fiscal surveillance framework; looks forward to the Commission's communication, expected soon, on the concrete operational framework to be presented to Parliament, in accordance with the declaration annexed to the two-pack;

21. Notes the communication on the harmonised framework for draft budgetary plans and debt issuance reports within the euro area adopted by the Commission as guidelines in the framework of Regulation (EU) No 473/2013; looks forward to the economic dialogue due to take place with the Commission on the content of these guidelines;

22. Welcomes the inclusion of reporting guidelines indicating how measures in the draft budgetary plans address CSRs, the targets set in the Europe 2020 strategy, and reporting guidelines on the expected distributional impact of the main expenditure and revenue measures, as well as details on the general government expenditure by function; points out that such guidelines will facilitate the monitoring of budgetary measures taken with a view to achieving Europe 2020 national targets;

23. Looks forward to the forthcoming disclosure, agreed in the 'two pack' outcome, of the Commission's and Member States' parameters and methodological benchmarks, including the fiscal multiplier estimates underlying their macroeconomic prospects;

24. Notes that recent wage developments in 'surplus' countries are contributing to sustaining demand and are also having positive spill-over effects elsewhere in the EU; welcomes the Commission's statement that 'surplus' countries with sufficient fiscal space have a role to play in overcoming the current crisis, including by reducing taxes and social security contributions and by developing wages in order to boost sustainable domestic demand, taking into account international competitiveness; the 'surplus' countries could also promote new growth-friendly investment opportunities by means of their purchasing power, especially through investment in education, research and development, energy and infrastructure, modernise their health care and pension systems, and open up their services sector; stresses the importance of the positive spill-over effects which these actions will have across the EU, particularly if they are implemented by the largest economies within the Union;

25. Urges the Commission to develop a genuine European industrial policy, based on enhanced competitiveness and innovation, that focuses on restoring European industrial competitiveness and scaling back policies which cause companies to relocate outside the EU; urges the Commission, furthermore, to develop a coherent European external trade policy, based on shared minimum standards, in particular in social and environmental matters; believes that it is only by intelligently managing its interface with 'globalisation' that Europe can guarantee growth, jobs, consumer protection, compliance with international and European law and human rights standards and, for several Member States, the recommended progressive reallocation of resources away from non-tradable sectors into tradable sectors;

26. Commends the Commission's statement that financial support measures taken by Member States and the EU should devote greater attention to the distributional impact of reforms, and calls on the Commission to carry out a thorough ex-ante assessment of both the short- and long-term impact of all the new recommended reforms and to derive all the necessary conclusions from previous recommendations, including those made to Member States under financial assistance programmes;

27. Calls on the Commission to submit legislative proposals to complete the EMU, as recommended by Parliament in its resolution of 20 November 2012 entitled 'Towards a genuine Economic and Monetary Union'; urges the Commission, to this end, to establish a standalone scoreboard related to the EMU social dimension; suggests that the in-depth reviews provided for in the Macroeconomic Imbalances Procedure could regularly review employment and social policies with a view to identifying those policies that mitigate social problems and improve employment; believes that this enhanced monitoring system would help to coordinate policies more effectively with a view to identifying and tackling major challenges in a timely fashion and integrating employment and social concerns more effectively in the overall policy landscape

**Wednesday 23 October 2013**

28. Agrees that the ECB's action, which came in addition to structural reforms and the consolidation of public finances, has 'decisively contributed to the stability of the euro area'; recognises that this action has had the effect of decreasing unsustainably high financing costs for some Member States through the Securities Market Programme (SMP) and providing a liquidity backstop for sovereign debt markets through Outright Monetary Transactions (OMTs), averting a melt-down of the banking sector and helping to sever the link between banks and sovereigns, limiting speculation on sovereign debt and temporarily reducing excessive spreads; considers, however, that a lack of sustainable growth and high (and still growing) levels of private and public debt in many Member States mean that 'a carefully managed process of deleveraging' is required; agrees with the Commission that the improvement of the health of the banking sector must remain a priority; welcomes the establishment by the Commission, according to the commitment it made to Parliament in the declaration annexed to the two-pack, of the high-level group chaired by Gertrude Tumpel-Gugerell to deepen the analysis on, and assess thoroughly the partial substitution of national debt issuance through joint issuance in the form of a redemption fund and eurobills, considering the pros and cons of the different options; looks forward to the report of the high-level group;

29. Stresses that the financing of the real economy, and of SMEs in particular, has not been restored on the EU's periphery; points out that major differences in access to finance tend to exaggerate internal divergences in the EU, and the euro area in particular, and distort the internal market through uneven competition conditions; reiterates that cleaning up bank portfolios is a precondition and stresses that negative economic prospects only partially justify such restrictive credit constraints; calls for closer monitoring of the application of the new prudential rules and the banking sector practices in financing the real economy, in particular economically viable SMEs; acknowledges, in this regard, the important role that the new innovative financial instruments can play in various European programmes and in the Cohesion Policy in fostering public and private investment, and urges the Commission to guarantee legal clarity and transparency of implementation around new financial instruments in a timely manner and before the start of the 2014-2020 programming period; calls for more analysis and supervision of the shadow banking system and its impact on the real economy; calls for the Commission to prioritise work on alternative and diversified sources of financing for SMEs, in particular through the financial markets, the European structural and investment funds, the European Investment Bank, the European Investment Fund and public development banks;

30. Stresses that the retreat of various financial actors to national markets suggests that they are being weakened by the fragmentation of the internal market through excessive concentration, which is blocking the interbank market and negating the advantages of the internal market, i.e. risk diversification and greater opportunities;

31. Stresses the need to continue with programmes designed to encourage entrepreneurship among young people through the creation of special business start-up opportunities for them, accompanied by increased access to European funding and business advice;

32. Welcomes the Commission's legislative proposal to create a Single Resolution Mechanism (including a Single European Authority and an industry-financed Single European Fund), which is essential for completing the Banking Union; calls for the Member States, the Commission and Parliament to agree swiftly on the creation of the Single Resolution Mechanism; urges the Council to rapidly conclude negotiations with Parliament on the Deposit Guarantee Schemes Directive and on the Banking Recovery and Resolution Directive (to be negotiated in parallel);

33. Calls for direct banking recapitalisation by the European Stability Mechanism (ESM) to be available as soon as the Single Supervisory Mechanism (SSM) is in place, as announced by the Heads of State and Government of the eurozone in their June 2012 declaration; given the urgency of having a Single Resolution Fund to accompany the SSM, supports the immediate establishment of a backstop mechanism, with a reimbursement period by industry; asks the Commission to put forward a proposal to bring the ESM under the Community acquis while providing for comprehensive European Parliament democratic accountability;

34. Welcomes the Commission's 'Action Plan to strengthen the fight against tax fraud and tax evasion' and its recommendations on 'measures intended to encourage all EU Member States and third countries to apply minimum standards of good governance in tax matters' and on 'aggressive tax planning', adopted on 6 December 2012; recalls Parliament's resolution of 21 May 2013 on the fight against tax fraud, tax evasion and tax havens, which identified further measures that needed to be taken in the field of tax fraud, tax evasion, aggressive tax planning and tax havens; stresses that

Wednesday 23 October 2013

fairness and justice in burden sharing require a reinforced approach to tax fraud and evasion; calls for urgent action and a comprehensive strategy based on concrete legislative measures by the Commission to fight tax fraud and tax evasion and for clear support from the Council on all blocked or pending dossiers related to taxation;

35. Calls on the Council to conclude the negotiations for the Financial Transaction Tax, to urge the introduction of the tax throughout Europe and to include in its agenda, as a matter of urgency, measures to close the tax gap, tackle tax havens and work on convergence of tax systems within the EU;

36. Believes that the introduction of the Financial Transaction Tax, to be pursued through enhanced cooperation, should be regarded as the first step towards its introduction worldwide;

37. Calls for the full and urgent application of the 6-pack and of the 2-pack, with the aim of reshaping the ad hoc system of 'troikas' into a legally sound structure under Community law, guaranteeing democratic accountability; urges the Troika to revise its communication strategy, which has repeatedly proved to be a disaster; stresses that, in the medium term, a purely European system would be preferable and that the Commission should draw up proposals to reshape the 'troika' model adequately;

38. Recalls that the President of the European Council, Herman Van Rompuy, confirmed in his remarks to Parliament on 1 February 2012 that the ESM's operation would be subject to the scrutiny of the European Parliament; to this end, looks forward to the negotiation of an arrangement with the Eurogroup providing, inter alia, for the possibility of organising hearings and addressing written questions to the ESM's Managing Director and Board of Governors;

39. Stresses that the European Semester must in no way jeopardise the prerogatives of the European Parliament and of the national parliaments; urges the Commission to ensure the proper formal involvement of the European Parliament in all the steps of the European Semester process in order to increase the legitimacy of decisions which affect all citizens; calls on the Commission to find ways to increase the visibility of the process;

40. Stresses the need to strengthen the democratic accountability to the European Parliament and to the national parliaments of essential elements of the euro area's operation, such as the ESM, Eurogroup decisions and the monitoring and evaluation of financial assistance programmes; asks the Commission, in this connection, to conduct and publish internal ex-post evaluations of its recommendations and its participation in the Troika;

41. Urges the Member States to actively involve their national parliaments, the social partners and civil society in the European Semester process as a whole, and particularly in the development, discussion, monitoring and evaluation of their national reform programmes; urges the Commission to ensure that involvement; stresses that the engagement of all stakeholders in the development of the necessary reforms is crucial to their delivery and success;

42. Emphasises the importance of the dialogue between the European Parliament and national parliaments with a view to achieving a fully operational European Semester process and attaining the necessary level of democratic accountability with regard to all those involved; underlines the usefulness of the European Parliamentary Week on the European Semester for Economic Policy Coordination (EPW 2013);

43. Regrets the fact that the Council position on the country-specific recommendations proposed by the Commission was not made public in real time; regrets the fact that the European Council's deliberations on the Council position on the country-specific recommendations were not made public in real time;

44. Stresses that there should be a clear division between EU and national competences and that the European Parliament is the seat of accountability at Union level; requests that, whenever new competences are transferred to or created at Union level or new Union institutions are established, corresponding democratic scrutiny by, and accountability to, the European Parliament be ensured;

### ***Sectoral contributions to the European Semester 2013***

#### ***Employment and social policies***

45. Considers the Commission's recognition of the need to reduce taxes on employment in favour of other sources of income to be a positive development, which will speed up the fiscal consolidation process on a fairer basis;

**Wednesday 23 October 2013**

46. Recognises that this year's country specific recommendations (CSRs) are particularly important because the Member States are defining their investment priorities for cohesion policy in the next Multiannual Financial Framework (MFF); calls, in this connection, for increased targeting of EU funding on all priorities under the Europe 2020 strategy, in particular through growth and employment policies, including combating youth unemployment and long-term unemployment, and creating lasting jobs which are not precarious, entail the compulsory payment of social security contributions and are adequately remunerated; expresses its concern at the increasing social and economic divergences among Member States;

47. Notes that several Member States have adopted major labour market reforms aimed at improving the labour market's resilience, introducing more internal and external flexibility, reducing segmentation and facilitating transition between jobs; stresses that labour reforms should be carried out with adequate consensus among the social partners;

48. Asks the Member States and the Commission, in its policy guidance and CSRs, to ensure that the necessary flexibility that is needed on the labour market is balanced with adequate levels of social protection which are characteristic of our socialmarket economy, and that labour market reforms aim at promoting high levels of employment quality in work, improving social risk management, achieving progress in the inclusion of vulnerable groups in the labour market, reducing in-work poverty, reconciling work and family life, promoting gender equality, promoting health and safety at work, strengthening the rights of workers with atypical contracts and improving social protection for self-employed workers;

49. Notes that all the Member States received recommendations with regard to levels of labour market participation; calls on those Member States with low levels of labour market participation to step up, in consultation with the social partners, active, comprehensive and inclusive labour market measures, such as training and employment services, and to introduce further reforms to facilitate access to quality employment, facilitate the reconciliation of work and private life, prevent early withdrawal from the labour market, improve competitiveness and combat labour market segmentation, as well as matching workers' skills with labour market requirements;

50. Points out that the situation of unemployed young people is particularly worrying and that urgent action is needed; calls for a European Pact for Youth Employment to put into effect the long-agreed measures and for new resources and measures to be committed to tackling youth unemployment, reducing the number of young people not in employment, education or training (NEET) and poverty among young people, taking into account the qualitative aspect of decent work fully respecting core labour standards;

51. Looks forward to the frontloading of the Youth Employment Initiative in accordance with the Committee on Employment and Social Affairs' callthrough its amendments to the Common Provisions Regulation (CPR);

52. Welcomes the adoption of the Youth Guarantee by the Council and the earmarking of EUR 6 billion for the Youth Employment Initiative under the next MFF; calls on the Member States to urgently implement Youth Guarantee Schemes and use available resources in an efficient way, concentrating activities on those in the most difficult situation;

53. Notes with satisfaction that these funds can be used during the first two years of the next MFF; stresses that this amount is, however, insufficient to combat youth unemployment in a lasting manner and that it should form merely an initial tranche with which to combat youth unemployment;

54. Encourages the Commission to continue the work of the Youth Employment Action Teams to help the Member States with the highest levels of youth unemployment to reprogramme EU structural funding under the 2007-2013 MFF in order to target it at young people; welcomes the Commission's intention to build on the European Job Mobility Portal (EURES) by intensifying and broadening its activities and, in particular, by promoting youth mobility; notes, however, that mobility must remain voluntary and that efforts to create jobs and training places on the spot must not be limited by it;

55. Calls on the Commission to propose a quality framework for traineeships comprising, inter alia, criteria for proper remuneration, learning outcomes, working conditions and health and safety standards; calls on the Commission, the Member States and the EU social partners to implement the Alliance for Apprenticeships in an ambitious manner;

Wednesday 23 October 2013

56. Believes there is an urgent need, given the numbers of workers, particularly young people, departing their countries of origin for other EU countries in search of employment opportunities, to develop appropriate measures to revise European law in order to guarantee the portability of pension rights and, for a period of at least three months, the continuation of employment benefits while searching work in another Member State; welcomes the improvements to the European mobility portal and calls for a specific strategy to be drafted for it together with the Member States;

57. Welcomes the fact that for the first time some CSRs address the particular situation of Member States regarding poverty; strongly condemns the fact that no CSR specifically addresses the case of labour markets from which women are excluded and where no measure is foreseen to include them;

58. Stresses that specific action is needed to increase the labour participation of women, older workers and workers with disabilities by ensuring that there are efficient incentives to return to, and stay in, work; recalls that the quality, affordability and accessibility of services related to early childhood education, childcare and eldercare play a crucial role;

59. Stresses that the long-term unemployed should be supported by job creation and integrated active inclusion approaches, including positive activation incentives such as personalised guidance and welfare-to-work programmes, adequate benefit systems and access to quality services in order to support them in reconnecting with the labour market and accessing quality jobs;

60. Recalls the skills mismatches and bottlenecks in many regions and sectors and the inability of certain education and training systems to cope with market demands and workers' needs in this context; welcomes the reforms to vocational education and training systems undertaken by several Member States in order to adapt skills and competences to the labour market and to future workers' needs, especially those of young people; stresses, in this context, the advantages of dual training systems; recalls that almost all Member States need to take further action and invest more in education and training, research, innovation and development;

61. Notes that, in addition to reform of the education and training sector, a long-term sustainable, criteria-based immigration strategy is needed to respond to the shortage of skilled labour and to demographic change;

62. Notes that the crisis has had a severe and lasting impact on the Member States' levels of unemployment and their social situation, which has led to unsustainable increases in poverty and social exclusion, including child poverty, homelessness, social inequality, in-work poverty and over-indebtedness of households; calls, in this context, on the Member States to reinforce safety nets and ensure the effectiveness of the welfare systems that deal with those affected, as well as to invest in preventive measures;

#### *Budgetary policies*

63. Recalls the fact that, despite it being too modest in size in absolute and relative terms when compared with the Union's economic wealth, the EU budget has important added value as a tool in promoting the Europe 2020 objectives, considering its role as a catalyst for investment;

64. Regrets the fact that the Member States are continuing to underestimate the role and contribution of the EU budget in strengthening economic governance and budget coordination throughout the Union; urges the Council, in this connection and with due regard for the joint declaration signed by Parliament, the Council and the Commission in December 2012 and to Parliament's resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework (MFF) 2014-2020, to adopt in full any amending budget for 2013 submitted by the Commission which may still be needed over the course of the year, in order to close the current Multiannual Financial Framework period with a clean balance sheet;

65. Reiterates that the compromise reached at the European Council meeting of 8 February 2013 on the MFF 2014-2020 did not match Parliament's expectations; insists that any agreement on such a low level could only be acceptable on the terms set out in its resolution of 3 July 2013;

**Wednesday 23 October 2013**

66. Is convinced that a credible EU contribution to ending the current crisis must be based on a fundamental shift in the way the EU budget is financed, i.e. towards genuine own resources;

67. Urges the Member States to do their utmost to decide in a timely manner on their national programming for the Structural Funds and the Cohesion Fund, in order to avoid delays in using these funds, whose aim is to support growth and job creation;

68. Stresses the importance of science and innovation for the strategic development of competitiveness and, therefore, job creation at European level in order to overcome the economic and financial crisis;

#### *Internal market*

69. Recalls that the Single Market is a key driver for growth and jobs and has an indispensable role to play in meeting the objectives of the Europe 2020 strategy for smart, sustainable and inclusive growth; notes, however, that this potential remains untapped in many respects;

70. Recalls that the full economic and job potential of the services sector remains untapped; calls for full and appropriate implementation of the EU Services Directive whilst safeguarding public service obligations which can ensure universal access to affordable quality services for all; calls on the Member States to invest particularly in quality social services; notes, at the same time, that wage and social standards must be complied with; calls on the Member States to remove barriers in the retail sector and excessive restrictions in professional services and regulated professions; calls, at the same time, for the removal of barriers to the free movement of workers in order to improve mobility and optimise the use of EU human capital;

71. Welcomes the fact that, in the European Semester 2013, the Annual Growth Survey has for the first time been underpinned by a report on the state of single market integration;

72. Regrets, however, that, despite the strong evidence for the importance of the single market in overcoming the crisis, the 2013 country-specific recommendations do not sufficiently address the growth, consumer-confidence and jobs potential of the proper implementation and enforcement of single market rules;

73. Supports the emphasis in this year's country-specific recommendations on the importance of removing unjustified restrictions and barriers to entry in the services sectors; urges the Member States concerned to give those recommendations their utmost consideration and to remove, with urgent priority, these obstacles to the growth of the single market;

74. Calls on the Commission to make single market governance a priority in its next Annual Growth Survey and in the European Semester 2014, and, in the next country-specific recommendations, to take full account of the key growth areas — identified as the services sector, the energy sector, the transport sector and the digital single market — and of the measures included in the Single Market Acts I and II;

75. Regrets the fact that the lack of national and European investment is impeding the achievement of the priority goals and objectives in the key areas of energy, transport and digital market indicated in the report on the 'State of the Single Market Integration 2013 — Contribution to the Annual Growth Survey 2013';

76. Urges the Member States and the Commission, in the meantime, to step up their efforts to enforce single market legislation and to monitor this enforcement, inter alia through regular EU sweeps;

77. Reiterates its call on the Commission to strengthen single market governance by establishing, as a specific pillar of the European Semester, an annual Single Market governance cycle that includes the Internal Market Scoreboard, an annual report on the integration of the Single Market as part of the Annual Growth Survey, European Council guidance to Member States, national action plans aimed at implementing the Single Market guidelines, and dedicated country-specific recommendations;

78. Is greatly concerned by the persistent uncertainty of private investors, their lack of confidence and their reluctance to invest, in particular as a consequence of productivity standards with persisting single market fragmentation and changes in industrial policy; deplores the fact that, as a consequence of the crisis, a low-confidence environment is making both private investors and financial sector institutions highly risk-averse and reiterates that the work to reinforce the banking sector should continue;

Wednesday 23 October 2013

*Regional policies*

79. Is deeply concerned by the sharp downturn in public and private investment in the productive economy and especially at local and regional level; takes the view that decisive measures are needed to reform product and labour markets, adopt cautious wage policies and base the future growth model on innovation and shift production towards high value-added activities; takes the view that a sustainable economic policy depends on very favourable conditions for business start-ups; expresses its firm belief that the Structural and Investment Funds are essential in order to prevent and mitigate any shortfall in the aforementioned respects and to boost public investment; points to the opportunities which could be used in the Member States to support public investment from the Structural Funds by giving the financial procedures for these funds a degree of flexibility, e.g. by increasing the co-financing rates of states which become involved in an adjustment programme and receive EU financial assistance or by prolonging the decommitment rule by one year for all Member States in the programming period 2007-2013 (as will be the case in the programming period 2014-2020);

80. Considers that the involvement of regional and local authorities in the planning and implementation of relevant programmes, in particular the Europe 2020 strategy, should be increased, in order to enhance their sense of responsibility for the strategy's goals at all levels and ensure greater awareness on the ground of its objectives and results;

*Women's rights and gender equality*

81. Welcomes the country-specific recommendations (CSRs) regarding measures to improve childcare facilities, to remove disincentives for second earners, to harmonise the statutory retirement age for men and women, to accommodate the need to combine work and private life, in particular by improving access to new technologies and to training in their use, and to eliminate gender and pension gaps; expresses its concern at the fact that many of these recommendations were already laid down in 2012, indicating a lack of implementation in Member States;

82. Stresses that Member States should improve the participation rate of children and young adults in educational systems and should put more focus on the problem of early school leaving, especially by collecting information on its main causes with a view to adopting and implementing policies for its prevention;

83. Calls on the Commission and the Member States to take due account of gender-related targets in national employment programmes, paying particular attention to women with elderly dependents, single mothers and women having children with disabilities; calls, furthermore, for proper attention to be paid to the issue of early school leaving, given the sharp rise in the number of children who drop out of education between the ages of 10 and 16 and the loss of resources that this clearly represents for the EU as a whole;

84. Calls on the Commission, in its upcoming Annual Growth Survey, to raise the issue of specific policy guidelines on reducing gender inequalities, including, in particular, guidelines on closing the gender pay gap — which often results in women finding themselves below the poverty line at a later stage of their lives — as well as the gender pension gap, on increasing the participation of women in the labour market and on combating gender segregation in the labour market, since the future prosperity of the EU depends crucially on its ability to fully utilise its labour resources;

85. Points to the importance of gender budgeting with a view to examining all government programmes and policies, their effects on resource allocation, and their contribution to equality between women and men;

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86. Instructs its President to forward this resolution to the European Council, the governments of the Member States, the Commission, the national parliaments and the European Central Bank.

Wednesday 23 October 2013

P7\_TA(2013)0448

## **Migratory flows in the Mediterranean, with particular attention to the tragic events off Lampedusa**

**European Parliament resolution of 23 October 2013 on migratory flows in the Mediterranean, with particular attention to the tragic events off Lampedusa (2013/2827(RSP))**

(2016/C 208/13)

*The European Parliament,*

- having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms,
- having regard to the Universal Declaration of Human Rights of 1948,
- having regard to the Geneva Conventions of 1949 and the additional protocols thereto,
- having regard to the statement of the United Nations High Commissioner for Refugees (UNHCR) of 12 October 2013,
- having regard to the Parliamentary Assembly of the Council of Europe (PACE) in its April 2012 report ‘Lives lost in the Mediterranean Sea’,
- having regard to previous statements by and the latest report, published in April 2013, of the UN Special Rapporteur on the Human Rights of Migrants on the management of the EU’s external borders and its impact on the human rights of migrants,
- having regard to its resolution of 9 October 2013 on EU and Member State measures to tackle the flow of refugees as a result of the conflict in Syria <sup>(1)</sup>,
- having regard to Regulation (EU) No 439/2010 of the European Parliament and of the Council of 19 May 2010 establishing a European Asylum Support Office <sup>(2)</sup>,
- having regard to the proposal for a regulation of the European Parliament and of the Council establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (COM(2013)0197),
- having regard to Regulation (EU) No 1168/2011 of the European Parliament and of the Council of 25 October 2011 amending Council Regulation (EC) No 2007/2004 establishing a European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union <sup>(3)</sup>,
- having regard to the position of the European Parliament adopted at first reading on 10 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council establishing the European Border Surveillance System (EUROSUR) <sup>(4)</sup>,
- having regard to the Joint Communication of the Commission and of the High Representative of the Union for Foreign Affairs and Security Policy of 20 March 2013 entitled ‘European Neighbourhood Policy: Working towards a Stronger Partnership’ (JOIN(2013)0004),

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<sup>(1)</sup> Texts adopted, P7\_TA(2013)0414.

<sup>(2)</sup> OJ L 132, 29.5.2010, p. 11.

<sup>(3)</sup> OJ L 304, 22.11.2011, p. 1.

<sup>(4)</sup> Texts adopted, P7\_TA(2013)0416.

Wednesday 23 October 2013

- having regard to its resolution of 7 April 2011 on the ‘review of the European Neighbourhood Policy — Southern Dimension’ <sup>(1)</sup>,
  - having regard to Directive 2008/115/EC of the European Parliament and of the Council of 16 December 2008 on common standards and procedures in Member States for returning illegally staying third-country nationals <sup>(2)</sup>,
  - having regard to Council Decision 2009/371/JHA of 6 April 2009 establishing the European Police Office (Europol) <sup>(3)</sup>,
  - having regard to Oral Question O-000021/2013 — B7-0119/2013 of 25 February 2013 on a voluntary permanent Union relocation scheme,
  - having regard to the report of its Committee on Civil Liberties, Justice and Home Affairs on the visit by its delegation to Lampedusa in November 2011,
  - having regard to the visit to Lampedusa by Commission President José Manuel Barroso and Home Affairs Commissioner Cecilia Malmström of 9 October 2013 and the related debate in plenary, held on the same day, on EU migratory policies in the Mediterranean, with particular attention to the tragic events off Lampedusa,
  - having regard to its resolution of 23 October 2013 on organised crime, corruption and money laundering: recommendations on action and initiatives to be taken <sup>(4)</sup>, with particular reference to the fight against human trafficking and death traffickers,
  - having regard to Articles 77, 78, 79 and 80 of the Treaty on the Functioning of the European Union (TFEU), and to Articles 18 and 19 of the EU Charter of Fundamental Rights,
  - having regard to Rule 110(2) and (4) of its Rules of Procedure,
- A. whereas the latest tragedies off Lampedusa left at least 360 migrants dead, with many more missing;
- B. whereas at least 20 000 persons have died at sea since 1993 according to the International Organisation for Migration, pointing once more to the need to do everything possible to save the lives of people in danger and to the need for Member States to abide by their international sea-rescue obligations;
- C. whereas there is still a lack of clarity at EU level regarding the division of responsibility among the various entities involved in rendering assistance to vessels in distress, and regarding responsibility for coordinating search and rescue operations;
- D. whereas smugglers and human traffickers exploit irregular migration, and victims are forced, lured or deceived into coming to Europe by criminal networks, and whereas those networks pose a serious risk to the lives of migrants and a challenge for the EU;
- E. whereas the principle of solidarity and fair sharing of responsibility is laid down in Article 80 of the TFEU;
- F. whereas the new revised Common European Asylum System (CEAS) aims to provide clearer rules and to guarantee fair and adequate protection of people in need of international protection;
- G. whereas EU legislation provides some tools, such as the Visa Code and the Schengen Borders Code, which make it possible to grant humanitarian visas;

<sup>(1)</sup> OJ C 296 E, 2.10.2012, p. 114.

<sup>(2)</sup> OJ L 348, 24.12.2008, p. 98.

<sup>(3)</sup> OJ L 121, 15.5.2009, p. 37.

<sup>(4)</sup> Texts adopted, P7\_TA(2013)0444.

**Wednesday 23 October 2013**

- H. whereas the Member States should be encouraged to make use of the funds that will be available from the Asylum and Migration Fund and of the funds available under the Preparatory Action to 'Enable the resettlement of refugees during emergency situations', which covers, among other things, the following measures: supporting persons already recognised as refugees by the Office of the UN High Commissioner for Refugees (UNHCR); supporting emergency action in the case of groups of refugees, identified as priorities, who are under armed attack and who face conjunctures of extreme vulnerability and of a life-threatening nature; providing, where needed, extra financial support during emergencies to the UNHCR and to its liaison organisations in the Member States and at EU level;
- I. whereas a new 'Mare Nostrum' patrolling, rescue and surveillance operation has been launched by Italy to enhance the humanitarian rescue activities in the Mediterranean;
- J. whereas during his recent visit to Lampedusa President Barroso pledged EUR 30 million in EU funds to support the local population;
1. Expresses deep sadness and regret at the tragic loss of life in Lampedusa; urges the European Union and the Member States to do more to prevent further loss of life at sea;
  2. Is of the opinion that Lampedusa should be a turning point for Europe and that the only way of preventing another tragedy is to adopt a coordinated approach based on solidarity and responsibility, with the support of common instruments;
  3. Calls for humanitarian assistance to survivors of such tragic events, and asks that the EU and the Member States be committed to guaranteeing migrants' universal fundamental rights, in particular the rights of unaccompanied minors;
  4. Recognises the huge efforts made by the inhabitants of Italy and Malta, and especially Lampedusa, and by non-governmental organisations such as Caritas and the Red Cross as regards the initial reception of, and rescue operations for, all immigrants;
  5. Welcomes the Commission's intention to establish a task force on the issue of migratory flows in the Mediterranean; considers that this task force should comprise both a political and an operational element; insists, in this connection, that Parliament should be involved in such a task force at either a political or a technical level; insists also that the establishment of such a task force can be considered only to be a first step towards a more ambitious approach;
  6. Asks for an increase in the budget for the European Asylum Support Office (EASO) and for the European Agency for the Management of Operational Cooperation at the External Borders of the Member States (Frontex) in order to assist Member States in circumstances requiring increased technical and operational assistance at the external borders, including situations which involve humanitarian emergencies and rescue at sea; recalls that the proper funding of these agencies is vital in order to develop a coordinated approach; calls also on Member States to increase their practical cooperation with EASO and Frontex, including through aid in kind (posted officers, material support, etc.); asks the Council and the Commission to consider the possibility of establishing an EU coast guard and of setting up another Frontex operational office in areas of migratory pressure, and in particular in the Mediterranean region, with related costs covered by the Member State selected;
  7. Underlines the importance of responsibility-sharing in the field of asylum, and recommends creating a mechanism based on objective criteria to reduce the pressure on those Member States receiving higher numbers of asylum seekers and beneficiaries of international protection, in either absolute or proportional terms;
  8. Stresses that the relocation of beneficiaries of international protection and asylum seekers is one of the most concrete forms of solidarity and responsibility-sharing; stresses the importance of projects such as the Pilot Project for Intra-EU Relocation from Malta (EUREMA) and the extension thereof, under which beneficiaries of international protection have been, and are being, relocated from Malta to other Member States, and advocates developing more initiatives of this kind;
  9. Welcomes the Commission's proposals to deploy a search-and-rescue operation from Cyprus to Spain and to strengthen Frontex by increasing its budget and capabilities in order to save lives and combat human trafficking and smuggling;

Wednesday 23 October 2013

10. Calls on the co-legislators to agree swiftly on new binding interception rules for Frontex-coordinated operations at sea in order to achieve effective and coordinated rescue measures at EU level and to ensure that operations are conducted in full compliance with relevant international human rights and refugee law and standards, and obligations under the Law of the Sea;
11. Calls for the Union and its Member States to consider the possibility of establishing mechanisms for identifying places of safety for the disembarkation of rescued refugees and migrants;
12. Calls for the Union and its Member States to establish profiling and referral mechanisms, including access to fair and efficient asylum procedures for those who may be in need of international protection, based on the understanding that disembarkation does not necessarily imply sole responsibility on the part of the state on whose territory people rescued at sea are disembarked;
13. Calls on the Member States to make sure that all the provisions of the various CEAS instruments are correctly implemented; reminds the Member States that people who are seeking international protection should be referred to competent national asylum authorities and have access to fair and efficient asylum procedures;
14. Calls on the Member States to consider, where necessary, applying Article 3(2) of Regulation (EU) No 604/2013 <sup>(1)</sup> in order to assume responsibility for the asylum claims of people who are at risk of being unable to enjoy access to their rights in any Member State unable to fulfil its obligations; affirms that, similarly, the Member States should consider applying Article 15 of the aforementioned regulation in order to bring extended family members together;
15. Calls on Frontex and the Member States to ensure that all border guards and other personnel of the Member States who participate in the European Border Guard Teams, along with Frontex staff, receive training in relevant Union and international law, including fundamental rights, in accordance with Article 5 of the revised Frontex Regulation;
16. Calls for the EU and its Member States to monitor mixed migratory flows by using the available European and national instruments, and to maintain good coordination and communications, such as the facilitation of information-sharing between national coast guards;
17. Calls on the Union, Frontex and the Member States to ensure that assisting migrants in distress and rescue at sea are among the key priorities of the implementation of the newly adopted EUROSUR Regulation;
18. Calls, as a matter of priority, for better coordination of EU means and resources including those at the disposal of Frontex (such as EUROSUR) and Europol, in order to step up, together with third countries, the fight against the criminal networks of human traffickers and smugglers;
19. Recalls that EU solidarity should go hand in hand with responsibility; recalls that the Member States have a legal obligation to come to the assistance of migrants at sea;
20. Urges the Member States to use their prerogative to rescue lives at sea in accordance with their international obligations;
21. Expresses concern that a growing number of people are risking their lives by embarking on dangerous boat crossings across the Mediterranean to the EU; calls on the Member States to take measures to enable asylum seekers to access the Union asylum system in a safe and fair manner;
22. Notes that legal entry into the EU is preferable to a more dangerous irregular entry, which could entail human trafficking risks and loss of life;
23. Calls for a more holistic approach to migration in order to ensure that issues interlinked with migration can be dealt with in a comprehensive manner;
24. Encourages the EU to develop a more comprehensive strategy, in particular for the Mediterranean, which places labour migration within the context of the social, economic and political development of its neighbourhood; calls for the EU and its Member States to consider the tools available under the EU's visa policy and EU labour migration legislation;

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<sup>(1)</sup> OJ L 180, 29.6.2013, p. 31.

**Wednesday 23 October 2013**

25. Calls on the Member States to lay down strong criminal sanctions for those individuals who facilitate human trafficking both into and across the EU, and to set up wide-ranging information campaigns to raise awareness of the kinds of risks faced by those who put their lives into the hands of traffickers and smugglers;
  26. Calls for the EU and the Member States to amend or review any legislation sanctioning people assisting migrants in distress at sea; calls on the Commission to review Council Directive 2002/90/EC, which defines the sanctions in the event of facilitation of unauthorised entry, transit and residence in order to clarify that the provision of humanitarian assistance to migrants at sea who are in distress is to be welcomed, and is not an action which should ever lead to any form of sanction;
  27. Calls for better, more efficient cooperation between the EU and third countries to prevent a repetition of such tragic occurrences as those off Lampedusa; considers agreements on migration management between the EU and transit countries to the EU to be a priority for the Union in the near future, including the funding of police facilities and training in law enforcement capabilities, and assistance for these countries — and migrants' countries of origin — to diversify and improve their economies, and stresses the need for third countries to respect international law with regard to saving lives at sea, and to ensure the protection of refugees and respect for fundamental rights;
  28. Calls for the EU to continue to offer humanitarian, financial and political assistance in crisis areas in North Africa and the Middle East in order to tackle the root causes of migration and humanitarian pressures; calls on the EU, therefore, to monitor and make more democratically accountable the distribution of that funding, in order for such resources to have a positive effect, which has so far been lacking;
  29. Calls for the EU and the Member States to take appropriate, responsible measures regarding a possible influx of refugees into the Member States; calls on the Commission and the Member States to continue to monitor the current situation and to work on contingency planning, capacity building, policy dialogue, and the upholding of their human rights obligations regarding detention conditions;
  30. Calls on the Member States to respect the principle of non-refoulement, in compliance with existing international and EU law; calls on the Member States to put an immediate end to any improper and extended detention practices in violation of international and European law, and points out that measures to detain migrants must always be subject to an administrative decision, and must be duly substantiated and temporary;
  31. Encourages the Member States to address acute needs through resettlement in addition to existing national quotas and through humanitarian admission;
  32. Instructs its President to forward this resolution to the Council, the Commission, the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy, the parliaments and governments of the Member States, the Secretary-General of the United Nations and the UN High Commissioner for Refugees.
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Wednesday 23 October 2013

P7\_TA(2013)0449

**Suspension of the SWIFT agreement as a result of NSA surveillance****European Parliament resolution of 23 October 2013 on the suspension of the TFTP agreement as a result of US National Security Agency surveillance (2013/2831(RSP))**

(2016/C 208/14)

*The European Parliament,*

- having regard to Article 16 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to Article 87 TFEU,
- having regard to Article 225 TFEU,
- having regard to Article 226 TFEU,
- having regard to Article 218 TFEU,
- having regard to Article 234 TFEU,
- having regard to Article 314 TFEU,
- having regard to the Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for the purposes of the Terrorist Finance Tracking Program (TFTP Agreement),
- having regard to its resolution of 4 July 2013 on the US National Security Agency surveillance programme, surveillance bodies in various Member States and their impact on EU citizens' privacy <sup>(1)</sup>,
- having regard to Council Decision 2010/412/EU of 13 July 2010 on the conclusion of the Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for the purposes of the Terrorist Finance Tracking Program <sup>(2)</sup> and the accompanying declarations by the Commission and the Council,
- having regard to its resolution of 17 September 2009 on the envisaged international agreement to make available to the United States Treasury Department financial payment messaging data to prevent and combat terrorism and terrorist financing <sup>(3)</sup>,
- having regard to its position of 11 February 2010 on the proposal for a Council decision on the conclusion of the Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for purposes of the Terrorist Finance Tracking Program <sup>(4)</sup>,
- having regard to its resolution of 5 May 2010 on the Recommendation from the Commission to the Council to authorise the opening of negotiations for an agreement between the European Union and the United States of America to make available to the United States Treasury Department financial messaging data to prevent and combat terrorism and terrorist financing <sup>(5)</sup>,

<sup>(1)</sup> Texts adopted, P7\_TA(2013)0322.

<sup>(2)</sup> OJ L 195, 27.7.2010, p. 3.

<sup>(3)</sup> OJ C 224 E, 19.8.2010, p. 8.

<sup>(4)</sup> OJ C 341 E, 16.12.2010, p. 100.

<sup>(5)</sup> OJ C 81 E, 15.3.2011, p. 66.

**Wednesday 23 October 2013**

- having regard to its position of 8 July 2010 on the draft Council decision on the conclusion of the Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for the purposes of the Terrorist Finance Tracking Program <sup>(1)</sup>, and to the recommendation of its Committee on Civil Liberties, Justice and Home Affairs,
  - having regard to the Commission reports of 30 March 2011 (SEC(2011)0438) and of 14 December 2012 (SWD(2012) 0454) on the joint review of the implementation of the Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for the purposes of the Terrorist Finance Tracking Program,
  - having regard to the report of 1 March 2011 on the inspection of Europol's implementation of the TFTP Agreement, conducted in November 2010 by the Europol Joint Supervisory Body,
  - having regard to the Europol Joint Supervisory Body's public statement of 14 March 2012 on the implementation of the TFTP Agreement,
  - having regard to the assessment of 18 March 2013 by the Europol Joint Supervisory Body of the outcome of its third inspection of Europol's implementation of its tasks under the TFTP Agreement,
  - having regard to the letter of 18 April 2011 from Paul Breitbarth, of the Dutch Data Protection Authority, to the Head of Delegation of the EU Joint Review Team TFTP,
  - having regard to the letter of 7 June 2011 from Jacob Kohnstamm, on behalf of the Article 29 Data Protection Working Party, to Ms Melissa A. Hartman, Deputy Assistant Secretary, US Department of the Treasury,
  - having regard to the letter of 21 December 2012 from Jacob Kohnstamm, on behalf of the Article 29 Data Protection Working Party, to Juan Fernando López Aguilar, Chair of the Committee on Civil Liberties, Justice and Home Affairs,
  - having regard to the letter of 12 September 2013 from Commissioner Malmström to David Cohen, Under-Secretary of the US Department of the Treasury for Terrorism and Financial Intelligence, and to Under-Secretary Cohen's answer of 18 September 2013,
  - having regard to the Commission communication of 13 July 2011 entitled 'A European terrorist finance tracking system: available options' (COM(2011)0429),
  - having regard to Written Questions E-011200/2010, E-002166/2011, E-002762/2011, E-002783/2011, E-003148/2011, E-003778/2011, E-003779/2011, E-004483/2011, E-006633/2011, E-008044/2011, E-008752/2011, E-000617/2012, E-002349/2012, E-003325/2012, E-007570/2012 and E-000351/2013,
  - having regard to Rule 110(2) and (4) of its Rules of Procedure,
- A. whereas the Agreement between the European Union and the United States of America on the processing and transfer of Financial Messaging Data from the European Union to the United States for the purposes of the Terrorist Finance Tracking Program (hereinafter 'the Agreement') entered into force on 1 August 2010;
- B. whereas press reports indicate that the US National Security Agency (NSA) has had direct access to the IT systems of a number of private companies and gained direct access to financial payment messages referring to financial transfers and related data by a provider of international financial payment messaging services currently covered by the Agreement;

<sup>(1)</sup> OJ C 351 E, 2.12.2011, p. 453.

Wednesday 23 October 2013

- C. whereas in its aforementioned resolution of 4 July 2013 Parliament instructed its Committee on Civil Liberties, Justice and Home Affairs to conduct an in-depth inquiry into the matter in collaboration with national parliaments and the EU-US expert group set up by the Commission and to report back by the end of the year;
- D. whereas, having rejected the temporary TFTP Agreement, a majority of the European Parliament gave its consent to the current TFTP Agreement only on account of the strengthened protection it afforded with a view to safeguarding EU citizens' personal data and privacy rights;
- E. whereas the US Treasury has classified a large quantity of relevant information regarding this Agreement as 'EU Secret';
- F. whereas, according to the Article 29 Data Protection Working Party, the current procedure for exercising the right of access may not be adequate and in practice it may not be possible to exercise the right to rectification, erasure and blocking;
- G. whereas the Commission has stated that while the Agreement sets out strict safeguards regarding the transfer of data;
- H. whereas the Commission was invited to submit to Parliament and the Council, no later than 1 August 2011, a legal and technical framework for the extraction of data on EU territory and, no later than 1 August 2013, a progress report on the development of an equivalent EU system under Article 11 of the Agreement;
- I. whereas instead of submitting the legal and technical framework for the extraction of data on EU territory, on 13 July 2011 the Commission presented a description of the different steps it has taken to move towards establishing such a legal and technical framework, communicating preliminary results and some theoretical options for a European terrorist finance tracking system without going into detail;
- J. whereas talks between Commission services and the US administration cannot be considered to count as an investigation, and nor does mere reliance on statements by the US;
1. Takes the view, given that the EU's core aim is to promote freedom of the individual, that security measures, including counterterrorism measures, must be pursued through the rule of law and must be subject to fundamental rights obligations, including those relating to privacy and data protection;
  2. Reiterates that any transfer of personal data must comply with EU and Member State law and with fundamental rights obligations, including those relating to privacy and data protection;
  3. Is seriously concerned about recently revealed documents on the NSA's activities as regards direct access to financial payment messages and related data, which would constitute a clear breach of the Agreement, in particular Article 1 thereof;
  4. Calls for a full on-site technical investigation into allegations that the US authorities have had unauthorised access or created possible back doors in the SWIFT servers; deplores the fact that no Member State has launched, or asked for, an investigation, in the absence of which the facts cannot be verified;
  5. Reiterates the need to base any data sharing agreement with the US on a coherent legal data protection framework offering legally binding personal data protection standards, including with regard to purpose limitation, data minimisation, information, access, correction, erasure and redress;
  6. Is concerned that the Agreement has not been implemented in accordance with its provisions, in particular those laid down in Articles 1, 4, 12, 13, 15 and 16 thereof;
  7. Strongly urges the three institutions to deliberate carefully on the human rights implications of any future data exchange alternatives which fully respect data protection principles, especially the necessity and proportionality test;

**Wednesday 23 October 2013**

8. Points out that the test of the necessity and proportionality of any measure that limits fundamental rights and freedoms needs to take into account the entire body of existing security measures targeting terrorism and serious crime; believes that blanket justification of every security measure by a general reference to the fight against terrorism or serious crime is not sufficient;
  9. Asks the Council and the Member States, in the light of the above, to authorise an investigation by the Europol Cybercrime Centre into the allegations of unauthorised access to financial payment data governed by the Agreement;
  10. Calls on the special inquiry by the Committee on Civil Liberties, Justice and Home Affairs into the mass surveillance of EU citizens to further investigate the allegations of unlawful access to financial payment messages covered by the Agreement;
  11. Considers that, although Parliament has no formal powers under Article 218 TFEU to initiate the suspension or termination of an international agreement, the Commission will have to act if Parliament withdraws its support for a particular agreement; points out that, when considering whether or not to give its consent to future international agreements, Parliament will take account of the responses of the Commission and the Council in relation to this Agreement;
  12. Asks the Commission, in the light of the above, to suspend the Agreement;
  13. Requests that all relevant information and documents be made available immediately for Parliament's deliberations;
  14. Instructs its President to forward this resolution to the Council, the Commission and Europol.
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Thursday 24 October 2013

P7\_TA(2013)0453

**Annual report from the Council to the European Parliament on the common foreign and security policy****European Parliament resolution of 24 October 2013 on the Annual Report from the Council to the European Parliament on the Common Foreign and Security Policy (2013/2081(INI))**

(2016/C 208/15)

*The European Parliament,*

- having regard to the Annual Report from the Council to the European Parliament on the Common Foreign and Security Policy (14605/1/2012),
  - having regard to Article 36 of the Treaty on European Union,
  - having regard to the Interinstitutional Agreement (IIA) of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management <sup>(1)</sup>, in particular Part II, Section G, paragraph 43 thereof,
  - having regard to its resolutions of 12 September 2012 <sup>(2)</sup>, 11 May 2011 <sup>(3)</sup> and 10 March 2010 <sup>(4)</sup> on the 2011, 2010 and 2009 annual reports on the Common Foreign and Security Policy, respectively,
  - having regard to the position it adopted on 8 July 2010 <sup>(5)</sup> on the European External Action Service (EEAS) and to its recommendation of 13 June 2013 to the High Representative of the Union for Foreign Affairs and Security Policy and Vice-President of the European Commission, to the Council and to the Commission on the 2013 review of the organisation and the functioning of the EEAS <sup>(6)</sup>,
  - having regard to the declaration by the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy (VP/HR) on political accountability <sup>(7)</sup>,
  - having regard to the statement given by the High Representative in the plenary of the European Parliament on 8 July 2010 on the basic organisation of the EEAS central administration <sup>(8)</sup>,
  - having regard to the Commission communication of 24 July 2013 entitled 'Towards a more competitive and efficient defence and security sector' (COM(2013)0542),
  - having regard to the ongoing negotiations between Parliament and the Council on the Union's new external financing instruments for the multiannual financial framework for 2014-2020,
  - having regard to the conclusions of the Inter-Parliamentary Conference for the Common Foreign and Security Policy and the Common Security and Defence Policy held in Vilnius from 4 to 6 September 2013,
  - having regard to Rules 48 and 119(1) of its Rules of Procedure,
  - having regard to the report of the Committee on Foreign Affairs and the opinion of the Committee on Budgets (A7-0330/2013),
- A. whereas scrutiny of EU foreign policy, exercised by the European Parliament and national parliaments at their respective levels, is essential if European external action is to be understood and supported by EU citizens; whereas parliamentary scrutiny enhances the legitimacy of this action;

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<sup>(1)</sup> OJ C 139, 14.6.2006, p. 1.

<sup>(2)</sup> Texts adopted, P7\_TA(2012)0334.

<sup>(3)</sup> OJ C 377 E, 7.12.2012, p. 35.

<sup>(4)</sup> OJ C 349 E, 22.12.2010, p. 51.

<sup>(5)</sup> OJ C 351 E, 2.12.2011, p. 454.

<sup>(6)</sup> Texts adopted, P7\_TA(2013)0278.

<sup>(7)</sup> OJ C 351 E, 2.12.2011, p. 470.

<sup>(8)</sup> OJ C 351 E, 2.12.2011, p. 472.

Thursday 24 October 2013

***A world in flux: balancing interests and values in a new eu foreign policy***

1. Considers that the first quarter of the twenty-first century is characterised by a period of prolonged structural change that is transforming the global order; stresses that this demands a fresh approach to shaping a new multi-polar world order that is inclusive and underpinned by the rule of law and a pluralist democratic model as well as universal values, including human rights; notes that many obstacles lie ahead, not least in engaging with emerging powers in reforming the multilateral system, re-balancing the fragile regional distribution of power and addressing multiple threats and challenges from nations, non-state actors, fragile states and regional instability;
2. Stresses that the world financial crisis and the growing assertiveness of new emerging economies pose major political, economic, social, cultural and environmental challenges, including internal problems, for all parties and takes the view that addressing such challenges requires collective and united EU action and the forging of alliances in order to promote and uphold peace, security, social progress, prosperity, cultural diversity democracy, the rule of law and respect for human rights; stresses that all EU policies and actions should be in accordance with international law and the Charter of the United Nations;
3. Is of the opinion that the EU must defend its citizens' interests in the world in a determined, unified manner, while always basing its policies on the promotion of the fundamental values on which the Union is founded (democracy, the rule of law and human rights, social justice and the fight against poverty) and on respect for other countries;
4. Underlines the need for EU foreign policy to be flexible in responding to emerging threats and challenges in areas such as health, energy, climate change and access to water, all of which may have an impact upon our political priorities and our economies as well as on international development;
5. Stresses that the EU needs to establish a new and credible foreign policy in response to the current challenges in the world; believes that in order to preserve and promote its values, image and interests and its position on the global stage, the EU needs not only to be coherent and consistent in its external action, but, first and foremost, to clearly define and implement its strategic objectives, making full use of the opportunities provided by the Lisbon Treaty; considers that both the EU as a whole and the Member States have an interest in developing a common vision which goes beyond the perceptions and historical experience of individual Member States; demands that the instrument of enhanced cooperation be used to secure greater capacity to act, and to overcome the inappropriate use of the veto within the Council;
6. States that only by acting jointly or in unity do we have the strength to pursue our interests and defend our values in this world, and that the Member States must therefore — more than in the past — demonstrate their preparedness and political will for collective, fast and effective action; affirms that the Member States must fulfil their contractual duty of loyalty towards the CFSP in both action and spirit, which is enshrined in the Treaty of Lisbon <sup>(1)</sup>;
7. Stresses that the effectiveness of the EU's external action also depends on the full support of its citizens and on the legitimacy it acquires by being anchored in the EU's fundamental values of democracy, the rule of law and human rights, and therefore calls for close, regular and timely consultation of the European Parliament in setting clear priorities and objectives for EU foreign policy;
8. Believes that the development of European media is desirable in order to promote solidarity, bring the various national perceptions closer together and raise awareness on the CFSP;

***Building a new, comprehensive approach to the EU's foreign policy***

9. Urges the Member States to play a constructive role in the Union's foreign and security policy by promoting strategic policy coordination at the Union level, in particular through effective cooperation between their capitals and Brussels concerning the positions they adopt in multilateral fora, notably at the United Nations and within NATO; stresses the need, during a period characterised by economic constraints, to improve the Union's effectiveness as a cohesive global actor;

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<sup>(1)</sup> 'The Member States shall support the Union's external and security policy actively and unreservedly in a spirit of loyalty and mutual solidarity and shall comply with the Union's action in this area. [...] They shall refrain from any action which is contrary to the interests of the Union or likely to impair its effectiveness as a cohesive force in international relations. The Council and the High Representative shall ensure compliance with these principles.' (Article 24(3) of the Treaty on European Union).

Thursday 24 October 2013

notes in particular that the Member States have an important role to play in the development and effective implementation of the CSDP, not only by making available civilian and military capabilities, but also by ensuring the common financing of CSDP operations and strengthening the European industrial and technological base, and expects this role to be reinforced following the discussion on the future of European defence at the December 2013 European Council;

10. Considers, in this regard, it to be of the utmost importance to enhance cooperation, step up coordination and develop synergies with programmes and projects of EU Member States in third countries in order to improve the effectiveness of EU external action and cope with current budgetary restraints;

11. Welcomes the VP/HR's initiative to develop the concept of a 'Comprehensive Approach' in order to achieve the full potential of the Lisbon Treaty and ensure the overall effectiveness and coherence of the CFSP and the CSDP; calls for the VP/HR to engage in a debate with Parliament on the best way to ensure that this comprehensive approach is consistently implemented, and in particular that our foreign policy priorities are further developed in a manner consistent with our interests and values and are supported by the necessary financial means and by effective and flexible instruments; stresses that military structures and capabilities, including a permanent planning structure and military Operational Headquarters, form an integral part of such an approach, and considers that strengthening the coordination between Heads of Missions, EU Special Representatives and Heads of Delegations will also contribute to delivering consistent and coherent EU foreign and security policies on the ground; calls on the Member States to support the VP/HR in order to achieve the full potential of the comprehensive approach;

12. Regrets the fact that the EU has not yet developed a clear strategy for its relations with the rest of the world and that its activities are defined more by reaction than by action; demands, therefore, a fundamental strategic debate, which should include the Council, the Commission and Parliament; calls, as a contribution to this debate, for the European Council in December to further elaborate on the European Global Strategy initiative;

13. Stresses, therefore, that a comprehensive understanding of the CFSP covers all areas of foreign policy, including the progressive framing of the CSDP, which could lead to a common defence, with an emphasis on pursuing coherence and consistency while respecting the specificity of each component of external action; believes that there should be closer coordination, under the VP/HR's leadership, of EU internal policies and Member States' policy choices in key areas such as connectivity, trade, transport, energy, the environment and communication, where these have clearly transnational implications, in particular with regard to the diversification and security of the EU's energy supply;

14. Calls on the Council and the VP/HR to respond to Parliament's recommendation on the 2013 review of the organisation and the functioning of the EEAS in order to ensure the further development of an appropriate and gender-balanced structure within the EEAS (with the participation of the relevant Commission services), in which geographic and thematic expertise are integrated and drive a comprehensive approach to policy planning, formulation and implementation;

### ***Providing leadership and coherence in EU foreign policy***

15. Underlines the political leadership role that the VP/HR is expected to play in ensuring the unity, consistency and effectiveness of Union action; notes that the VP/HR, in her review of the EEAS, has identified areas in which her role should be strengthened and made more effective in initiating, executing and ensuring compliance with CFSP decisions, and has issued recommendations intended to ensure close coordination with the Commission, making full use of her position as Vice-President of the Commission; underlines, with a view to the Hearings of the new Commission in 2014, the fact that the European Parliament should support this trend by strengthening the role of the Vice-President in external relations and thereby reinforcing the coordination between the EEAS and the Commission;

16. Reiterates its support for the VP/HR's leadership, under difficult circumstances, of negotiations with Iran, and congratulates her on her success in bringing the parties together in the EU-facilitated dialogue between Kosovo and Serbia; considers that these examples of leadership and priority-setting should be applied further in the EU's candidate and potential candidate countries and in its neighbourhood, and in response to an arc of strategic challenges stretching from Central Asia to the Middle East and from the Horn of Africa across the Sahel; expresses its willingness to support this process;

17. Calls for a review of the infrastructure distribution and staffing of EU delegations in order to ensure that the Union's efficiency, visibility and representation in third countries reflects our political ambitions and expected priorities; calls for such a review to be discussed with Parliament's competent committee, especially where the outcome requires any redistribution of resources or a decision to open or close delegations in third countries; reiterates, notably, its demand for the opening of an EU delegation in Iran;

Thursday 24 October 2013

***Matching objectives with appropriate resources***

18. Questions, in view of the range of challenges and demands for EU engagement in the world, the Council's rationale for cutting the multiannual financial framework, which will reduce the Union's capacity to promote peace, security and sustainable economic development and its credibility in respect of such efforts; cautions that if such cuts are applied in an uncoordinated fashion, they risk undermining the effective pursuit of our interests and values as well as our collective ability to promote peace, democracy, human security and prosperity in our neighbourhood and further afield;

19. Recognises, at the same time, the need for strategic choices to be made, and priorities established, in order to ensure that the Union's resources are used in a focused and effective manner; calls, in this regard, on the Member States to ensure that their national policies are consistent and coordinated with the Union's strategic objectives and commitments;

20. Stresses the importance of ensuring that the new external relations financial instruments under consideration by Parliament and the Council are fully funded, tailored to furthering the Union's strategic interests, and able to be adapted to changing political circumstances;

21. Insists that the revision of the 2006 IIA on budgetary discipline and sound financial management should mark a further step forward in terms of greater transparency in respect of the CFSP; believes that democratic scrutiny requires separate budget lines for each and every CSDP mission or operation, including the work of EU Special Representatives, accompanied by streamlined — yet transparent — procedures for the internal transfer of funds if circumstances so require;

***Assessing the achievements of the VP/HR and of the council in 2011***

22. Welcomes the steps taken by the Council, with the VP/HR's support, in the 2011 Annual Report towards mapping out the Union's foreign policy in a forward-looking and strategic policy document;

23. Notes the efforts made to address the shortcomings outlined in Parliament's last resolution on this topic, in particular by developing new CSDP missions and operations within the framework of the Union's overall approach to a country or region;

24. Believes, however, that the Council's Annual Report still falls short of the ambitions of the Lisbon Treaty in important ways, and therefore calls for the following in future:

- establishing clear priorities and strategic guidelines for the CFSP as an essential part of the process of applying our diplomatic, economic, financial, development and — where necessary — crisis management resources more effectively in pursuit of the Union's foreign and security policy,
- setting out a framework for assessing existing strategic partners and developing new partnerships, including with international and regional organisations.
- setting out a roadmap for making progress on important innovations of the Lisbon Treaty, in particular (1) by making operational the assignment of special tasks and missions to a core group of Member States, (2) through the establishment by capable and willing Member States of permanent structured cooperation in defence, and (3) by enhancing the role of, and providing more resources for, the European Defence Agency,
- addressing acute problems in CSDP decision-making, inter alia in relation to funding procedures and the financing of operations, that result in incomprehensible delays between the taking of political decisions to launch a mission and the actual deployment of that mission on the ground (Libya and Mali being the most recent in a long line of examples), including through a reassessment of the purpose and capability of the EU Battlegroups, thereby improving the overall framework for streamlining CSDP political decision-making;

25. Calls on the Council to request that the VP/HR set out in the next Annual Report her foreign policy objectives for the years 2014 and 2015, along with the timeframe and necessary resources for their implementation; stresses that these priorities should focus on the EU's strategic aims, starting with the transatlantic partnership, the economic and political development of its Eastern and Southern Neighbourhoods, and the Middle East Peace Process;

Thursday 24 October 2013

26. Calls on the Council and the VP/HR, when drawing up future Annual Reports on the CFSP, to engage with the Committee on Foreign Affairs at an early stage in order to discuss foreign policy objectives for the coming years and provide EU citizens with a clear statement concerning the evolution, priorities and progress of the Union's foreign policy, thus reassessing and demonstrating the VP/HR's role as a leader in the EU's foreign policy;

27. Welcomes the initiative of holding a European Council Summit in December 2013 on the future of European defence, as an opportunity to review the EU's strategic goals and security interests, concepts that should be further developed in a White Book on European defence; calls for this meeting to deliver a clear roadmap with timelines for achieving key objectives, including, in the first instance, the timely review of the European Security Strategy and the use of a White Book serving as a common template for concurrent national security and defence reviews; stresses the need to develop closer cooperation in order to guarantee military security and achieve savings;

***Strategic priorities: concentric circles of peace, security and socio-economic development***

28. Welcomes the development of 'strategic partnerships' as a format for the EU's engagement with both established and emerging powers; contends, however, that the concept requires clear and consistent criteria as regards its place in the EU foreign policy architecture; calls for future decisions on strategic partners to be framed in accordance with the foreign policy priorities of the Union and for Parliament to be regularly informed ahead of decisions on future partnerships, particularly where such partnerships receive financial support from the Union budget or entail a closer contractual relationship with the EU;

**USA**

29. Underlines the fact that the partnership with the USA is based on strong political, cultural, economic and historical links and on shared values such as freedom, democracy, human rights and the rule of law; strongly believes that the USA is the EU's most important strategic partner, notwithstanding diverging views on important issues; urges the EU, therefore, to give clear political priority to deepening transatlantic relations at all levels and broadening them to include other transatlantic partners, with the objective of pursuing mutual benefit and reciprocity;

30. Takes the view that the EU and the USA need to cooperate closely with regard to the peaceful resolution of the conflicts and crises arising as a result of Iran's nuclear programme and the transition process in the Arab Spring countries and the Middle East; welcomes President Obama's commitment to a two-state solution to the Israeli-Palestinian conflict; calls on the EU, following parliamentary debate, to intensify diplomatic activity as part of an agreed comprehensive political strategy for the long-term stability and security of the whole region;

31. Welcomes the announcement concerning the launch of negotiations on the Transatlantic Trade and Investment Partnership (TTIP), which could give the EU and US economies an important boost, stimulate progress on other international agreements and represent a model to be followed by other regional and global actors; recalls the need to set up a Transatlantic Political Council; notes that, in the meantime, the practice of holding annual EU-US summits provides an opportunity to identify common objectives, coordinate strategies in relation to threats and challenges of global relevance, develop a common approach to emerging powers, ensure multilateralism and exchange best practices; recalls that the annual EU-US summit has not yet been held this year; points out, furthermore, that the eventual conclusion of the TTIP, and of the ongoing EU negotiations with Canada, will create the prospect of a wide economic space that would include North America, the EU, and many Latin American countries and bring economic growth and jobs; suggests exploring further political opportunities for triangular transatlantic cooperation;

32. Considers that in order to build trust it is necessary for the USA to comply with sensible data protection legislation and change its data collection activities directed against the EU and its citizens, and asks for the speedy conclusion of the EU-US umbrella agreement on data protection, which would provide information and legal redress for EU citizens; stresses that the recent disclosures have raised concerns across Europe that may harm EU-US relations; recalls that data protection must be respected by both the EU and its partners, and considers that common standards for the sharing of classified information that protect the freedom of both US and EU citizens are necessary;

Thursday 24 October 2013

*Russia*

33. Reiterates its support for the Union's policy of critical engagement with Russia; considers Russia to be an important strategic neighbour, but takes the view that in order to build a genuine partnership the fundamental values of democracy, human rights and the rule of law must be respected; welcomes cooperation with Russia on important international issues, especially with regard to the Middle East, Iran, Afghanistan and Syria;

34. Deplores, nevertheless, the fact that Russia uses its veto in the UN Security Council (UNSC) to undermine the international community's efforts to react effectively and promptly to humanitarian crises, such as the tragedy and spiralling violence in Syria; calls, therefore, on the VP/HR to put the EU's diplomatic weight and efforts into further engaging with Russia on such matters; welcomes Russia's mediation with regard to Syria's stockpile of chemical weapons, along with the proposal outlined by Russian Foreign Minister Sergei Lavrov urging Syria to relinquish control of its chemical arsenal, and Russia's offer to assist in such an operation; regrets the fact that such mediation did not come at an earlier stage, which would have avoided the loss of thousands of lives;

35. Remains concerned about Russia's lack of commitment to the rule of law, pluralist democracy and human rights, as demonstrated by recent legislation that hinders the work of civil society organisations and targets minorities, including LGBT communities, as well as restricting the freedom of expression, the freedom of assembly and the freedom of association; emphasises that strengthening the rule of law in all areas of Russian public life, including the economy, would be a constructive response to the discontent expressed by many Russian citizens, and is essential in order to build a genuine, constructive partnership between the EU and Russia; stresses that a determined effort to tackle corruption is important to enhancing confidence in the EU-Russia economic relationship and that progress on the negotiations on visa facilitation — the preliminary stage of which was positive — should be dependent on progress in areas such as selective justice and free, fair and competitive elections;

36. Underlines the EU's willingness to contribute to the Partnership for Modernisation and to any successor to the current partnership and cooperation agreement, provided that Russia makes progress in areas such as human rights, the rule of law and pluralist democracy (including free, fair and competitive elections); stresses also that the EU remains committed to building mutual trust and furthering political dialogue with Russia, including on matters of global importance such as the fight against terrorism, non-proliferation, organised crime and climate change;

37. Criticises Russia's use, in violation of international norms (e.g. the Helsinki Accords), of the instruments of energy and trade policy to pressure countries in the European neighbourhood so as to compel them to join the Russia-led customs union instead of signing Association Agreements with the EU, thereby hindering their sovereign decisions; believes, furthermore, that the progressive integration of partner countries with the EU can be consistent with their pursuit of good-neighbourly relations with Russia; urges Russia to adopt a constructive position with regard to frozen conflicts; regrets the fact that the EU has not been more firmly involved in the resolution of these conflicts; warns Russia that using unresolved conflicts for political ends may trigger new hostilities and destabilise the whole region;

*China*

38. Encourages the EU to further develop its comprehensive, strategic partnership with China, promoting both parties' global interests, joint projects based on geostrategic standards, and mutual respect; calls for the EU and its Member States to speak with one voice to the Chinese Government; calls, while welcoming the almost 60 active sectoral dialogues and the proposed negotiations on an investment treaty, for further sectoral dialogues to be developed, and for the speedy resolution of ongoing trade investigations; reiterates the need for the EU-China human rights dialogue to be strengthened, inter alia through the involvement of civil society and cooperation with the UN;

39. Stresses that cooperation between the EU and China in the multilateral arena is crucial in order to promote stability and address global challenges, inter alia in relation to economic and financial matters, including efforts to curb tax evasion, tax avoidance and tax havens; stresses that cooperation is also necessary in order to address climate change, environmental issues, the use of the planet's limited natural resources, and development cooperation, to uphold peace and respect for international law in conflicts such as the one in Syria, and to respond to the challenges posed by Iran and North Korea in respect of non-proliferation;

Thursday 24 October 2013

40. Expresses its concern at China's continuing violation of human rights and cultural and religious minority rights, namely in Tibet;

#### *Japan*

41. Underlines the need to consolidate the Union's relations with Japan as a strategic partner and major international actor that shares the EU's democratic values and is a natural cooperation partner in multilateral fora; looks forward to the negotiation of a comprehensive Framework Agreement and a Free Trade Agreement;

#### *South Korea*

42. Calls on the EU to deepen its political cooperation with South Korea, a major democratic Asian actor that has recently intensified trade relations with the EU through an ambitious Free Trade Agreement;

#### *India*

43. Calls for the EU and its Member States to strengthen relations with India, based on the promotion of democracy, social inclusion, the rule of law and human rights, and urges both sides to do their utmost to conclude the negotiation of a comprehensive EU-India free trade agreement, which will stimulate European and Indian trade and economic growth;

#### *Turkey*

44. Stresses the strategic importance of the EU's dialogue and cooperation with Turkey on stability, democracy and security, with particular reference to the wider Middle East; points out that Turkey is not only a NATO ally but also a candidate to join the EU if and when the accession criteria can be fulfilled and a decision on full membership meets with democratic approval; asks for the opening of crucial chapters, especially in order to trigger the necessary political reforms; notes that Turkey has strongly and repeatedly condemned the Syrian regime's violence against civilians and is providing vital humanitarian assistance to Syrians fleeing violence across the borders; calls for further cooperation between the Member States and Turkey, along with measures at Union level, in view of the growing flow of refugees at the EU's external borders; stresses that Turkey's growing international standing should also be based on its commitment to fundamental rights, a secular state, pluralist democracy and the rule of law at home, and that the most crucial reforms have yet to be achieved; notes the vitality of the democratic demands being made by civil society in Turkey and reiterates its concern about the violent, repressive and often inadequate response by the authorities; asks for Turkey's support against fundamentalist, undemocratic movements in the region;

#### *South Africa*

45. Reiterates the importance of the EU's strategic partnership with South Africa; contends that South Africa, given its record of a successful and peaceful transition to democracy and its role as a regional power, can be a major force in promoting democracy and good governance, fostering regional economic integration and supporting national reconciliation across Africa, and a key partner for the EU in these efforts; stresses the importance of close cooperation between the EU and South Africa on climate change, sustainable development and the reform of international institutions;

#### ***An enlarging EU***

46. Emphasises that EU membership provides peace, prosperity, democratic development, stability and security in the swiftly changing international environment, and that belonging to the EU continues to offer the prospect of socioeconomic development; takes the view that enlargement remains an important tool of EU foreign policy and is in the EU's long-term strategic interest, which cannot necessarily be measured in terms of short-term balance sheets; points out, however, that the enlargement policy needs to take into account the EU's own integration capacity and the genuine commitment of the Western Balkan countries and of Turkey to take up their responsibilities and address outstanding concerns; welcomes the agreement on telecommunications and energy reached between Serbia and Kosovo during the 16th round of the negotiations brokered by the VP/HR, and calls for more efforts to overcome all remaining obstacles;

Thursday 24 October 2013

### *The EU's neighbourhood*

47. Stresses that the EU needs to put further effort into, place a higher priority on, and show greater commitment to, the European Neighbourhood Policy (ENP) at a time when this policy is in difficulty and is being challenged by developments in numerous countries; believes, therefore, that for reasons of solidarity and on account of its own interest in peaceful and free development, the EU must strongly focus its instruments, inter alia by strengthening multilateral approaches in the region, and make strong links between its policy, financial instruments and funding in order to achieve its main policy objectives, notably as regards delivering on human rights, democracy, the rule of law and economic reforms; notes that the European perspective remains a key incentive, in particular for European neighbourhood countries, to deliver on ambitious reforms;

48. Emphasises that the modernisation of the whole European neighbourhood rests on the gradual development of liberal democracy in which those who are elected democratically also govern democratically in accordance with constitutional principles, respecting opposition, dissent and non-conformism;

49. Calls for the principles underlying the new ENP approach, as set out by the VP/HR and the Commission in the relevant joint communications <sup>(1)</sup>, in particular the 'more-for-more', differentiation and mutual accountability principles and the 'partnership with society', to be fully operational and for Union assistance to be fully aligned to this new approach;

50. Emphasises that in order to avoid post-accession social tensions and/or socioeconomic imbalances within the enlarged Union, the Commission must promote pre-accession policies aimed at mitigating structural social inequities and overcoming cultural divisions within acceding states prior to the time of accession; stresses that priority should be given to the national integration of social and cultural minorities, thus preventing their mass displacement towards other Member States following accession;

### *Eastern Neighbourhood*

51. Recalls that the Eastern Neighbourhood is of strategic importance and recalls the European perspective of the countries concerned, which remains a key incentive for these countries to deliver on reforms; emphasises that the EU has real leverage in this area and should fully assert its transformative power; considers that it is high time for intensified efforts, coupled with greater political commitment, to achieve the objectives of the Eastern Partnership, including the need to establish a closer link between the CFSP and the ENP; welcomes the progress made, and further calls on all sides to make the necessary efforts to sign or initial Association Agreements, Deep and Comprehensive Free Trade Agreements and the agreements on the liberalisation of the EU visa regime once all the conditions set have been fulfilled, and calls on our Eastern partners to meet the requirements for a successful Vilnius Summit in November 2013; stresses that the summit should mark a clear step forward in bringing closer together the societies of the Member States and of Eastern Partnership countries;

52. Considers it regrettable, nevertheless, that the overall situation with regard to democratic standards and respect for human rights in many of the Eastern Partnership countries has scarcely progressed, if not deteriorated; calls for the EU to play a more active and sustained role in the search for political solutions to the frozen conflicts in the Eastern Neighbourhood, in particular with a view to breaking the deadlock on South Ossetia and Abkhazia and on the Nagorno-Karabakh conflict and playing a full role in support of any ensuing peace agreement; encourages further progress on the question of Transnistria; stresses, furthermore, that the full development of the Eastern Partnership can only take place once the frozen conflicts have been solved in a peaceful manner, which should be a priority; calls for the EU to make full use of the tools at its disposal to mediate and to ensure that human rights are fully respected; reiterates its view that the development of relations should be conditional on a meaningful commitment to human rights, democracy and the rule of law;

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<sup>(1)</sup> Joint communication of 25 May 2011 entitled 'A New Response to a Changing Neighbourhood' (COM(2011)0303); joint communication of 20 March 2013 entitled 'European Neighbourhood Policy: Working towards a Stronger Partnership' (JOIN(2013)0004).

Thursday 24 October 2013

53. Recalls that democratic reforms promoted by the EU are in the interest of the partner countries themselves and can contribute to their economic and social development; points out that strong democratic institutions and closer ties with the EU through Association Agreements, DCFTAs and visa facilitation measures will help to strengthen the sovereignty of these countries against the influence of powerful neighbours; is deeply concerned about the mounting pressure being exerted on some partner countries, such as Moldova, Ukraine and Armenia, which is ultimately aimed at slowing down their progress towards further engagement with the EU; calls for the EU to address these issues in a politically coherent manner; reaffirms the EU's readiness to be a reliable and strong partner for these countries on the basis of shared common values and solidarity, and to share with them all the advantages of the EU *acquis*, along the lines of an Economic Area Plus arrangement;

54. Stress that although the EU-Ukraine agreement has been initialled, it can only be signed and ratified if Ukraine fulfils the necessary requirements as set out in the Council conclusions on Ukraine of 10 December 2012; reiterates its call on the Ukrainian Parliament and Government to address the issue of selective justice, namely by releasing Yulia Tymoshenko, and to implement the reforms set out in the jointly agreed Association Agenda, including judicial reform (i.e. the Office of the General Prosecutor) and reform of the electoral law; calls on Ukraine to amend its penal code by removing criminal sanctions for clearly political acts carried out by state functionaries acting in an official capacity;

55. Supports the EU-Georgia Association Agreement, but believes that tangible progress by the Georgian authorities in the area of the rule of law is necessary; calls, in particular, for all political prisoners, including former Prime Minister Vano Merabishvili, to be released and for European standards to be met in the upcoming presidential elections;

#### *Southern Neighbourhood and Middle East*

56. Highlights the EU's longstanding relations with the countries of Europe's Southern Neighbourhood; calls for the principles underlying the new ENP approach, as set out by the VP/HR and the Commission in the aforementioned joint communications, in particular the 'more-for-more', differentiation and mutual accountability principles and the 'partnership with society', to be fully operational and for Union assistance to be fully aligned to this new approach;

57. Recalls its support for the VP/HR's use of new concepts, such as the Task Force for the Southern Mediterranean, as a way to maximise the leverage achieved by financing from the EU and its partners, for the benefit of these countries' citizens; expects tangible outcomes from such innovative approaches in terms of better coordination between EU and Member State contributions, capacity-building assistance for beneficiary countries and the accountability of their administrations;

58. Expresses its deep concern about the situation in Egypt and the excessive violence by all parties, including both state security forces and opposition forces; stresses that the EU should support democracy and human rights, and welcomes the EU foreign ministers' decision of 21 August 2013 to suspend all export licences for equipment which could be used for internal repression; urges all political actors in Egypt to resolve their differences through peaceful dialogue and calls for an inclusive political agreement and for power to be transferred to democratically elected leaders as soon as possible; urges the EU, and in particular the VP/HR, to capitalise on its unique position and its networks of relationships among the key players and to continue its mediation efforts towards a political settlement regarding the basic parameters of a democratic transition;

59. Regrets the fact that the EU gave up its common policy of an arms embargo on Syria, thereby undermining a common approach; condemns the tragic and ongoing bloodshed in Syria, which has already had a devastating and destabilising humanitarian impact, including on neighbouring countries, in particular Jordan, Lebanon, Iraq and Turkey; calls on the Member States to show solidarity and to provide help to refugees from Syria and displaced persons within Syria; strongly condemns the mass killing of civilians and stresses that the Syrian Government's use of chemical weapons is a gross breach of international norms that may lead to the referral of all those responsible to the International Criminal Court; welcomes the firm international response and calls for the speedy implementation, under international supervision, of the plan to destroy all such chemical weapons; stresses that the severity of the situation in Syria requires a high level of coherence and solidarity among the EU Member States, working in cooperation with NATO and regional actors, especially Russia, Iran, Israel and Turkey; calls for the EU actively to support efforts to convene the Geneva II talks in order to promote a political solution agreeable to the Syrians and bring an end to the deadly spiral of violence;

**Thursday 24 October 2013**

60. Reiterates its call for the EU to play a more active role in the resolution of the Western Sahara conflict, which currently represents an insurmountable obstacle to the full development of good-neighbourly relations in the Maghreb;

61. Continues to support the twin-track approach adopted by the EU, the USA, Russia and China with the objective of pursuing non-proliferation; calls on the Iranian President to follow up on recent positive declarations by cooperating fully with the international community in addressing concerns regarding the exclusively peaceful nature of the Iranian nuclear programme; calls on the EU 3-plus-3 to consider both additional measures and incentives dependent on Iran making concrete progress in taking verifiable steps to address the international community's concerns; stresses that any failure or stalling in the negotiations between the EU 3-plus-3 and Iran on nuclear non-proliferation will pose serious risks to regional and global security;

62. Expresses hope for the Middle East peace negotiations and recalls that resolving the conflict in the Middle East is a fundamental interest of the EU, as well as of the parties themselves and of the wider region; stresses, therefore, that the need for progress is even more urgent on account of the ongoing changes in the Arab world, the Syrian crisis and the particularly volatile situation in the wider Middle East; calls on the Member States to find common ground for more decisive action by the EU in close cooperation with the Arab League and the other members of the Quartet; welcomes the resumption of direct negotiations between the Israelis and the Palestinians as a basis for achieving a two-state solution; criticises Israeli settlement policy, which is in violation of international law and is undermining the prospects for peace and a negotiated resolution of the conflict; reiterates that a stable and peaceful Middle East is in the EU's interest and calls for more active engagement with a view to achieving this aim; welcomes the publication of the Guidelines on EU funding instruments and calls for their sensitive, non-bureaucratic implementation;

63. Asks both Iran and the United Arab Emirates to engage in an open and frank dialogue making it possible to arrive at a peaceful solution, entirely consistent with international law, to their territorial dispute;

#### **Latin America**

64. Welcomes the EU-Latin America political dialogue, including the summits of heads of state and the EUROLAT Parliamentary Assembly;

65. Believes that the EU and the countries of Latin America share a common commitment to socially sustainable economic development and a common attachment to democratic values and the rule of law, but also experience tensions in reconciling those values and goals with conditions of governance;

66. Expresses its support for the process of negotiating an Association Agreement between the EU and Mercosur and notes the commitment of both parties to arriving at an exchange of offers on market access by the end of 2013; welcomes the entry into force of the EU-Central America Association Agreement and of the Multiparty Free Trade Agreement with Colombia and Peru, and looks forward to removing visa requirements with these two countries, as well as to working on further Association Agreements, including with Ecuador; notes that such agreements represent important advances in developing strategic relations between the EU and Latin America;

67. Stresses the need to strengthen contacts and coordination with Latin American partners in multilateral forums; calls for the adoption of a Euro-Latin American Charter for Peace and Security, as requested by the Eurolat Assembly;

#### **Africa**

68. Insists that preparations for the Fourth EU-Africa Summit in 2014 afford an opportunity to move beyond institutional capacity-building at continental level and towards the establishment of a political partnership for peace, security, socioeconomic development, efforts to combat illicit financial flows from Africa, the achievement of the Millennium Development Goals and good governance, at the regional and sub-regional level;

69. Underlines the importance of the respective EU strategies for the Horn of Africa and the Sahel region as a key means of addressing the complexity of the security, governance and development challenges affecting these regions, which span the breadth of Africa;

70. Recalls that longer-term state stability and human security in these two regions require not only the defeating of violent radical extremists and those trafficking in arms, drugs and people, but also the promotion of reconciliation, the strengthening of state and civil society institutions and the provision of alternative economic activities to give people a dignified livelihood, in particular through creating jobs for young people by facilitating the development and implementation of confidence-building measures;

Thursday 24 October 2013

**Central Asia**

71. Supports the EU's promotion of a regional approach in Central Asia, which is essential in tackling common challenges, in particular as regards stability, security, water and energy, in facilitating dialogue, in developing good-neighbourly relations and in promoting the EU's strategic interests; calls for the EU's engagement in this region to be linked to progress on democratisation, human rights, good governance, sustainable socioeconomic development, the rule of law and the fight against corruption; further emphasises the importance of the EU's presence on the ground in order closely to monitor politically motivated trials, and the necessity of promoting political pluralism;

72. Underlines also the importance of the EU's dialogue with Central Asian countries on regional environmental and security matters, in particular as regards the management of water resources and the situation in Afghanistan after 2014; welcomes the launch of the EU-Central Asia High-Level Security Dialogue on 13 June 2013;

73. Notes that the energy- and natural-resource-rich Central Asian countries are potentially significant for the EU's diversification of sources and supply routes in order to achieve a higher degree of energy security; calls on the EEAS and the Commission to continue to strongly support energy supply diversification projects such as the Southern Corridor and the trans-Caspian pipeline;

**Afghanistan**

74. Is deeply concerned about the continued violence, in all forms, in Afghanistan, in particular that directed against women; urges the Afghan Government to prepare for taking over full responsibility after the withdrawal of international forces from 2014; calls for the Member States to gear up to support the military and civilian capacity-building of the Afghan Government and its National Security Forces in order to create stability and security as a prerequisite for development, avoiding the creation of a security and economic vacuum once the country assumes full responsibility for its own security after 2014; highlights the need to continue the EU's support for the fight against corruption; reiterates the need to establish a plan for the elimination of opium production; recalls that Parliament has repeatedly called for the promotion of a five-year plan for the elimination of opium production;

75. Reiterates the EU's long-term commitment to assisting Afghanistan in a peaceful transition and sustainable socioeconomic development; welcomes the fact that the EU and Afghanistan are about to conclude the negotiations on a Cooperation Agreement on Partnership and Development; calls on both sides to conclude the negotiations swiftly;

76. Emphasises the need for enhanced cooperation within the sub-region of Central Asia and with Russia, Pakistan, India and Iran in order to address the challenges of cross-border trafficking in people and goods and to combat the illegal production and trafficking of drugs; warns against the risk of such problems spilling over to neighbouring countries and to the wider sub-region after 2014; stresses Pakistan's key role in the fight against terrorism;

**Asia**

77. Calls for the EU to have a greater presence in the Asia-Pacific region, with a focus beyond China, India and Japan; stresses the political and economic potential of the partnerships being established between the EU and Indonesia, a democracy with the world's fourth-largest — mostly Muslim — population, and a G-20 member, and between the EU and the Philippines; underlines the new prospects for EU-ASEAN relations following the democratic changes in Myanmar; regards the Bandar Seri Begawan Plan of Action to strengthen the Association of Southeast Asian Nations (ASEAN)-EU enhanced partnership as a relevant step; also regards the Treaty of Amity as a chance to deepen cooperation and looks forward to tangible outcomes in this respect;

78. Emphasises the need to conclude the negotiations on partnership and cooperation agreements and political framework agreements with several Southeast and East Asian countries, based on social standards and European corporate social responsibility, in order to consolidate and heighten the EU's relations with the region;

79. Underlines the importance of Asia-Pacific regional security and is concerned about tensions, including territorial disputes around the East and South China Sea, as well as having increasing concerns about North Korea; suggests that the EU could take a more active role and call for all parties concerned to be included in all dialogue and cooperation mechanisms, especially in the multilateral arena, in view of the importance of stability in this area to the EU's maritime security and commercial interests;

**Thursday 24 October 2013**

80. Notes the efforts made towards cooperation between the EU and the USA following the 'pivot' to Asia, as demonstrated by the common approach to the lifting of sanctions on Myanmar; calls, therefore, for greater coordination of US and EU policies towards Asia, together with those of key partners such as Australia and New Zealand; urges, to this end, the swift conclusion of the negotiations on framework agreements with Australia and New Zealand, which should reflect the EU's common approach to the inclusion of clearly worded political clauses on human rights and democracy in all international agreements negotiated by the EU;

81. Recalls the first EU-Pakistan Strategic Dialogue held in June 2012 and the commitment to constructive discussions on enhancing bilateral cooperation and shared views on regional and international issues of mutual concern, including more proactive engagement in favour of a pluralistic society as an essential element in the fight against terrorism; calls on the VP/HR to update Parliament on follow-up to that strategic dialogue and preparations for the next one, which should take place in Brussels in 2013;

82. Commends Taiwan's continuous efforts to maintain peace and stability in the Asia-Pacific region; recognises the progress made in cross-Straits relations, especially the flourishing economic links, tourism and cultural cooperation; reiterates its firm support for Taiwan's meaningful participation in relevant international organisations and activities, including the UN Framework Convention on Climate Change; urges the Commission and the Council to facilitate the negotiation of an EU-Taiwan economic cooperation agreement (ECA); encourages closer bilateral cooperation between the EU and Taiwan in areas such as trade, research, culture, education and environmental protection;

83. Remains deeply concerned about the continuing massive human rights violations in North Korea and its continuing tests of increasingly powerful nuclear devices and longer-range missiles, which remain a serious threat to international peace, stability and security and to the country's economic development;

### ***Multilateral partners***

84. Believes that the G-20 could prove a useful and particularly appropriate forum for consensus-building that is inclusive, based on partnership and able to foster convergence, including regulatory convergence; takes the view, however, that the G-20 has yet to prove its value in converting summit conclusions into sustainable policies that address critical challenges;

85. Acknowledges the role of the UNSC as the highest international body responsible for peacekeeping and international security, while noting that recent crises have highlighted its growing inability to act in a timely manner in response to serious threats to international peace and security, on account of its structures and working methods; urges the VP/HR, therefore, to put her efforts into securing a permanent EU seat in the UNSC and steering the reform of the UNSC; calls on those EU Member States that hold a permanent seat to involve the VP/HR in their decision-making;

86. Calls for the EU and its Member States to reconfirm the EU's commitment to advancing effective multilateralism, with the UN system at its core, by enhancing the representativeness, accountability and effectiveness of the UN, which necessitates the reform of the UNSC, including restrictions on the power of veto; stresses the importance of working with other international partners in order to respond to international challenges; stresses that an EU seat in an enlarged UNSC remains a central, long-term goal of the EU; calls, furthermore, on the Member States, in order to strengthen the EU's presence within the UN system, to coordinate their efforts in selecting senior officials for high-level posts in the UN and other international institutions;

87. Calls for the EU and its Member States to cooperate with partners in strengthening the role of regional organisations in peacekeeping, conflict prevention, civilian and military crisis management, and conflict resolution; stresses the need to work with partners in ensuring that the Responsibility to Protect (R2P) concept is legally developed and is exercised whenever it is needed, encompassing prevention, protection and post-conflict reconstruction; recalls its recommendation that an interinstitutional EU 'Consensus on R2P' be adopted, and expects the EEAS to start consultations to this end; underlines the need to develop more effective mediation guidelines and capacities, including through collaboration between the EU and the UN;

Thursday 24 October 2013

88. Welcomes the commitments made by the EU and NATO to strengthen their strategic partnership through a complementary approach; notes that the current global and European economic crisis has spurred efforts to seek more cost-effective operational capabilities in both the EU and NATO, which are urgently needed; calls for an urgent political solution to the ongoing stalemate which is hindering proper, close cooperation between the EU and NATO; welcomes initiatives such as additional EU Member States applying for membership of NATO's Partnership for Peace (PfP) as a first step towards removing the existing obstacles between the EU and NATO;

89. Remains concerned about the problems in starting CSDP missions, such as delays in planning and deployment, staff shortages, financial planning and implementation difficulties, issues regarding the status of CFSP agreements with third countries and start-up difficulties; requests that a follow-up mechanism be created to ensure that such recurring problems are addressed together;

90. Calls on the VP/HR to mainstream cyber security in the EU's external action, to coordinate with the action being taken under the Stockholm Programme and to develop networks of like-minded partners to deal with cyber security threats and challenges; emphasises that efforts should be made to ensure that existing international legal instruments are enforced in the cyber-sphere;

91. Stresses the need to regulate at the EU level the sale, supply, transfer and export to third countries of equipment or software intended primarily for the monitoring or interception of the internet and of telephone communications; stresses the urgent need to prevent EU companies from exporting such dual-use items to non-democratic, authoritarian and repressive regimes;

92. Reiterates its call on the VP/HR to take stock of the effectiveness of the EU's Strategy Against the Proliferation of Weapons of Mass Destruction and its policies for tackling conventional weapons, including arms exports;

93. Welcomes the EU's coordinated approach during the negotiation of the Arms Trade Treaty, which resulted in a successful outcome; calls on the Member States to ratify the Treaty expeditiously so that it can enter into force, following the consent of Parliament; calls for competence in respect of the rules governing exports of arms and of equipment or software intended primarily for the monitoring or interception of the internet and of telephone communications on mobile or fixed networks to be fully transferred to the EU;

94. Supports the dialogue on reform of the Organisation for Security and Cooperation in Europe (OSCE) and the launch of the Helsinki 40+ process in December 2012, which provides a strategic road map for strengthening the OSCE; fully supports the activities of the Office for Democratic Institutions and Human Rights (ODIHR), which carries out invaluable work in the field of promotion and protection of human rights and democratic standards;

95. Acknowledges the increasingly important role of regional organisations, in particular the Arab League, the Gulf Cooperation Council (GCC), the Organisation of the Islamic Conference and the Economic Cooperation Organisation, and calls for the EU to strengthen its cooperation, especially on matters relating to transition processes and crisis management in the Southern Neighbourhood; welcomes EU efforts to assist the Arab League in its integration process;

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96. Instructs its President to forward this resolution to the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy, the Council, the Commission, the governments and parliaments of the Member States, the Secretary-General of the United Nations, the Secretary-General of NATO, the President of the NATO Parliamentary Assembly, the Chairman-in-Office of the OSCE, the President of the OSCE Parliamentary Assembly, the Chairman of the Committee of Ministers of the Council of Europe, and the President of the Parliamentary Assembly of the Council of Europe.

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Thursday 24 October 2013

P7\_TA(2013)0454

## **Implementation report on the regulatory framework for electronic communications**

**European Parliament resolution of 24 October 2013 on Implementation report on the regulatory framework for electronic communications (2013/2080(INI))**

(2016/C 208/16)

*The European Parliament,*

- having regard to Directive 2009/140/EC (Better Regulation Directive),
  - having regard to Directive 2009/136/EC (Citizens' Rights Directive),
  - having regard to Regulation (EC) No 1211/2009 (BEREC Regulation),
  - having regard to Directive 2002/21/EC (Framework Directive),
  - having regard to Directive 2002/20/EC (Authorisation Directive),
  - having regard to Directive 2002/19/EC (Access Directive),
  - having regard to Directive 2002/22/EC (Universal Service Directive),
  - having regard to Directive 2002/58/EC (Directive on privacy and electronic communications),
  - having regard to Regulation (EU) No 531/2012 (recast Roaming Regulation),
  - having regard to Recommendation 2010/572/EU (Recommendation on regulated access to Next Generation Access Networks),
  - having regard to Recommendation 2007/879/EC (Recommendation on relevant markets),
  - having regard to Recommendation 2009/396/EC (Recommendation on termination rates),
  - having regard to COM 2002/C 165/03 (SMP Guidelines),
  - having regard to Recommendation 2008/850/EC (Rules of procedure in Article 7 of the Framework Directive),
  - having regard to Decision No 243/2012/EU establishing a multiannual radio spectrum policy programme (RSPP),
  - having regard to the proposal of 19 October 2011 for a Regulation of the European Parliament and of the Council establishing the Connecting Europe Facility (COM(2011)0665),
  - having regard to the proposal of 7 February 2013 for a Directive of the European Parliament and of the Council concerning measures to ensure a high common level of network and information security (COM(2013)0048),
  - having regard to the recent work done by the Body of European Regulators for Electronic Communications (BEREC) on net neutrality,
  - having regard to the proposal of 26 March 2013 for a Regulation of the European Parliament and of the Council on measures to reduce the cost of deploying high-speed electronic communications networks (COM(2013)0147),
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on the Internal Market and Consumer Protection (A7-0313/2013),
- A. whereas the regulatory framework for electronic communications in the Union was last amended in 2009, on the basis of proposals presented in 2007 and following years of preparatory work;
- B. whereas transposition of the 2009 amendments in the Member States was due by 25 May 2011 and was completed in the last Member State in January 2013;

Thursday 24 October 2013

- C. whereas there is a margin of interpretation for each National Regulatory Authority (NRA) in the way it implements the framework, so that the evaluation of the framework's efficiency can also take account of the conditions under which the framework is implemented in the Member States;
- D. whereas the differences in enforcement and implementation of the regulatory framework have led to higher costs for operators active in more than one country, thereby hindering investment and the development of a single market for telecoms;
- E. whereas the Commission has not made use of the possibility of adopting a decision identifying transnational markets as specified in Article 15(4) of the Framework Directive (FD);
- F. Whereas pan-European business users have not been recognised as a separate market segment, resulting in a lack of standardised wholesale offers, unnecessary costs and a fragmented internal market;
- G. whereas the aims of the framework are to promote an ecosystem of competition, investment and innovation that contributes to the development of the internal market in communications to the benefit of consumers and enterprises — and in particular European enterprises — in that sector;
- H. whereas the regulatory framework should be maintained as a coherent whole;
- I. whereas, in line with better regulation principles, the Commission is obliged to periodically review the framework in order to ensure that it keeps pace with technological and market developments;
- J. whereas, rather than building on the regulatory framework, the Commission has engaged in a parallel trail of individual initiatives, with the 'single digital market' as the latest avatar;
- K. whereas the Commission has declared its intention to review the Directive on privacy and electronic communications and the recommendation on relevant markets, but not yet the other parts of the regulatory framework;
- L. whereas the Commission has not updated the universal service obligations since 1998, despite the request included in the 2009 Citizens' Rights Directive;
- M. whereas a relevant, stable and consistent framework is essential to promote investment, innovation and competition and hence services of better quality;
- N. whereas a collective NRA-based bottom-up approach has proven to be effective in promoting common regulatory case-law;
- O. whereas functional separation, i.e. the obligation of a vertically integrated operator to place the activities related to the wholesale provision of relevant access products in an independently operating internal business unit, remains a remedy of last resort;
- P. whereas effective and sustainable competition is an important driver of efficient investment over time;
- Q. whereas the regulatory framework has promoted competition in the provision of electronic communications networks and services, to the benefit of consumers;
- R. whereas the promotion of competition in the provision of electronic communications networks and services, along with the promotion of investment, are key policy objectives laid down in Article 8 of the FD;
- S. whereas despite the progress being made, the EU is only taking small steps towards achieving the Digital Agenda's broadband objectives within the targeted timeframe;
- T. whereas the rollout of high-speed broadband internet access has been gradual (54 % of European households now have access to speeds of over 30 Mbps), but European consumers have been slow to adopt this type of access (only 4,2 % of households); whereas the rollout of ultrafast internet access (over 100 Mbps) has been slow, representing only 3,4 % of all fixed lines, and user demand appears weak, with only about 2 % of households subscribing to such lines <sup>(1)</sup>;

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<sup>(1)</sup> SWD(2013)0217 — Digital agenda scoreboard, p. 43.

**Thursday 24 October 2013**

- U. whereas transparency in network traffic management is insufficient in itself to ensure net neutrality;
  - V. whereas issues regarding competition both between electronic communications services providers and between them and information society services providers deserve attention, in particular threats to the open character of the internet;
  - W. whereas obstructions to competition continue to be present on many networks; having regard to the failure to define and apply a principle of net neutrality to ensure non-discrimination of services for end-users;
  - X. whereas 4G deployment in Europe has been hindered by a lack of sufficient coordination in radio spectrum allocations, in particular the delay by Member States in carrying out the authorisation process in order to allow use of the 800 MHz band for electronic communications services by 1 January 2013, as stipulated by the Radio Spectrum Policy Programme (RSPP);
  - Y. whereas the RSPP has called on the Commission to review the use of the spectrum between 400 MHz and 6 GHz and assess whether additional spectrum could be freed and made available for new applications, such as, though not exclusively, the 700 Mhz band;
  - Z. whereas innovation and the development of new technologies and infrastructures should be taken into consideration when assessing the impact of the legal framework on the options offered to users and consumers;
- AA. whereas the framework should remain neutral, and the same rules should apply to equivalent services;
- 1. Regrets the delay by Member States in transposing the 2009 changes to the regulatory framework for electronic communications, and draws attention to the fragmentation of the internal market in communications caused by the varying implementation of that framework in the 28 Member States;
  - 2. Underlines the fact that while the framework has made substantial progress towards achieving its aims, the EU telecoms market remains fragmented along national borders, making it difficult for businesses and citizens to fully benefit from a single market;
  - 3. Considers that only by having a competitive European market in high-speed broadband services can innovation, economic growth and job creation be stimulated and competitive prices offered to end users;
  - 4. Considers that the next review should aim at a further evolution of the framework, with a view to addressing any weaknesses and taking account of market, social and technological developments and future trends;
  - 5. Considers that the aspects to be considered in a review of the entire regulatory framework should include:
    - (i) the overdue review of the universal service obligation, including the obligation to offer broadband internet access at a fair price in response to the urgent need to reduce the digital divide, and in doing so mitigate the constraints imposed by state aid guidelines;
    - (ii) the competence of NRAs for all issues, including spectrum, that are addressed by the framework; the powers granted to the NRAs in the Member States and the scope of the NRA independence requirement, accordingly;
    - (iii) cooperation between the NRAs and national competition authorities;
    - (iv) the symmetric obligations relating to network access (Article 12 FD), since in certain Member States such regulatory powers were not given to NRAs;
    - (v) the rules on leverage effects (Article 14 FD) and joint dominance (Annex II FD), since despite the 2009 amendments the NRAs still find those tools difficult to use;
    - (vi) the market review processes;

Thursday 24 October 2013

- (vii) the impact of services that are fully substitutable to those provided by traditional providers; in certain cases clarifications regarding the reach of the framework's technological neutrality would be needed, as would clarifications on the dichotomy between services in the 'information society' bracket and those in the 'electronic communications' bracket;
  - (viii) the necessity of abolishing redundant regulation;
  - (ix) the lifting of regulation where a market analysis has shown the market concerned to be truly competitive and that ways and means exist for extended monitoring;
  - (x) giving NRAs the opportunity to report on their experience with non-discrimination obligations and remedies;
  - (xi) the effectiveness and workings of the Article 7/7a procedures ('co-regulation'): while overall both the Commission and BEREC agree that they work well, allowing for a proper balancing, the former argues that in some cases NRAs did not adjust all their regulatory measures, or were slow to adapt them, and the latter complain of tight time constraints;
  - (xii) the situation where phase II of the procedure is not triggered due to an NRA withdrawing its draft measure or where an NRA does not propose a remedy to a problem recognised on a certain market, in which case the only solution is an infringement procedure: for both such cases, a way to trigger a proper Article 7/7a procedure should exist;
  - (xiii) the effectiveness and workings of the Article 19 procedure: the Commission used its Article 19 powers twice (the NGA recommendation in September 2010, and the recommendation on non-discrimination and costing methodologies); since unlike for Article 7/7a there is no timeframe for the Article 19 procedure, the regulatory dialogue between BEREC and the Commission was less smooth, leading to complaints from BEREC that its opinion was requested at very short notice, and from the Commission that certain NRAs were reluctant in the drafting and implementation period;
  - (xiv) pan-European services and operators, taking into account the (unused) provision of Article 15(4) of the FD allowing the Commission to identify transnational markets; more focus should be given to the competitive provision of communications services to EU businesses and to the effective and consistent application of business grade remedies across the EU;
  - (xv) identification of transnational markets, as a first step at least with respect to business services; enabling providers to notify BEREC that they intend to serve such markets, and supervision of providers serving such markets by BEREC;
  - (xvi) BEREC and its functioning as well as the extension of the scope of its competences;
  - (xvii) freedom of access to content for all, following Article 1(3a) of the Framework Directive, and net neutrality building on Article 8(4)(g) of the Framework Directive;
  - (xviii) the recommendation on relevant markets;
  - (xix) the regulation of equipment, including bundling of equipment and operating systems;
  - (xx) recent global developments in cybersecurity and cyberespionage and the expectations of European citizens regarding respect of their privacy when using electronic communications and information society services, and
  - (xxi) the fact that the internet has become a crucial infrastructure for conducting a wide array of economic and social activities;
6. Considers that the main goals of the review should include:
- (i) ensuring that fully substitutable services are subject to the same rules; to this end the definition of electronic communications services in Article 2(c) of the FD should be taken into consideration;
  - (ii) ensuring that consumers have access to comprehensive and comprehensible information on internet connection speeds to enable them to compare the services offered by different operators;
  - (iii) further promoting effective and sustainable competition, which is the main driver of efficient investment over time;

**Thursday 24 October 2013**

- (iv) increasing competition on the European high-speed broadband market;
  - (v) providing a stable and sustainable framework for investment;
  - (vi) ensuring harmonised, consistent and effective application;
  - (vii) facilitating the development of pan-European providers and the provision of cross-border business services;
  - (viii) ensuring that the framework is fit for the digital age and delivers an internet ecosystem that support the entire economy, and
  - (ix) increasing user confidence in the internal market in communications, including through measures to implement the future regulatory framework for the protection of personal data and measures to increase the security of electronic communications on the internal market;
7. Believes that the overall aim of the framework should continue to be the promotion of a sectoral ecosystem of competition and investment which benefits consumers and users, while encouraging the creation of a true internal market in communications and promoting the global competitiveness of the Union;
8. Underlines that the regulatory framework must remain coherent, relevant and effective;
9. Believes that the framework must serve to maintain consistency and provide regulatory certainty so as to ensure fair and balanced competition in which European players stand every chance; considers that all the provisions proposed by the Commission, including a single European authorisation, consumer aspects and technical arrangements for spectrum auctions, could play an important role with a view to creating a single market for communications, but that they need to be assessed in the light of that objective; considers that the procedure for the review of the framework as called for herein must be viewed as a step forward for the Union's digital economy and should hence be addressed by means of a cohesive and planned approach;
10. Stresses that non-discrimination of information in the sending, transmitting and receiving phase is necessary for encouraging innovation and eliminating entry barriers;
11. Emphasises that there is a potential for anti-competitive and discriminative behaviour in traffic management; calls, therefore, on the Member States to prevent any violation of net neutrality;
12. Notes that the provisions allowing N RAs to intervene to mandate service quality in the event of anti-competitive service blocking or restrictions, combined with better contract transparency, are powerful tools to ensure that consumers have access to and use of the services they choose;
13. Stresses that end-to-end quality of service prioritisation alongside best effort delivery could undermine the principle of net neutrality; calls on the Commission and the regulators to monitor these trends and, if appropriate, to deploy the quality of service obligation tools set out in Article 22 of the Universal Service and Users Rights Directive; calls for the consideration, if necessary, of additional legislative measures at EU level;
14. Stresses that in order to stimulate innovation, increase consumer choice, reduce costs and increase efficiency in the deployment of the high-speed electronic communication infrastructure, a mix of different measures and all available technologies should be explored and offered to consumers, so as to prevent the deterioration of service, the blocking of access and the slowing of traffic over networks;
15. Emphasises that the competent national authorities should aim to apply regulatory principles, procedures and conditions for spectrum usage which do not impede European electronic communications providers from providing networks and services in several Member States or across the Union;
16. Is convinced that increased spectrum coordination combined with the application of common principles for spectrum use rights across the Union would constitute a key remedy for tackling the problem of lack of predictability regarding spectrum availability, thus encouraging investment and economies of scale;
17. Stresses that incentive payments and/or the revoking of right of use in case of failure to use relevant radio spectrum could be important measures to free up sufficient harmonised radio spectrum in order to stimulate high-capacity wireless broadband services;

Thursday 24 October 2013

18. Emphasises that a pan-European auctioning of 4G and 5G wireless services, with a limited number of licensees collectively serving the whole territory of the EU, would enable pan-European wireless services, eroding the bases upon which roaming is built;
  19. Calls on the Member States to give the consumer aspects of electronic communications a much higher priority; emphasises that well-functioning markets, with well-informed and confident consumers, are the backbone of the EU market as a whole;
  20. Stresses that since consumers are increasingly choosing bundled contracts covering multiple services, it is particularly important that pre-contractual and existing contract update information requirements are strictly enforced;
  21. Stresses the importance of enhanced consumer information requirements regarding service restrictions, device subsidies and traffic management; calls on the Member States and the Commission to ensure consistent enforcement of the ban on misleading advertising;
  22. Emphasises that bundling of content can be a barrier to switching, and asks the Commission and BEREC to look at the potential anti-competitive aspects involved in this regard;
  23. Notes that there are cases where carriers have restricted the tethering functionality (whereby a mobile phone can be used as a router/hotspot) of consumers' mobile phones even though the consumer contract specifies unlimited data usage; asks the Commission and BEREC, therefore, to look into the issue of potentially misleading advertising in the light of the need for increased clarity in this regard;
  24. Notes the importance of switching, ease of number portability in a dynamic market, contract transparency and provision of information to consumers regarding contract changes; regrets the fact that portability targets are not being met, and calls for action by the Commission and BEREC;
  25. Supports those Member States which have implemented reinforced requirements for equivalent access for disabled users, and calls on all Member States to follow their example; calls on BEREC to improve the promotion of provisions and access for disabled users;
  26. Commends all Member States for the implementation of the 112 common emergency telephone number; calls for improvements regarding caller location response time; notes that several Member States have already configured technologies that provide near-instant caller location;
  27. Welcomes the Commission's work on the practical implementation of the 116 numbers, especially the missing child hotline (116 000); calls for better promotion of these numbers by the Commission;
  28. Notes that the Commission has abandoned its ambitions for a pan-European telephone numbering system;
  29. Emphasises the significant progress made in providing entry-level universal broadband access, while noting that it has been very uneven; encourages the Member States to meet the digital agenda targets by stimulating private and deploying public investment in new network capacity;
  30. Emphasises that increasing data volume, limited availability of spectrum resources and the convergence of technologies, equipment and content require intelligent data traffic management and different methods of dissemination, such as cooperation between digital terrestrial broadcasting and wireless broadband networks;
  31. Stresses that a review must be based on broad consultations with all interested parties and a thorough analysis of all issues;
  32. Calls on the Commission, therefore, to initiate the next review of the entire framework, in order to allow a proper debate during the next parliamentary term;
  33. Instructs its President to forward this resolution to the Council and the Commission.
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Tuesday 22 October 2013

### III

(Preparatory acts)

## EUROPEAN PARLIAMENT

P7\_TA(2013)0425

### **Tariff quotas for wine \*\*\*I**

**European Parliament legislative resolution of 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on amending Council Regulation (EC) No 1215/2009 in relation to tariff quotas for wine (COM(2013)0187 — C7-0090/2013 — 2013/0099(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/17)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0187),
  - having regard to Article 294(2) and Article 207(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0090/2013),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the undertaking given by the Council representative by letter of 16 October 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on International Trade (A7-0293/2013),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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### **P7\_TC1-COD(2013)0099**

**Position of the European Parliament adopted at first reading on 22 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council amending Council Regulation (EC) No 1215/2009 in relation to tariff quotas for wine**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1202/2013.)*

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Tuesday 22 October 2013

P7\_TA(2013)0426

**Macro-financial assistance to the Kyrgyz Republic \*\*\*II**

**European Parliament legislative resolution of 22 October 2013 on the Council position at first reading with a view to the adoption of a decision of the European Parliament and of the Council providing macro-financial assistance to the Kyrgyz Republic (11703/1/2013 — C7-0314/2013 — 2011/0458(COD))**

**(Ordinary legislative procedure: second reading)**

(2016/C 208/18)

*The European Parliament,*

- having regard to the Council position at first reading (11703/1/2013 — C7-0314/2013),
  - having regard to its position at first reading <sup>(1)</sup> on the Commission proposal to Parliament and the Council (COM(2011) 0925),
  - having regard to the letter of the Chair of the Committee on International Trade of 11 July 2013 undertaking to recommend to the plenary to approve Council's position at first reading,
  - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 72 of its Rules of Procedure,
  - having regard to the recommendation for second reading of the Committee on International Trade (A7-0334/2013),
1. Approves the Council position at first reading;
  2. Notes that the act is adopted in accordance with the Council position;
  3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
  4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*,
  5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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<sup>(1)</sup> Texts adopted of 11.12.2012, P7\_TA(2012)0466.

Tuesday 22 October 2013

P7\_TA(2013)0427

**In vitro diagnostic medical devices \*\*\*I**

**Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012)0541 — C7-0317/2012 — 2012/0267(COD))** <sup>(1)</sup>

**(Ordinary legislative procedure: first reading)**

(2016/C 208/19)

**Amendment 1****Proposal for a regulation****Recital 2***Text proposed by the Commission*

- (2) This Regulation aims to ensure the functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union, this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) **of the Treaty on the Functioning of the European Union**, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical performance studies is protected.

*Amendment*

- (2) This Regulation aims to ensure the functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health **for patients, users and operators**. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union **(TFEU)**, this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) **TFEU**, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical performance studies is protected.

<sup>(1)</sup> The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0327/2013).

Tuesday 22 October 2013

**Amendment 2**  
**Proposal for a regulation**  
**Recital 3**

*Text proposed by the Commission*

- (3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, **risk classification**, conformity assessment procedures, clinical **evidence**, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding in vitro diagnostic medical devices should be introduced to improve health and safety.

*Amendment*

- (3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical **investigations and clinical evaluation**, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety **for health professionals, patients, users and operators, including in the waste disposal chain**.

**Amendment 3**  
**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

- (5) There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.

*Amendment*

- (5) There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned **without compromising the need for innovation in the Union**.

**Amendment 4**  
**Proposal for a regulation**  
**Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

- (5a) **The high number of small and medium enterprises (SMEs) active in the area of in-vitro diagnostic medical devices should be taken into account when regulating that area, while avoiding the creation of health and safety risks.**

Tuesday 22 October 2013

**Amendment 5**  
**Proposal for a regulation**  
**Recital 7 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (7a) ***A multidisciplinary Medical Device Advisory Committee (MDAC) composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, regulatory status of devices and other aspects of implementation of this Regulation as necessary.***

**Amendment 6**  
**Proposal for a regulation**  
**Recital 8**

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*Text proposed by the Commission*

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*Amendment*

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- (8) ***It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of an in vitro diagnostic medical device or of an accessory to an in vitro diagnostic medical device.***

- (8) ***In order to ensure consistent classification across all Member States, particularly with regard to borderline cases, it should be the responsibility of the Commission, having consulted the MDCG and the MDAC, to decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation. Member States should also have the possibility to request the Commission to take a decision on the appropriate regulatory status of a product, or category or group of products.***

**Amendment 7**  
**Proposal for a regulation**  
**Recital 9 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (9a) ***In the case of urgent or unmet medical needs for patients, such as emerging pathogens and rare diseases, single health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, within a non-commercial and flexible framework, specific needs which cannot be met by an available CE-marked device.***

Tuesday 22 October 2013

**Amendment 8**  
**Proposal for a regulation**  
**Recital 9 b (new)**

Text proposed by the Commission

Amendment

- (9b) *However, devices which are manufactured within non-health-institution laboratories and put into service without being placed onto the market should be subject to this Regulation.*

**Amendment 9**  
**Proposal for a regulation**  
**Recital 13 a (new)**

Text proposed by the Commission

Amendment

- (13a) *Directive 2013/35/EU of the European Parliament and of the Council<sup>(1)</sup> should be the reference text for ensuring that people working in the vicinity of magnetic resonance imaging equipment when it is in operation are properly protected.*

<sup>(1)</sup> *Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC (OJ L 197, 29.6.2013, p. 1).*

**Amendment 10**  
**Proposal for a regulation**  
**Recital 22**

Text proposed by the Commission

Amendment

- (22) It should be ensured that supervision and control of the manufacture of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification.

- (22) It should be ensured that supervision and control of the manufacture of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification. ***In addition to regulatory compliance, that person could also be responsible for compliance in other fields such as manufacturing processes and quality assessment. The required qualifications of the person responsible for the regulatory compliance should be without prejudice to national provisions regarding professional qualifications, in particular for manufacturers of custom-made devices where such requirements could be met through different educational and professional training systems at national level.***

Tuesday 22 October 2013

**Amendment 11**  
**Proposal for a regulation**  
**Recital 25 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (25a) *To ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty in vitro diagnostic medical device, that the risk of damage as well as the risk of the manufacturer's insolvency are not shifted to patients harmed by a faulty in vitro diagnostic medical device, manufacturers should be obliged to take liability insurance with sufficient minimum coverage.*

**Amendment 12**  
**Proposal for a regulation**  
**Recital 26**

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*Text proposed by the Commission*

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*Amendment*

- (26) In vitro diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation.

- (26) In vitro diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. ***However Member States should be allowed to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.***

Tuesday 22 October 2013

**Amendment 13**  
**Proposal for a regulation**  
**Recital 27**

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*Text proposed by the Commission*

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- (27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve ***purchase-policy and stock-management by hospitals.***

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*Amendment*

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- (27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve ***purchasing and waste disposal policies and hospitals', wholesalers' and pharmacists' management of stock and, where possible, be compatible with other authentication systems already in place in those settings.***

**Amendment 14**  
**Proposal for a regulation**  
**Recital 28**

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*Text proposed by the Commission*

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- (28) Transparency and ***better*** information are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

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*Amendment*

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- (28) Transparency and ***adequate access to*** information, ***appropriately presented for the intended user,*** are essential to empower patients and healthcare professionals ***and all others concerned,*** and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Tuesday 22 October 2013

**Amendment 15**  
**Proposal for a regulation**  
**Recital 29**

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*Text proposed by the Commission*

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- (29) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding in vitro diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

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*Amendment*

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- (29) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding in vitro diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, **via better access to information for the public and healthcare professionals**, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Tuesday 22 October 2013

**Amendment 16**  
**Proposal for a regulation**  
**Recital 30**

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*Text proposed by the Commission*

- (30) Eudamed's electronic systems **regarding devices on the market, the relevant economic operators and certificates** should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

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*Amendment*

- (30) Eudamed's electronic systems should enable the public **and healthcare professionals** to be adequately informed about devices on the Union market. **Adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on in vitro diagnostic medical devices that may pose a risk to public health and safety is essential. Where such access is limited, it should be possible, upon a reasoned request, to disclose the existing information on in vitro diagnostic medical devices, unless the limitation of access is justified on grounds of confidentiality.** The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities. **A regular overview of vigilance and market surveillance information should be made available to healthcare professionals and the public.**

**Amendment 17**  
**Proposal for a regulation**  
**Recital 32**

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*Text proposed by the Commission*

- (32) For high-risk *in vitro* diagnostic medical devices, manufacturers should **summarise the main** safety and performance aspects of the device and the outcome of the clinical evaluation **in a document that** should be publicly available.

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*Amendment*

- (32) For high-risk *in vitro* diagnostic medical devices, **in the interests of increased transparency,** manufacturers should **draw up a report on the** safety and performance aspects of the device and the outcome of the clinical evaluation. **A summary of the safety and performance report** should be publicly available **via Eudamed.**

Tuesday 22 October 2013

**Amendment 18**  
**Proposal for a regulation**  
**Recital 32 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (32a) *According to the policy of the European Medicines Agency (EMA) on access to documents, the EMA releases documents submitted as part of applications for marketing authorisation for medicinal products, including clinical trial reports, on request once the decision-making process for the medicinal product in question has been completed. Corresponding standards on transparency and access to documents should be upheld and reinforced for high-risk in vitro diagnostic medical devices, in particular as they are not subject to pre-market approval. For the purposes of this Regulation, in general the data included in clinical performance studies should not be considered commercially sensitive provided that compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure. This should be without prejudice to intellectual property rights concerning the use by other manufacturers of data from clinical performance studies by the manufacturer.*

**Amendment 19**  
**Proposal for a regulation**  
**Recital 33**

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*Text proposed by the Commission*

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*Amendment*

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| <p>(33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.</p> | <p>(33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, <b>and where applicable by EMA</b>, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.</p> |
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Tuesday 22 October 2013

**Amendment 20**  
**Proposal for a regulation**  
**Recital 35**

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*Text proposed by the Commission*

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*Amendment*

- (35) *For high risk in vitro diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which no common technical specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk in vitro diagnostic medical device before submitting the application to the notified body.*

*deleted*

**Amendment 262**  
**Proposal for a regulation**  
**Recital 40 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (40a) *Clinical expertise and specialist product knowledge within notified bodies, Special notified bodies and the Medical Device Coordination Group should be appropriate for the specifications of in vitro diagnostic medical devices. Clinical experts should have expertise in clinical interpretation of in vitro diagnostic results, metrology and Good Laboratory Practice. Clinical experts and product specialists should have expertise in fields such as virology, haematology, clinical analysis, genetics.*

Tuesday 22 October 2013

**Amendment 22**  
**Proposal for a regulation**  
**Recital 43 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- 43a. *The Declaration of Helsinki of the World Medical Association<sup>(1)</sup> states in Article 15 that ‘the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins.’ Interventional clinical performance studies and other clinical performance studies involving risk for the subject should only be allowed after assessment and approval by an ethics committee. The reporting Member State and the other concerned Member States need to organise themselves in a way that the competent authority concerned receives approval by an ethics committee on the clinical performance study protocol.*

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<sup>(1)</sup> WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and lastly amended by the 59<sup>th</sup> WMA General Assembly, Seoul, Korea, October 2008  
[http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage])

**Amendment 23**  
**Proposal for a regulation**  
**Recital 44 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (44a) *For the sake of transparency, sponsors should submit the results of a clinical performance study together with a ‘layperson’ summary within the deadlines specified by the regulation. The Commission should be empowered to adopt delegated acts on the preparation of the layperson’s summary and the communication of the clinical performance study report. The Commission should provide guidelines for managing, and facilitating the sharing of, raw data from all clinical performance studies.*

Tuesday 22 October 2013

**Amendment 24**  
**Proposal for a regulation**  
**Recital 45**

Text proposed by the Commission

- (45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member States, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. ***The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical performance study, including informed consent.*** Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.

Amendment

- (45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member States, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.

**Amendment 25**  
**Proposal for a regulation**  
**Recital 45a (new)**

Text proposed by the Commission

Amendment

- (45a) ***Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC of the European Parliament and of the Council<sup>(1)</sup>.***

<sup>(1)</sup> Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

Tuesday 22 October 2013

**Amendment 26**  
**Proposal for a regulation**  
**Recital 48**

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*Text proposed by the Commission*

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- (48) In order to better protect health and safety regarding devices on the market, the vigilance system for in vitro diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

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*Amendment*

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- (48) In order to better protect health and safety regarding devices on the market, the vigilance system for in vitro diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions **within and outside the Union.**

**Amendment 27**  
**Proposal for a regulation**  
**Recital 49**

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*Text proposed by the Commission*

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- (49) Healthcare professionals and patients should be empowered to report **suspected serious** incidents at national level using harmonised formats. **The** national competent authorities should inform manufacturers and **share** the information **with their peers** when they confirm that **a serious** incident has occurred **in order to minimise recurrence of those incidents.**

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*Amendment*

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- (49) **Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents.** Healthcare professionals, **users** and patients should be empowered **and enabled** to report such incidents at national level using harmonised formats **and guaranteeing anonymity, where appropriate. In order to minimise the recurrence of such incidents, the** national competent authorities should inform manufacturers, **and, if appropriate, their subsidiaries and sub-contractors, and report** the information **via the respective electronic system in Eudamed** when they confirm that **an** incident has occurred.

**Amendment 28**  
**Proposal for a regulation**  
**Recital 53**

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*Text proposed by the Commission*

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- (53) The Member States **shall** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.

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*Amendment*

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- (53) The Member States **should** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies. **These fees should be comparable across Member States and should be made public.**

Tuesday 22 October 2013

**Amendment 29**  
**Proposal for a regulation**  
**Recital 54**

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*Text proposed by the Commission*

- (54) Whilst this Regulation should not affect the right of the Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency.

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*Amendment*

- (54) Whilst this Regulation should not affect the right of the Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the **comparable** level and structure of the fees to ensure transparency.

**Amendment 30**  
**Proposal for a regulation**  
**Recital 54 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (54a) **Member States should adopt provisions on standard fees for notified bodies, which should be comparable across Member States. The Commission should provide guidelines to facilitate the comparability of those fees. Member States should transmit their list of standard fees to the Commission and ensure that the notified bodies registered on their territory make the lists of standard fees for their conformity assessment activities publicly available.**

Tuesday 22 October 2013

**Amendment 31**  
**Proposal for a regulation**  
**Recital 55**

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*Text proposed by the Commission*

- (55) **An expert committee, the Medical Device Coordination Group** (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

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*Amendment*

- (55) A MDCG, composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. **Prior to taking up their duties, members of the MDCG should make available a declaration of commitment and a declaration of interests indicating either the absence of any interests which could be considered prejudicial to their independence or any direct or indirect interests which could be prejudicial to their independence. Those declarations should be verified by the Commission.**

**Amendment 32**  
**Proposal for a regulation**  
**Recital 59**

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*Text proposed by the Commission*

- (59) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

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*Amendment*

- (59) This Regulation respects the fundamental rights and observes the principles recognized in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, **the principle of free and informed consent of the person concerned**, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property, **as well as the European Convention on Human Rights and Biomedicine as well as the Additional Protocol to that Convention concerning Genetic Testing for Health Purposes**. This Regulation should be applied by the Member States in accordance with those rights and principles.

Tuesday 22 October 2013

**Amendment 33**  
**Proposal for a regulation**  
**Recital 59 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (59a) *Clear rules on the application of DNA tests are important. It is however advisable to regulate only on some basic elements and leave room for the Member States for more specific regulation in this area. Member States should for example regulate, that all devices providing an indication of a genetic disease which develops in adulthood or affects family planning may not be used on minors unless preventive treatment is available*

**Amendment 34**  
**Proposal for a regulation**  
**Recital 59 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (59b) *While genetic counselling should be mandatory in specific cases it should not be mandatory in cases where a diagnosis of a patient already suffering from a disease is confirmed by a genetic test or where a companion diagnostic is used.*

**Amendment 35**  
**Proposal for a regulation**  
**Recital 59 c (new)**

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*Text proposed by the Commission*

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*Amendment*

- (59c) *This Regulation is in keeping with the United Nations Convention on the Rights of Persons with Disabilities of 13 December 2006, ratified by the European Union on 23 December 2010, pursuant to which the signatories commit themselves, in particular, to promote, protect and guarantee the full and equal exercise of all human rights and basic freedoms by all persons with disabilities and to promote the respect of their inherent dignity, inter alia by raising awareness about the abilities of disabled persons and the contribution they make.*

Tuesday 22 October 2013

**Amendment 270**  
**Proposal for a regulation**  
**Recital 59 d (new)**

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Text proposed by the Commission

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Amendment

59d. *Whereas, in view of the need to protect the integrity of the human person during the sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.*

**Amendment 36**  
**Proposal for a regulation**  
**Recital 60**

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Text proposed by the Commission

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Amendment

(60) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect **of the adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies**, of the minimum requirements to be met by notified bodies, of the classification rules, **of the conformity assessment procedures**, and of the documentation to be submitted for the approval of clinical performance studies; the establishment of the UDI system; the information to be submitted for the registration of *in vitro* diagnostic medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical performance studies; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(60) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the minimum requirements to be met by notified bodies, of the classification rules and of the documentation to be submitted for the approval of clinical performance studies; the establishment of the UDI system; the information to be submitted for the registration of *in vitro* diagnostic medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical performance studies; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. **However, basic aspects elements of this Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure.** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Tuesday 22 October 2013

**Amendment 37**  
**Proposal for a regulation**  
**Recital 64**

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*Text proposed by the Commission*

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- (64) To allow economic operators, **notified bodies, Member States and the Commission** to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period **for that adaptation and for the** organisational arrangements **to be taken for its proper application**. It is particularly important that **by the date of application**, a sufficient number of notified bodies **are designated** in accordance with the new requirements to avoid any shortage of *in vitro* diagnostic medical devices on the market.

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*Amendment*

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- (64) To allow economic operators, **especially SMEs**, to adapt to the changes introduced by this Regulation **and to ensure its proper application**, it is appropriate to provide for a sufficient transitional period **to allow for** organisational arrangements **to be made. However, parts of the Regulation that concern Member States and the Commission should be implemented as soon as possible**. It is particularly important that a sufficient number of notified bodies **is designated** in accordance with the new requirements, **as soon as possible**, to avoid any shortage of *in-vitro* diagnostics medical devices on the market.

**Amendment 38**  
**Proposal for a regulation**  
**Recital 65**

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*Text proposed by the Commission*

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- (65) In order to ensure a smooth transition to the registration of *in vitro* diagnostic medical devices, **of relevant economic operators and of certificates, the obligation to submit the relevant information to** the electronic systems put in place by this Regulation at Union level should become **fully effective only 18 months after the date of application of this Regulation. During this transitional period, Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC should remain in force. However**, economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.

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*Amendment*

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- (65) In order to ensure a smooth transition to the registration of *in vitro* diagnostic medical devices the electronic systems put in place by this Regulation at Union level should become **operational as soon as possible**. Economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.

Tuesday 22 October 2013

**Amendment 39**  
**Proposal for a regulation**  
**Recital 67 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(67 a) *It is a long standing policy of the Union not to interfere with national policy allowing, prohibiting or limiting at national level ethically controversial technologies, such as preimplantation genetic testing. This Regulation should not interfere with this principle, and the decision to allow, prohibit or restrict such technologies should therefore remain at national level. Where a Member State allows such technologies whether with or without restriction, the standards laid down in this Regulation should apply.*

**Amendment 272**  
**Proposal for a regulation**  
**Recital 67 b (new)**

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*Text proposed by the Commission*

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*Amendment*

(67b) *Although internationally certified reference materials and materials used for external quality assessment schemes are not covered by this Directive, calibrators and control materials needed by the user to establish or verify performances of devices are in vitro diagnostic medical devices.*

**Amendment 268**  
**Proposal for a regulation**  
**Article 1 — paragraph 6**

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*Text proposed by the Commission*

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*Amendment*

6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.

6. This Regulation ***provides that certain devices may only be supplied on a medical prescription but*** it shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.***

***The following devices may only be supplied on a medical prescription:***

***1) Class D devices;***

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**2) Class C devices in the following categories:****(a) devices for genetic testing;****(b) companion diagnostics.**

***By derogation, justified by the attainment of a high level of public health protection, Member States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that case, they shall duly inform the Commission.***

***The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide that other class C tests may only be supplied on a medical prescription after consultation with stakeholders.***

**Amendment 41****Proposal for a regulation****Article 1 — paragraph 7 a (new)**

Text proposed by the Commission

Amendment

***7a. The regulation of in-vitro diagnostic medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.***

**Amendments 42 and 43****Proposal for a regulation****Article 2 — paragraph 1 — point 1**

Text proposed by the Commission

Amendment

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ***direct or indirect*** medical purposes of:

— diagnosis, prevention, monitoring, ***prediction, prognosis***, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,

Tuesday 22 October 2013

<i>Text proposed by the Commission</i>	<i>Amendment</i>
— investigation, replacement or modification of the anatomy or of a physiological process or state,	— investigation, replacement or modification of the anatomy or of a physiological process or state,
— control or support of conception,	— control or support of conception,
— disinfection or sterilisation of any of the above-mentioned products,	— disinfection or sterilisation of any of the above-mentioned products,
	— <b>providing information concerning direct or indirect impacts on health,</b>
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.	and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

**Amendment 44****Proposal for a regulation****Article 2 — paragraph 1 — point 2 — indent 2**

<i>Text proposed by the Commission</i>	<i>Amendment</i>
— concerning <b>a</b> congenital <b>abnormality</b> ;	— concerning congenital <b>physical or mental impairments</b> ,

**Amendment 45****Proposal for a regulation****Article 2 — paragraph 1 — point 2 — subparagraph 2 a (new)**

<i>Text proposed by the Commission</i>	<i>Amendment</i>
	<b><i>In vitro diagnostic medical devices used for DNA-testing shall be subject to this Regulation.</i></b>

**Amendment 46****Proposal for a regulation****Article 2 — paragraph 1 — point 4**

<i>Text proposed by the Commission</i>	<i>Amendment</i>
(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons;	(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, <b>including testing services offered to lay persons by means of information society services</b> ;

Tuesday 22 October 2013

## Amendment 47

## Proposal for a regulation

## Article 2 — paragraph 1 — point 6

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*Text proposed by the Commission*

- (6) ‘companion diagnostic’ means a device specifically intended **to select** patients with a previously diagnosed condition or predisposition as **eligible** for a **targeted** therapy;

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*Amendment*

- (6) ‘companion diagnostic’ means a device specifically intended **for and essential to the selection of** patients with a previously diagnosed condition or predisposition as **suitable or unsuitable** for a **specific** therapy **with a medicinal product or a range of medicinal products**;

## Amendment 48

## Proposal for a regulation

## Article 2 — paragraph 1 — point 12 a (new)

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*Text proposed by the Commission*

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*Amendment*

(12a) ‘novel device’ means:

- **a device which incorporates technology (the analyte, technology or test platform) not previously used in diagnostics, or;**
- **an existing device which is being used for a new intended purpose for the first time;**

## Amendment 49

## Proposal for a regulation

## Article 2 — paragraph 1 — point 12 b (new)

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*Text proposed by the Commission*

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*Amendment*

- (12b) ‘device for genetic testing’ means **an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development;**

Tuesday 22 October 2013

## Amendment 50

## Proposal for a regulation

## Article 2 — paragraph 1 — point 15 a (new)

Text proposed by the Commission

Amendment

(15a) **'Information Society service' means any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;**

## Amendment 51

## Proposal for a regulation

## Article 2 — paragraph 1 — point 16 — subparagraph 1

Text proposed by the Commission

Amendment

(16) 'manufacturer' means the natural or legal person **who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device** under his name or trademark.

(16) 'manufacturer' means the natural or legal person **with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by manufacturers also apply to natural or legal persons who assemble, package, process, fully refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market under that person's own** name or trademark.

## Amendment 52

## Proposal for a regulation

## Article 2 — paragraph 1 — point 21

Text proposed by the Commission

Amendment

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients **or the promotion of public health;**

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients **and which has the legal capacity to carry out such activities; commercial laboratories which provide diagnostic services shall not be considered to be health institutions;**

Tuesday 22 October 2013

## Amendment 53

## Proposal for a regulation

## Article 2 — paragraph 1 — point 25

*Text proposed by the Commission*

- (25) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including **calibration**, testing, certification and inspection;

*Amendment*

- (25) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including testing, certification and inspection;

## Amendment 54

## Proposal for a regulation

## Article 2 — paragraph 1 — point 28

*Text proposed by the Commission*

- (28) ‘clinical evidence’ means the **information that supports** the scientific validity and performance for the use of a device as intended by the manufacturer;

*Amendment*

- (28) ‘clinical evidence’ means the **data, positive and negative, supporting the evaluation of** the scientific validity and performance for the use of a device as intended by the manufacturer;

## Amendment 55

## Proposal for a regulation

## Article 2 — paragraph 1 — point 30

*Text proposed by the Commission*

- (30) ‘performance of a device’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of **the** analytical and, where applicable, the clinical performance supporting the intended purpose of the device;

*Amendment*

- (30) ‘performance of a device’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of **attainment of technical capabilities, analytical performance** and, where applicable, the clinical performance supporting the intended purpose of the device;

## Amendment 56

## Proposal for a regulation

## Article 2 — paragraph 1 — point 35

*Text proposed by the Commission*

- (35) ‘performance evaluation’ means the assessment and analysis of data to establish or verify **the** analytical and, where applicable, the clinical performance of a device;

*Amendment*

- (35) ‘performance evaluation’ means the assessment and analysis of data to establish or verify **that the device performs as intended by the manufacturer, including the technical**, analytical and, where applicable, the clinical performance of a device;

Tuesday 22 October 2013

## Amendment 57

## Proposal for a regulation

## Article 2 — paragraph 1 — point 37 a (new)

Text proposed by the Commission

Amendment

(37a) *'ethics committee' means an independent body in a Member State, consisting of health-care professionals and non-medical members including at least one well-experienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in interventional clinical performance studies and other clinical performance studies involving risk for the subject and to provide public assurance of that protection in full transparency. In cases of such studies involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise.*

## Amendment 58

## Proposal for a regulation

## Article 2 — paragraph 1 — point 43 a (new)

Text proposed by the Commission

Amendment

(43a) *'calibrator' means a measurement standard used in the calibration of a device;*

## Amendment 59

## Proposal for a regulation

## Article 2 — paragraph 1 — point 44

Text proposed by the Commission

Amendment

(44) *'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended purpose of that device;*

(44) *'control material' means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;*

Tuesday 22 October 2013

**Amendment 60****Proposal for a regulation****Article 2 — paragraph 1 — point 45***Text proposed by the Commission*

(45) ‘sponsor’ means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;

*Amendment*

(45) ‘sponsor’ means any individual, company, institution or organisation which takes responsibility for the initiation, management, **conduct or financing** of a clinical performance study;

**Amendment 61****Proposal for a regulation****Article 2 — paragraph 1 — point 47 — indent 2 — point iii***Text proposed by the Commission*

(iii) hospitalisation or **extending the duration of** hospitalisation,

*Amendment*

(iii) hospitalisation or **prolongation of patient** hospitalisation,

**Amendment 62****Proposal for a regulation****Article 2 — paragraph 1 — point 48***Text proposed by the Commission*

(48) ‘device deficiency’ means any inadequacy in the identity, quality, **durability**, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

*Amendment*

(48) ‘device deficiency’ means any inadequacy in the identity, quality, **stability**, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

**Amendment 63****Proposal for a regulation****Article 2 — paragraph 1 — point 48 a (new)***Text proposed by the Commission**Amendment*

(48a) ‘inspection’ means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor’s and/or contract research organisation’s facilities, or at other establishments which the competent authority sees fit to inspect;

Tuesday 22 October 2013

## Amendment 64

## Proposal for a regulation

## Article 2 — paragraph 1 — point 55

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Text proposed by the Commission

(55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

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Amendment

(55) 'field safety notice' means the communication sent by the manufacturer to users, **waste disposal operators** or customers in relation to a field safety corrective action;

## Amendment 65

## Proposal for a regulation

## Article 2 — paragraph 1 — point 56 a(new)

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Text proposed by the Commission

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Amendment

(56a) **'unannounced inspection' means an inspection conducted without advance notice;**

## Amendment 66

## Proposal for a regulation

## Article 3

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Text proposed by the Commission

1. The Commission may, at the request of a Member State **or on its own initiative**, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

2. **The Commission shall ensure the sharing of expertise between Member States in the fields of in vitro diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.**

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Amendment

1. The Commission may **on its own initiative or shall** at the request of a Member State, by means of implementing acts **on the basis of the opinions of the MDCG and the MDAC referred to in Articles 76 and 76a respectively**, determine whether or not a specific product, or category or group of products, **including borderline products**, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Tuesday 22 October 2013

**Amendment 67**  
**Proposal for a regulation**  
**Chapter II — title**

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*Text proposed by the Commission*

Chapter II

Making available of devices, obligations of economic operators, CE marking, free movement

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*Amendment*

Chapter VI (\*)

Making available **and application** of devices, obligations of economic operators, CE marking, free movement

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(\*) As a consequence of this amendment, this Chapter will cover Articles 4 to 20.

**Amendment 68**  
**Proposal for a regulation**  
**Article 4 — paragraph 3**

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*Text proposed by the Commission*

3. Demonstration of conformity with the general safety and performance requirements shall **be based on** clinical evidence in accordance with Article 47.

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*Amendment*

3. Demonstration of conformity with the general safety and performance requirements shall **include** clinical evidence in accordance with Article 47.

**Amendment 69**  
**Proposal for a regulation**  
**Article 4 — paragraph 5 — subparagraph 1**

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*Text proposed by the Commission*

With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is **compliant** with standard EN ISO 15189 or any other equivalent recognised standard. Member States **may** require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and **may** make the manufacture and use of the devices concerned subject to further safety requirements.

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*Amendment*

With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is **accredited** with standard EN ISO 15189 or any other equivalent recognised standard. **However, the requirements of this Regulation shall continue to apply to clinical or commercial pathology laboratories which do not have health care (i.e. care and treatment of patients) or the promotion of public health as their primary purpose.** Member States **are to** require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and **shall** make the manufacture and use of the devices concerned subject to further safety requirements.

Tuesday 22 October 2013

## Amendment 70

## Proposal for a regulation

## Article 4 — paragraph 5 — subparagraph 2

## Text proposed by the Commission

Devices classified as class D in accordance with the rules set out in Annex VII, **even** if manufactured and used within a single health institution, shall **comply with** the requirements of this Regulation. **However, the provisions regarding CE marking set out in Article 16 and the obligations** referred to in **Articles 21 to 25** shall **not apply to those** devices.

## Amendment

Devices classified as class D in accordance with the rules set out in Annex VII, if manufactured and used within a single health institution, shall **be exempt from** the requirements of this Regulation, **with the exception of Article 59(4) and general safety performance requirements set out in Annex I where the following conditions are met:**

- (a) **the recipient patient or patient group's specific needs cannot be met by an available CE-marked device as such, and therefore, either a CE-marked device needs to be modified or a new device needs to be manufactured;**
- (b) **the health institution is accredited to ISO standard 15189 quality management system, or any other equivalent recognised standard;**
- (c) **the health institution provides the Commission and the competent authority referred to in Article 26 with a list of such devices, which shall include a justification of their manufacturing, modification or use. This list shall be regularly updated.**

**The Commission shall verify that the devices on that list are eligible for exemption in accordance with the requirements under this paragraph.**

**The information on exempt devices shall be made public.**

**Member States shall retain the right to restrict the in-house manufacture and use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation, and may also make the manufacture and use of the devices concerned subject to further safety requirements. In such cases, Member States shall inform the Commission and the other Member States accordingly.**

Tuesday 22 October 2013

## Amendment 71

## Proposal for a regulation

## Article 4 — paragraph 6

Text proposed by the Commission

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.

Amendment

deleted

## Amendment 271

## Proposal for a regulation

## Article 4 a (new)

Text proposed by the Commission

Amendment

## Article 4a

## Genetic information, counselling and informed consent

1. A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.

2. A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.

3. Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.

4. Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians or another person qualified under national law in genetic counselling.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family.*

5. Consent. A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

6. Testing of minors and incapacitated subjects. In case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated subjects not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will of the incapacitated subject and may be revoked at any time, without detriment to the person.

7. A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation from Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.

8. The provisions of this Article on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.

Tuesday 22 October 2013

**Amendment 73****Proposal for a regulation****Article 5 — paragraph 2 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**2a.** *Service providers providing means of distance communication shall be obliged, upon receiving a request from the competent authority, to disclose the details of entities engaging in distance selling.*

**Amendment 74****Proposal for a regulation****Article 5 — paragraph 2 b (new)**

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*Text proposed by the Commission*

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*Amendment*

**2b.** *There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by:*

- a) ascribing characteristics, functions and effects to the product which the product does not have;*
- b) creating the false impression that treatment or diagnosis using the product is sure to be successful, or failing to inform of a likely risk associated with the use of the product in line with its intended use or for a longer-than-anticipated period;*
- c) suggesting uses or characteristics of the product other than those declared when the conformity assessment was carried out.*

*Promotional materials, presentations and information about the products may not mislead in the manner referred to in the first subparagraph.*

Tuesday 22 October 2013

## Amendment 75

## Proposal for a regulation

## Article 7 — paragraphs 1 and 1 a (new)

Text proposed by the Commission

1. Where no harmonised standards exist or where **relevant harmonised standards are not sufficient**, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

Amendment

1. Where no harmonised standards exist or where **there is a need to address public health concerns**, the Commission, **after having consulted the MDCG and the MDAC**, shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

**1a. Before adopting CTS referred to in paragraph 1, the Commission shall ensure that the CTS have been developed with the appropriate support of the relevant stakeholders and that they are coherent with the European and international standardisation system. CTS are coherent if they do not conflict with European standards, meaning they cover areas where no harmonised standards exist, the adoption of new European standards is not envisaged within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not envisaged within a reasonable period.**

## Amendment 76

## Proposal for a regulation

## Article 8 — paragraph 2 — subparagraph 2

Text proposed by the Commission

**The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.**

Amendment

**deleted**

Tuesday 22 October 2013

## Amendment 77

## Proposal for a regulation

## Article 8 — paragraph 6 — subparagraph 1

## Text proposed by the Commission

Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'. The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.

## Amendment

Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'. The post-market surveillance plan shall set out the process for collecting, recording, **communicating to the electronic system on vigilance referred in Article 60** and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan **and subject to approval by the competent authority.**

## Amendments 78, 79 and 263

## Proposal for a regulation

## Article 8 — paragraph 7

## Text proposed by the Commission

7. Manufacturers shall ensure that **the device is accompanied by** the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.

## Amendment

7. Manufacturers shall ensure that the information to be supplied **for the device** in accordance with Section 17 of Annex I **is provided** in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be **easily understandable and** provided in the **official Union** language(s) of the Member State where the device reaches its intended user.

Tuesday 22 October 2013

## Amendment 80

## Proposal for a regulation

## Article 8 — paragraph 8

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*Text proposed by the Commission*

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative accordingly.

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*Amendment*

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the **responsible national competent authority, the** distributors, **importers** and, where applicable, the authorised representative accordingly.

## Amendment 81

## Proposal for a regulation

## Article 8 — paragraph 9 — subparagraph 1 a (new)

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*Text proposed by the Commission*

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*Amendment*

***If a competent authority considers or has reason to believe that a device has caused damage, it shall ensure, where this is not already provided for by national litigation or judicial proceedings, that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to in the first subparagraph from the manufacturer or his authorised representative while ensuring due regard for the intellectual property rights.***

## Amendment 82

## Proposal for a regulation

## Article 8 — paragraph 9 — subparagraph 1 b (new)

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*Text proposed by the Commission*

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*Amendment*

***If facts exist that give reason to assume that an in-vitro medical device has caused damage, the potentially harmed user, his successor in title, his compulsory health insurance or other third parties affected by the damage may also demand the information referred to in sentence 1 from the manufacturer or his authorised representative.***

***This right to information shall also exist, subject to the conditions set forth in sentence 1, against the competent authorities of the Member States which are responsible for the surveillance of the relevant medical device, as well as against any notified body that issued a certificate pursuant to Article 45 or was otherwise involved in the conformity assessment procedure of the medical device in question.***

Tuesday 22 October 2013

**Amendment 83****Proposal for a regulation****Article 8 — paragraph 10a (new)***Text proposed by the Commission**Amendment*

**10a.** Before placing an in vitro diagnostic medical device on the market, manufacturers shall ensure they are covered by appropriate liability insurance covering the risk of insolvency and any damage to patients or users that can be directly attributed to a manufacturing defect of the same medical device, with a level of coverage proportionate to the potential risk associated with the in vitro diagnostic medical device produced, and in accordance with Directive 85/374/EEC.

**Amendment 84****Proposal for a regulation****Article 9 — paragraph 3 — subparagraph 3 — point a***Text proposed by the Commission**Amendment*

- (a) keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

- (a) keep **available the summary of technical documentation (STED) or on request** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

**Amendment 85****Proposal for a regulation****Article 11 — paragraph 2 — subparagraph 1 — point b***Text proposed by the Commission**Amendment*

- (b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;

- (b) that **a manufacturer is identified and, that** an authorised representative in accordance with Article 9 has been designated by the manufacturer;

**Amendment 86****Proposal for a regulation****Article 11 — paragraph 2 — subparagraph 1 — point e***Text proposed by the Commission**Amendment*

- (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use **and EU declaration of conformity**;

- (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

Tuesday 22 October 2013

## Amendment 87

## Proposal for a regulation

## Article 11 — paragraph 2 — subparagraph 1 — point f a (new)

Text proposed by the Commission

Amendment

(fa) *that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8 (10a) , unless the importer himself ensures sufficient coverage that meets the requirements of this provision.*

## Amendment 88

## Proposal for a regulation

## Article 11 — paragraph 7

Text proposed by the Commission

Amendment

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, **take** the necessary corrective action to bring that device into conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action **taken**.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer, **and where applicable** his authorised representative and, if appropriate, **ensure that** the necessary corrective action to bring that device in conformity, withdraw or recall it, **is taken and, implement that action**. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action **they have implemented**.

## Amendment 89

## Proposal for a regulation

## Article 12 — paragraph 4

Text proposed by the Commission

Amendment

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that, **within the limits of its respective activities**, the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Tuesday 22 October 2013

**Amendment 90**  
**Proposal for a regulation**  
**Article 13**

Text proposed by the Commission

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one **qualified** person who possesses **expert knowledge** in the field of *in vitro* diagnostic medical devices. The **expert knowledge** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices**;

(b) **five** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. The **qualified** person shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;

(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;

3. The **qualified** person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

Amendment

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person **responsible for regulatory compliance** who possesses **the requisite expertise** in the field of *in vitro* diagnostic medical devices. The **requisite expertise** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in **law**, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

(b) **three** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. The person **responsible for regulatory compliance** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;

(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;

***If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.***

3. The person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

Tuesday 22 October 2013

## Text proposed by the Commission

4. Authorised representatives shall have available within their organisation at least one **qualified** person who possesses **expert knowledge** regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The **expert knowledge** shall be demonstrated by either of the following qualifications:

- (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;**
- (b) **five** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

## Amendment

4. Authorised representatives shall have available within their organisation at least one person **responsible for regulatory compliance** who possesses **the requisite expertise** regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The **requisite expertise** shall be demonstrated by either of the following qualifications:

- (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline;
- (b) **three** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

## Amendment 91

## Proposal for a regulation

## Article 14 — paragraph 1 — subparagraph 2

## Text proposed by the Commission

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

## Amendment

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient **or a specific limited group of patients within a single healthcare institution.**

## Amendment 92

## Proposal for a regulation

## Article 14 — paragraph 4 a (new)

## Text proposed by the Commission

## Amendment

**4a. Distributors or affiliates who carry out, on behalf of the manufacturer, one or more of the activities mentioned under paragraph 2(a) and (b) — are exempted from additional requirements under paragraphs (3) and (4).**

Tuesday 22 October 2013

**Amendment 264****Proposal for a regulation****Article 15 — paragraph 1***Text proposed by the Commission*

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be **translated into** the official Union **language or languages required by the Member State(s) in which the device is made available**.

*Amendment*

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be **issued in one of** the official Union languages.

**Amendment 93****Proposal for a regulation****Article 15 — paragraph 4***Text proposed by the Commission*

**4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.**

*Amendment*

**deleted**

**Amendment 94****Proposal for a regulation****Article 19 — paragraph 1***Text proposed by the Commission*

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without **significantly** changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

*Amendment*

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

Tuesday 22 October 2013

## Amendment 95

## Proposal for a regulation

## Article 19 — paragraph 2

*Text proposed by the Commission*

2. An article that is intended specifically to replace a part or component of a device and that **significantly** changes the performance or safety characteristics of the device shall be considered a device.

*Amendment*

2. An article that is intended specifically to replace a part or component of a device and that changes the performance or safety characteristics of the device shall be considered **as a device and shall meet the requirements laid down in this Regulation.**

## Amendment 101

## Proposal for a regulation

## Chapter III — title

*Text proposed by the Commission*Chapter **III**

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

*Amendment*Chapter **VII** (\*)

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

(\*) As a consequence of this amendment, this Chapter will cover Articles 21 to 25.

## Amendment 96

## Proposal for a regulation

## Article 22 — paragraph 2 — point e — point i

*Text proposed by the Commission*

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **three** years after its designation;

*Amendment*

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **five** years after its designation;

## Amendment 97

## Proposal for a regulation

## Article 22 — paragraph 8 — point b

*Text proposed by the Commission*

(b) the legitimate interest in protecting commercially sensitive information;

*Amendment*

(b) the legitimate interest in protecting commercially sensitive information, **to the extent that it does not undermine public health protection;**

Tuesday 22 October 2013

**Amendment 98****Proposal for a regulation****Article 22 — paragraph 8 — point e a (new)***Text proposed by the Commission**Amendment*

**(ea) compatibility with medical device identification systems already on the market.**

**Amendment 99****Proposal for a regulation****Article 22 — paragraph 8 — point e b (new)***Text proposed by the Commission**Amendment*

**(eb) compatibility with the other traceability systems used by medical device stakeholders.**

**Amendment 100****Proposal for a regulation****Article 23 — paragraph 1***Text proposed by the Commission**Amendment*

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer, **and to ensure transparency and safe and effective use by making available to users current evidence concerning the clinical validity and, where applicable, utility of the device.** The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.

**Amendment 102****Proposal for a regulation****Article 24***Text proposed by the Commission**Amendment*

**Summary of safety** and performance

**Safety** and **clinical** performance **report**

Tuesday 22 October 2013

## Text proposed by the Commission

1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up **a summary of** safety and performance. **It** shall be written in a way that is **clear to the intended user**. The draft **of this summary** shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with **Article 40 and shall be validated by that body**.

2. The Commission may, by means of implementing acts, set out **the form and the** presentation of the data elements to be included in the summary **of safety and performance**. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

## Amendment

1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up **a report on the** safety and **clinical** performance **of the device based on the full information collected during the clinical performance study**. **The manufacturer shall also draw up a summary of that report which** shall be written in a way that is **easy for a lay person to understand in the official language(s) of the country where the device is made available on the market**. The draft **report** shall be part of the documentation to be submitted to **and validated by** the notified body, **and where relevant by the special notified body**, involved in the conformity assessment in accordance with **Articles 40 and 43a**.

**1a. The summary referred to in paragraph 1 shall be made available to the public through a Eudamed in accordance with provisions under point (b) of Article 25(2)(b) and point 15 of Annex V, Part A.**

2. The Commission may, by means of implementing acts, set out **the format of** the presentation of the data elements to be included in both the **report and the** summary **referred to in paragraph 1**. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84 (2).

## Amendment 103

## Proposal for a regulation

## Article 25 — paragraph 2 — points f a and f b (new)

## Text proposed by the Commission

## Amendment

**(fa) the electronic system on registration of subsidiaries and subcontracting referred to in Article 28a.**

**(fb) the electronic system on 'Special notified bodies' referred to in Article 41b.**

## Amendment 104

## Proposal for a regulation

## Article 26 — paragraph 5

## Text proposed by the Commission

## Amendment

5. The national authority responsible for notified bodies shall safeguard the **confidentiality** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

5. The national authority responsible for notified bodies shall safeguard the **confidential aspects** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

Tuesday 22 October 2013

## Amendment 105

## Proposal for a regulation

## Article 26 — paragraph 6

Text proposed by the Commission

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel **at its disposal** for the proper performance of its tasks.

**Without prejudice to Article 31(3), where** a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.

Amendment

6. The national authority responsible for notified bodies shall have a sufficient number of **permanent and** competent personnel **‘in house’**, for the proper performance of its tasks. **Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8.**

**In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI.**

**Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer’s quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.**

**Where** a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.

## Amendment 106

## Proposal for a regulation

## Article 26 — paragraph 7

Text proposed by the Commission

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.

Amendment

7. **The ultimate responsibility for the notified bodies and the national authority responsible for notified bodies lies with the Member State in which they are located. The Member State is required to check that the designated national authority responsible for notified bodies performs its work on the assessment, designation and notification of conformity assessment bodies and for the monitoring of the notified bodies properly and that the designated national authority responsible for notified bodies works impartially and objectively.** Member States shall provide the Commission and the other Member States with **all** information **they request** on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto. **Such information shall be publicly available subject to Article 80.**

Tuesday 22 October 2013

## Amendment 107

## Proposal for a regulation

## Article 26 — paragraph 8

*Text proposed by the Commission*

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission **may** participate in the review. The outcome of the peer-review shall be communicated to all Member States **and to the Commission** and a summary of the outcome shall be made publicly available.

*Amendment*

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission **shall** participate in the review. The outcome of the peer-review shall be communicated to all Member States and a summary of the outcome shall be made publicly available.

## Amendment 108

## Proposal for a regulation

## Article 27 — paragraph 1

*Text proposed by the Commission*

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. Minimum requirements to be met by notified bodies are set out in Annex VI.

*Amendment*

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. **In this respect, permanent 'in house' administrative, technical and scientific personnel, with medical, technical and, where needed, pharmacological knowledge shall be ensured. Permanent 'in house' personnel shall be used, but notified bodies may hire external experts on an ad hoc and temporary basis as and when needed.** Minimum requirements to be met by notified bodies are set out in Annex VI. **In particular, in accordance with point 1.2. of Annex VI, the notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities and avoid conflict of interests.**

**The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices. This list shall at least contain the qualifications, CV and declaration of interests for each member of staff. The list shall be sent to the national authority responsible for notified bodies which shall check that the staff satisfy the requirements of this Regulation. The list shall also be sent to the Commission.**

Tuesday 22 October 2013

**Amendment 109**  
**Proposal for a regulation**  
**Article 28**

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*Text proposed by the Commission*

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*Amendment*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.

4. Notified bodies shall **keep at the disposal of** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

***-1. Notified bodies shall have permanent ‘in house’ competent personnel and expertise, both in technical fields linked with the assessment of the performance of the devices, and in the medical field. They shall have the capacity to evaluate ‘in house’ the quality of subcontractors.***

***Contracts may be awarded to external experts for the assessment of in vitro diagnostic medical devices or technologies in particular where clinical expertise is limited.***

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

***2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.***

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the **explicit** agreement of the legal or natural person that applied for conformity assessment.

4. ***At least once a year,*** notified bodies shall **submit to** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

***4a. The annual assessment of notified bodies as provided for in Article 33(3) shall include verification of the compliance of the subcontractor(s) or the subsidiary/ies of notified bodies with the requirements set out in Annex VI.***

Tuesday 22 October 2013

**Amendment 110**  
**Proposal for a regulation**  
**Article 28 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 28 a**

***Electronic system on registration of subsidiaries and subcontractors***

- 1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on subcontractors and subsidiaries, as well as on the specific tasks for which they are responsible.***
- 2. Before subcontracting can effectively take place, the notified body which intends to subcontract specific tasks connected with conformity assessment or have recourse to a subsidiary for specific tasks connected with conformity assessment, shall register their name(s) together with their specific tasks.***
- 3. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.***
- 4. The data contained in the electronic system shall be accessible to the public.***

**Amendment 111**  
**Proposal for a regulation**  
**Article 29 — paragraph 1**

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*Text proposed by the Commission*

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*Amendment*

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.

***In case a conformity assessment body wants to be notified for devices referred to in Article 41a(1), it shall indicate so and submit an application for notification to the EMA in accordance with Article 41a***

Tuesday 22 October 2013

## Amendment 112

## Proposal for a regulation

## Article 30 — paragraph 3

*Text proposed by the Commission*

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **two** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission **who** shall lead the joint assessment team.

*Amendment*

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **three** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies **and free of conflicts of interest with the applicant conformity assessment body**. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission, **and at least one other shall come from a Member State other than the one in which the applicant conformity assessment body is established. The Commission representative** shall lead the joint assessment team. **In case the conformity assessment body has asked to be notified for devices referred to in Article 41 a(1) , EMA shall also be part of the joint assessment team.**

## Amendment 113

## Proposal for a regulation

## Article 30 — paragraph 4

*Text proposed by the Commission*

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.

*Amendment*

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.

Tuesday 22 October 2013

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Text proposed by the Commission

Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team **with a view to finding common agreement with respect to the assessment of the application. Divergent opinions shall be identified in the assessment report of the national authority responsible.**

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Amendment

Findings regarding non-compliance of **an applicant conformity assessment** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team. **The national authority shall set out in the assessment report the measures that the notified body shall take to ensure compliance of that applicant conformity assessment body with the requirements set out in Annex VI. In the event of a disagreement, a separate opinion drawn up by the assessment team setting out its reservations regarding notification shall be appended to the assessment report of the national authority responsible.**

#### Amendment 114

##### Proposal for a regulation

##### Article 30 — paragraph 5

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Text proposed by the Commission

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

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Amendment

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. **If the assessment team draws up a separate opinion, that too shall be submitted to the Commission for forwarding to the MDCG.** Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

Tuesday 22 October 2013

**Amendment 115**  
**Proposal for a regulation**  
**Article 30 — paragraph 6**

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*Text proposed by the Commission*

6. The joint assessment team shall provide its opinion regarding the assessment report **and** the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification **which the** relevant national authority shall **duly take into consideration for** its decision on the designation of the notified body.

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*Amendment*

6. The joint assessment team shall provide its **final** opinion regarding the assessment report, the draft notification **and, where appropriate, the separate opinion drawn up by the assessment team**, within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification. **The** relevant national authority shall **base** its decision on the designation of the notified body **on the recommendation by the MDCG. Where its decision differs from the MDCG recommendation, the relevant national authority shall provide the MDCG in writing all the necessary justifications for its decision.**

**Amendment 116**  
**Proposal for a regulation**  
**Article 31 — paragraph 2**

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*Text proposed by the Commission*

2. Member States **may** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.

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*Amendment*

2. Member States **shall** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI **and for which the application assessment procedure has been completed in accordance with Article 30.**

Tuesday 22 October 2013

## Amendment 117

## Proposal for a regulation

## Article 31 — paragraph 3

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Text proposed by the Commission

3. *Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.*

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Amendment

*deleted*

## Amendment 118

## Proposal for a regulation

## Article 31 — paragraph 4 — subparagraph 1

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Text proposed by the Commission

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.

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Amendment

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, the **risk class and the** type of devices which the notified body is authorised to assess.

## Amendment 119

## Proposal for a regulation

## Article 31 — paragraph 8

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Text proposed by the Commission

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

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Amendment

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be **immediately** suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

Tuesday 22 October 2013

**Amendment 120**  
**Proposal for a regulation**  
**Article 31 — paragraph 9**

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*Text proposed by the Commission*

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9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully **or partially**, the Commission shall publish the notification accordingly.

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*Amendment*

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9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully, the Commission shall publish the notification accordingly.

***The Commission shall also enter information on the notification of the notified body into the electronic system referred to in the second subparagraph of Article 25. That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG, as referred to in this article.***

***The full details of the notification, including the class and the typology of devices, as well as the annexes, shall be made publicly available.***

**Amendment 121**  
**Proposal for a regulation**  
**Article 32 — paragraph 2**

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*Text proposed by the Commission*

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2. The Commission shall make accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.

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*Amendment*

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2. The Commission shall make ***easily*** accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified ***and all documents for the notification procedure as referred to in Article 31(5).*** The Commission shall ensure that the list is kept up to date.

**Amendment 122**  
**Proposal for a regulation**  
**Article 33**

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*Text proposed by the Commission*

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1. The national authority responsible for notified bodies shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

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*Amendment*

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1. The national authority responsible for notified bodies, ***and where applicable EMA***, shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Tuesday 22 October 2013

Text proposed by the Commission

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission **unless** there is a legitimate reason for not doing so **in which case both sides may** consult the MDCG. **The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI. This assessment shall include an on-site visit to each notified body.

4. **Three** years after notification of a notified body, and again every **third** year thereafter, the assessment to determine whether the notified body still **satisfies** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.

Amendment

Notified bodies shall, without delay, **and within 15 days at the latest**, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay, **and within 15 days at the latest**, to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission. **Where** there is a legitimate reason for not doing so, **the notified bodies shall explain these reasons in writing and shall** consult the MDCG, **which shall then issue a recommendation. The national authority responsible for notified bodies shall comply with the MDCG's recommendation.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI, **including an assessment of whether its subcontractor(s) and subsidiary/-ies satisfy those requirements.** This assessment shall include an **unannounced inspection through an** on-site visit to each notified body, **and to each subsidiary or subcontractor within or outside the Union, if relevant.**

**The assessment shall also include a review of samples of the design dossier assessments carried out by the notified body to determine the ongoing competence of the notified body and quality of its assessments, in particular the notified body's ability to evaluate and assess clinical evidence.**

4. **Two** years after notification of a notified body, and again every **second** year thereafter, the assessment to determine whether the notified body **and its subsidiaries and subcontractors** still **satisfy** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body, **or a subsidiary or subcontractor of a notified body**, with the requirements set out in Annex VI.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

***For special notified bodies under Article 41a, the assessment referred to in this paragraph shall be performed every year.***

***The comprehensive results of the assessments shall be published.***

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

***5a. Every year, the notified bodies shall forward an annual activity report setting out the information referred to in Annex VI, point 5 to the competent authority and to the Commission, which shall forward it to the MDCG.***

#### Amendment 123

#### Proposal for a regulation

#### Article 34 — paragraph 2

Text proposed by the Commission

Amendment

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. **A suspension shall not exceed a period of one year, renewable once for the same period.** Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. ***Suspension shall apply until a decision to annul the suspension has been reached by the MDCG, which shall follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 30(3).*** Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission **and** the other Member States of any suspension, restriction or withdrawal of a notification.

The national authority responsible for notified bodies shall immediately **and within 10 days at the latest**, inform the Commission, the other Member States **and the relevant manufacturers and health professionals** of any suspension, restriction or withdrawal of a notification.

Tuesday 22 October 2013

## Amendment 124

## Proposal for a regulation

## Article 34 — paragraph 3

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*Text proposed by the Commission*

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.

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*Amendment*

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall **inform the Commission and shall** take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.

## Amendment 125

## Proposal for a regulation

## Article 34 — paragraph 4

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*Text proposed by the Commission*

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the **change to** the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

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*Amendment*

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the **suspension, restriction or withdrawal of** the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, **and at the latest 30 days after the publication of the report**, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

**With a view to verifying whether the reasons for the suspension, restriction or withdrawal of the notification have implications for the certificates issued, the national authority responsible shall ask the relevant manufacturers to supply evidence of conformity at notification, and the manufacturers shall have 30 days in which to respond to that request.**

## Amendment 126

## Proposal for a regulation

## Article 34 — paragraph 5

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*Text proposed by the Commission*

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

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*Amendment*

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

Tuesday 22 October 2013

## Text proposed by the Commission

- (a) in the case of suspension of a notification: on condition that, within three months of the suspension, ***either the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or*** another notified body responsible for in vitro diagnostic medical devices confirms in writing that it is assuming the functions of the notified body during the period of suspension;
- (b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

## Amendment

- (a) in the case of suspension of a notification: on condition that, within three months of the suspension another notified body responsible for in vitro diagnostic medical devices confirms in writing that it is assuming the functions of the notified body during the period of suspension;
- (b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately ***and within 10 days at the latest***, inform the Commission, the other Member States and the other notified bodies thereof.

***The Commission shall immediately and within 10 days at the latest enter information on the changes to the notification of the notified body into the electronic system referred to in the second subparagraph of Article 25.***

## Amendment 127

## Proposal for a regulation

## Article 35 — paragraph 1

## Text proposed by the Commission

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative.

## Amendment

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative, ***including the unannounced inspection of the notified body by a joint assessment team whose composition meets the conditions set out in Article 30(3).***

Tuesday 22 October 2013

## Amendment 128

## Proposal for a regulation

## Article 35 — paragraph 3 — subparagraph 1

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*Text proposed by the Commission*

3. Where the Commission **ascertains** that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary.

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*Amendment*

3. Where the Commission, **in consultation with the MDCG, decides** that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification, if necessary, **in line with Article 34(2)**.

## Amendment 129

## Proposal for a regulation

## Article 37 — paragraph 1

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*Text proposed by the Commission*

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].

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*Amendment*

The Commission, **in consultation with the MDCG**, shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices]. **This group shall meet on a regular basis and at least twice a year.**

## Amendment 130

## Proposal for a regulation

## Article 37 — paragraph 2 a (new)

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*Text proposed by the Commission*

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*Amendment*

**The Commission or the MDCG may request the participation of any notified body.**

## Amendment 131

## Proposal for a regulation

## Article 37 — paragraph 2 b (new)

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*Text proposed by the Commission*

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*Amendment*

**The Commission may, by means of implementing acts, adopt measures setting out the modalities for the functioning of the coordination group of notified bodies as set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).**

Tuesday 22 October 2013

**Amendment 132**  
**Proposal for a regulation**  
**Article 38**

Text proposed by the Commission

## Fees

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation **and** cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

Amendment

Fees **for the activities of national authorities**

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation, cost-effectiveness **and the need to create a level-playing field across Member States**. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

***These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made public.***

**Amendment 133**  
**Proposal for a regulation**  
**Article 38 a (new)**

Text proposed by the Commission

Amendment

**Article 38a**

***Transparency on fees charged by notified bodies for conformity assessment activities***

***1. Member States shall adopt provisions on standard fees for notified bodies.***

***2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees within 24 months of the date of entry into force of this Regulation.***

***3. Member States shall transmit their list of standard fees to the Commission.***

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available.**

#### Amendment 134

#### Proposal for a regulation

#### Chapter V — title

Text proposed by the Commission

Amendment

Chapter V

Chapter III (\*)

**Classification and conformity** assessment**Conformity** assessment

(\*) As a consequence of this amendment, this Chapter will cover Articles 40, 41, **41a, 41b, 41c, 42a**, 43, 44, 45, 46.

#### Amendment 135

#### Proposal for a regulation

#### Chapter V — section 1 — title

Text proposed by the Commission

Amendment

**Section 1** – Classification**Chapter II** (\*)Classification **of in vitro diagnostic medical devices**

(\*) As a consequence of this amendment, this Chapter will cover Article 39.

#### Amendment 136

#### Proposal for a regulation

#### Article 39 — paragraph 1

Text proposed by the Commission

Amendment

1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose, **novelty, complexity** and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

Tuesday 22 October 2013

**Amendment 137****Proposal for a regulation****Article 39 — paragraph 2 — subparagraph 2***Text proposed by the Commission*

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.

*Amendment*

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. ***That decision shall be made publically available in the European databank.***

**Amendment 138****Proposal for a regulation****Article 39 — paragraph 3 — subparagraph 1***Text proposed by the Commission*

The Commission may, at the request of a Member State, ***on its own initiative***, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification.

*Amendment*

The Commission may ***on its own initiative or shall*** at the request of a Member State, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification. ***Such a decision shall in particular be taken in order to resolve divergent decisions as regards the classification of devices between Member States.***

**Amendment 139****Proposal for a regulation****Article 39 — paragraph 4 — introductory part***Text proposed by the Commission*

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:

*Amendment*

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission, ***having consulted relevant stakeholders, including healthcare professionals' organisations, and manufacturers' associations***, shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:

Tuesday 22 October 2013

**Amendment 140****Proposal for a regulation****Article 40 — paragraph 2 — subparagraph 2***Text proposed by the Commission*

In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify compliance of the device with the applicable CTS, **when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX.**

*Amendment*

In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify **by laboratory testing** compliance of the device with the applicable CTS, **as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall focus on in particular analytic sensitivity and specificity using reference materials and diagnostic sensitivity and specificity using specimens from early and established infection.**

**Amendment 141****Proposal for a regulation****Article 40 — paragraph 4 — subparagraph 2***Text proposed by the Commission*

In addition, for devices for self-testing **and near-patient testing**, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

*Amendment*

In addition, for devices for self-testing the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

**Amendment 142****Proposal for a regulation****Article 40 — paragraph 5 — subparagraph 2 — point a***Text proposed by the Commission*

**(a) in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII,**

*Amendment*

**deleted**

**Amendment 143****Proposal for a regulation****Article 40 — paragraph 5 — subparagraph 2 — point c***Text proposed by the Commission*

**(c) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.**

*Amendment*

**deleted**

Tuesday 22 October 2013

## Amendment 144

## Proposal for a regulation

## Article 40 — paragraph 10

Text proposed by the Commission

10. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the conformity assessment procedures set out in Annexes VIII to X.

Amendment

deleted

## Amendment 145

## Proposal for a regulation

## Article 41 — paragraph 1

Text proposed by the Commission

Involvement of notified bodies

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

Amendment

Involvement of notified bodies **in conformity assessment procedures**

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer **of devices other than those listed in Article 41a(1)**, may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. **Where a manufacturer applies to a notified body located in a Member State other than the one where it is registered, the manufacturer shall inform its national authority responsible for the notified bodies of the application.** An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

## Amendment 146

## Proposal for a regulation

## Section 2 a (new) — Title — below Article 41

Text proposed by the Commission

Amendment

**Section 2a — Additional provisions for the conformity assessment of high-risk devices: Involvement of special notified bodies**

Tuesday 22 October 2013

**Amendment 147**  
**Proposal for a regulation**  
**Article 41 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 41a**

***Involvement of special notified bodies in conformity assessment procedures of high-risk devices***

- 1. Only special notified bodies (SNB) shall be entitled to conduct conformity assessments for class D devices.***
- 2. Applicant special notified bodies which consider they fulfil the requirements for special notified bodies referred to in Annex VI, point 3.6, shall submit their application to the EMA.***
- 3. The application shall be accompanied by the fee payable to the EMA to cover the costs relating to the examination of the application.***
- 4. The EMA shall select the special notified bodies among applicants, in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices listed in paragraph 1 within 90 days and send it to the Commission.***
- 5. The Commission shall then publish the notification accordingly and the names of the special notified bodies.***
- 6. This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the special notified body.***

***This notification shall be valid for five years and subject to renewal every five years, following a new application to the EMA.***
- 7. The manufacturer of devices specified in paragraph 1 may apply to a special notified body of its choice, whose name appears in the electronic system of Article 41b.***
- 8. An application may not be lodged in parallel with more than one special notified body for the same conformity assessment activity.***

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**9. The Special notified body shall notify the EMA and the Commission of applications for conformity assessments for devices specified in paragraph 1.**

**10. Article 41(2), (3) and (4) apply to special notified bodies.**

**Amendment 148****Proposal for a regulation****Article 41 b (new)**

Text proposed by the Commission

Amendment

**Article 41b****Electronic system on special notified bodies**

**1. The Commission, in collaboration with the Agency, shall establish and regularly update an electronic registration system for:**

- the registration of applications and granted authorisations to perform conformity assessments as special notified bodies under this Section and to collate and process information on the name of the special notified bodies;**
- the exchange of information with national authorities;**
- and for the publication of assessment reports.**

**2. The information collated and processed in the electronic system which relates to special notified bodies shall be entered into the electronic registration system by the EMA.**

**3. The information collated and processed in the electronic system and which relates to special notified bodies shall be accessible to the public.**

**Amendment 149****Proposal for a regulation****Article 41 c (new)**

Text proposed by the Commission

Amendment

**Article 41c****Network of special notified bodies**

**1. The EMA shall establish, host, coordinate and manage the network of special notified bodies.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

2. The network shall have the following objectives:

- (a) to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of in vitro diagnostic medical devices;
- (b) to contribute to the pooling of knowledge regarding in vitro diagnostic medical devices;
- (c) to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network;
- (d) to help identify the experts in innovative fields;
- (e) to develop and update rules on conflicts of interest; and
- (f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies.

3. Meetings of the network shall be convened whenever requested by at least two of its members or by the EMA. It shall meet at least twice a year.

#### Amendment 150

#### Proposal for a regulation

#### Article 42

Text proposed by the Commission

Amendment

Article 42

deleted

*Mechanism for scrutiny of certain conformity assessments*

*Measures pursuant to this paragraph may be justified only by one or more of the following criteria:*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.

2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4) of Regulation [Ref. of future Regulation on medical devices]. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.

Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

5. Where deemed necessary for the protection of patient safety and public health, the Commission may determine, by means of implementing acts, specific categories or groups of devices, other than devices classified as class D, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Measures pursuant to this paragraph may be justified only by one or more of the following criteria:

- (a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;
- (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;
- (c) an increased rate of serious incidents reported in accordance with Article 59 in respect of a specific category or group of devices;
- (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;
- (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.

8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Tuesday 22 October 2013

**Amendment 151**  
**Proposal for a regulation**  
**Article 42 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 42a**

**Case-by-case assessment procedure for the conformity assessments of certain high-risk devices**

1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups.

2. Within 20 days of receipt of the information referred to in paragraph 1, the CG may decide, upon suggestion by at least three of the members of the relevant sub-groups of the ACMD or by the Commission, to request the special notified body to submit the following documents prior to issuing a certificate:

- the summary of the preliminary conformity assessment;
- the clinical evidence report and the clinical performance study report as referred to in Annex XII;
- data obtained from the post-market follow-up referred to in Annex XII; and
- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,

The members of the relevant sub-groups of the ACMD shall decide on making such case-by-case requests notably on the basis of the following criteria:

- (a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- (b) *an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;*
- (c) *an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;*
- (d) *significant discrepancies in the conformity assessments carried out by different Special notified bodies on substantially similar devices.*

*In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.*

*In its request the ACMD shall indicate the scientifically valid health reason for having selected the specific file.*

*In the absence of request from the ACMD within 20 days of receipt of the information referred to in paragraph 1, the special notified body shall proceed with the conformity assessment procedure.*

3. The ACMD, following the consultation of the relevant sub-groups, shall issue an opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the special notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the ACMD shall not suspend the period for the submission of comments.

4. In its opinion the ACMD may recommend modifications of the documents referred to in paragraph 2.

5. The ACMD shall inform the Commission, the special notified body and the manufacturer of its opinion within 5 days of its adoption.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the ACMD. In the latter case, it may give written notice to the ACMD that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the ACMD the detailed grounds for the request within 30 days after receipt of the opinion. The ACMD shall immediately transmit this information to the Commission

Within 30 days following receipt of the grounds for the request, the ACMD shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Within 15 days after its adoption, the ACMD shall send its final opinion to the Commission, the special notified body and the manufacturer.

8. Within 15 days after receipt of the opinion referred to in paragraph 6 in case of agreement by the special notified body or of the final opinion as referred to in paragraph 7, the Commission shall prepare, on the basis of the opinion, a draft of the decision to be taken in respect of the examined application for conformity assessment. This draft decision shall include or make reference to the opinion referred to in paragraph 6 and 7 as applicable. Where the draft decision is not in accordance with the ACMD opinion, the Commission shall annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to the Member States, the special notified body and the manufacturer.

The Commission shall take a final decision in accordance with and within 15 days after the end of, the examination procedure referred to in Article 84(3).

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinions referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

13. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups.

## Amendment 152

### Proposal for a regulation

#### Article 44 — paragraph 1 — introductory part

Text proposed by the Commission

1. **In cases** where a manufacturer **terminates** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:

Amendment

1. Where a manufacturer **decides to terminate** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, **it shall inform its national authority responsible for the notified bodies of this change**. The modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:

Tuesday 22 October 2013

## Amendments 259 and 269

## Proposal for a regulation

## Article 44a (new)

Text proposed by the Commission

Amendment

## Article 44a

*Additional assessment procedure in extraordinary cases*

1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, where no CTS standard exists, with the exception of applications to renew or supplement existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the Special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a.

2. Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:

- the clinical evidence report and the clinical performance study report as referred to in Annex XII,
- data obtained from the post market follow-up referred to in Annex XII, and
- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,

The members of the MDCG shall decide on making such a request on the basis of the following criteria:

- (a) the novelty of the device with possible major clinical or health impact
- (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- (c) *an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;*

*In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.*

*In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.*

*In the absence of a request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the Special notified body shall proceed with the conformity assessment procedure.*

3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.

5. The MDCG shall inform the Commission, the Special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the Special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the Special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the Commission

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

Within 30 days following receipt of the grounds for the request, the MDCG shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MDCG shall send its final opinion to the Commission, the Special notified body and the manufacturer.

8. In case of a favourable MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on condition that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device or group of devices concerned and adopt them where possible.

In case of an unfavourable MDCG opinion, the special notified body shall not deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the Special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

13. The company concerned shall not be charged for the additional costs due to this assessment.

## Amendment 153

## Proposal for a regulation

## Chapter VI — title

Text proposed by the Commission

Amendment

Chapter VI

Chapter V (\*)

Clinical evidence

Clinical evidence

(\*) As a consequence of this amendment, this Chapter will cover Articles 47, 48, 49, **49a**, 50, 51, 52, 53, 54, 55, 57, 58

Tuesday 22 October 2013

**Amendment 154****Proposal for a regulation****Article 47 — paragraph 1**

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*Text proposed by the Commission*

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence.

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*Amendment*

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence, **or additional safety data for general safety and performance requirements not covered by clinical evidence.**

**Amendment 155****Proposal for a regulation****Article 47 — paragraph 3 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**3a. Where the manufacturer claims and/or describes a clinical use, evidence attesting to that use shall constitute part of the requirements.**

**Amendment 156****Proposal for a regulation****Article 47 — paragraph 4 — subparagraph 2 (new)**

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*Text proposed by the Commission*

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*Amendment*

**Exemption from demonstration of conformity with general safety and performance requirements based on clinical data under the first subparagraph shall be subject to prior approval by the competent authority.**

Tuesday 22 October 2013

## Amendment 157

## Proposal for a regulation

## Article 47 — paragraph 5

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Text proposed by the Commission

5. The scientific validity data, the analytical performance data and, where applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included **or fully referenced** in the technical documentation referred to in Annex II relating to the device concerned.

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Amendment

5. The scientific validity data, the analytical performance data and, where applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included in the technical documentation referred to in Annex II relating to the device concerned.

## Amendment 158

## Proposal for a regulation

## Article 48 — paragraph 1 — point a

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Text proposed by the Commission

(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers;

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Amendment

(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers **or sponsor**;

## Amendment 159

## Proposal for a regulation

## Article 48 — paragraph 1 — point b

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Text proposed by the Commission

(b) to verify **that devices achieve** the intended benefits to the patient **as specified by the manufacturer**;

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Amendment

(b) to verify **the clinical safety and efficacy of the device, including** the intended benefits to the patient, **when used for the intended purpose, in the target population and in accordance with the instructions of use**;

Tuesday 22 October 2013

## Amendment 160

## Proposal for a regulation

## Article 48 — paragraph 4

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*Text proposed by the Commission*

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.

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*Amendment*

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust. **Such studies shall not be conducted if the risks associated with the investigation are not medically justifiable in terms of the potential benefits of the device.**

## Amendment 161

## Proposal for a regulation

## Article 48 — paragraph 6

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*Text proposed by the Commission*

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.

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*Amendment*

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article. **The Commission shall be empowered to adopt delegated acts in accordance with Article 85 concerning the provision of a list with negligible risks, which allows a derogation to be made from the relevant Article.**

## Amendment 162

## Proposal for a regulation

## Article 49 — paragraph 2 — subparagraph 1

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*Text proposed by the Commission*

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within **six** days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

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*Amendment*

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within **14** days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

Tuesday 22 October 2013

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Text proposed by the Commission

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Amendment

*In case of more than one Member State concerned, where a Member State disagrees with the coordinating Member State on whether the clinical performance study should be approved, on grounds other than intrinsically national, local or ethical concerns, the Member States concerned shall make an attempt to agree on a conclusion. If no conclusion is found, the Commission shall take a decision after having consulted the Member States concerned, and if appropriate, having taken advice from the MDCG.*

*In case where the concerned Member States object to the clinical performance study for intrinsically national, local or ethical concerns the clinical performance study should not take place in the Member States concerned.*

**Amendment 163****Proposal for a regulation****Article 49 — paragraph 3 — subparagraph 1**

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Text proposed by the Commission

Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of **six** days for the sponsor to comment or to complete the application.

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Amendment

Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of **ten** days for the sponsor to comment or to complete the application.

**Amendment 164****Proposal for a regulation****Article 49 — paragraph 3 — subparagraph 3**

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Text proposed by the Commission

Where the Member State has not notified the sponsor according to paragraph 2 within **three** days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

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Amendment

Where the Member State has not notified the sponsor according to paragraph 2 within **seven** days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Tuesday 22 October 2013

**Amendment 165****Proposal for a regulation****Article 49 — paragraph 5 — point c***Text proposed by the Commission*

- c) after the expiry of **35** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

*Amendment*

- c) after the expiry of **60** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

**Amendment 166****Proposal for a regulation****Article 49 — paragraph 5 a (new)***Text proposed by the Commission**Amendment*

**5a.** Member States shall ensure that a clinical performance study is suspended, cancelled or temporarily interrupted if in the light of new facts it would no longer be approved by the competent authority or if it would no longer receive a favourable opinion from the ethics committee.

**Amendment 167****Proposal for a regulation****Article 49 — paragraphs 6 a to 6 e (new)***Text proposed by the Commission**Amendment*

**6a.** Every step in the clinical performance study, from first consideration of the need and justification for the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, such as those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul in 2008.

**6b.** Authorisation by the Member State concerned for conducting a clinical performance study under this Article shall be granted only after examination and approval by an independent ethics committee in accordance with the World Medical Association's Declaration of Helsinki.

**6c.** The examination of the Ethics Committee shall cover in particular the medical justification for the study, the consent of the test subjects participating in the clinical performance study following the provision of full information about the clinical performance study and the suitability of the investigators and investigation facilities.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*The ethics committee shall act in accordance with the respective laws and regulations of the country or countries in which the study is to be conducted and shall abide by all relevant international norms and standards. It shall also work with such efficiency as to enable the Member State concerned to comply with the procedural deadlines set out in this Chapter.*

*The ethics committee shall be made up of an appropriate number of members, who together are in possession of the relevant qualifications and experience in order to be able to assess the scientific, medical and ethical aspects of the clinical investigation under scrutiny.*

*The members of the Ethics Committee assessing the application for a clinical performance study shall be independent from the sponsor, the institution of the performance study site, and the investigators involved, as well as free of any other undue influence. Names, qualifications, and declaration of interest of the assessors of the application shall be made publicly available.*

*6d. Member States shall take the necessary measures to establish Ethics Committees in the field of clinical performance studies where such committees do not exist, and to facilitate their work.*

*6e. The Commission shall facilitate cooperation of ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment.*

*The Commission shall develop guidelines on patient involvement in ethics committees, drawing upon existing good practices.*

#### Amendment 168

#### Proposal for a regulation

#### Article 49 a (new)

Text proposed by the Commission

Amendment

#### Article 49a

#### Supervision by Member States

*1. Member States shall appoint inspectors to supervise compliance with this Regulation and shall ensure that those inspectors are adequately qualified and trained.*

*2. Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

3. Where a Member State intends to carry out an inspection with regard to one or several interventional clinical performance studies which are conducted in more than one Member State, it shall notify its intention to the other Member States concerned, the Commission and the EMA, through the Union portal, and shall inform them of its findings after the inspection.

4. The MDCG shall coordinate cooperation on inspections between Member States and on inspections conducted by Member States in third countries.

5. Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the sponsor of the relevant clinical trial and shall submit the inspection report through the Union portal to the Union database. When making the inspection report available to the sponsor, the Member State concerned shall ensure that confidentiality is protected.

6. The Commission shall specify the details for the arrangement of the inspection procedures by means of implementing acts in accordance with Article 85.

#### Amendment 169

##### Proposal for a regulation

##### Article 50 — paragraph 1 — point g a (new)

Text proposed by the Commission

Amendment

(g a) the methodology to be used, the number of subjects involved and the intended result of the study.

#### Amendment 170

##### Proposal for a regulation

##### Article 51

Text proposed by the Commission

Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:

(a) the registration of clinical performance studies in accordance with Article 50;

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:

(a) the registration of clinical performance studies in accordance with Article 50;

Tuesday 22 October 2013

*Text proposed by the Commission*

- (b) the exchange of information between the Member States and between them and the Commission in accordance with Article 54;
- (c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;
- (d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.

*Amendment*

- (b) the exchange of information between the Member States and between them and the Commission in accordance with Article 54;
- (c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;
- (d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.

**(da) the clinical performance study report and summary submitted by the sponsor in accordance with Article 55 (3)**

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50 **and in points (d) and (da) of Article 51**, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission. **The Commission shall also ensure that healthcare professionals have access to the electronic system.**

**The information referred to in points (d) and (da) of Article 51 shall be accessible to the public in accordance with Article 50 (3) and (4).**

**2a. Upon a reasoned request, all information on a specific in vitro diagnostic medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified in accordance with Article 50(3).**

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.

Tuesday 22 October 2013

**Amendment 171****Proposal for a regulation****Article 54 — paragraph 1***Text proposed by the Commission*

1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety grounds, that Member State shall communicate its decision and the grounds **therefor** to all Member States and the Commission by means of the electronic system referred to in Article 51.

*Amendment*

1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety **or efficacy** grounds, that Member State shall communicate **such facts and** its decision and the grounds **for that decision** to all Member States and the Commission by means of the electronic system referred to in Article 51.

**Amendment 172****Proposal for a regulation****Article 55 — paragraph 1***Text proposed by the Commission*

1. If the sponsor has temporarily halted a clinical performance study on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

*Amendment*

1. If the sponsor has temporarily halted a clinical performance study on safety **or efficacy** grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

**Amendment 173****Proposal for a regulation****Article 55 — paragraph 2 — subparagraph 1***Text proposed by the Commission*

The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that Member State, providing a justification in the event of early termination. That notification shall be made within 15 days from the end of the clinical performance study in relation to that Member State.

*Amendment*

The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that Member State, providing a justification in the event of early termination, **so that all Member States can inform sponsors conducting similar clinical performance studies at the same time within the Union of the results of that clinical performance study.** That notification shall be made within 15 days from the end of the clinical performance study in relation to that Member State.

Tuesday 22 October 2013

## Amendment 174

## Proposal for a regulation

## Article 55 — paragraph 2 — subparagraph 2

Text proposed by the Commission

If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. That notification shall be made within 15 days from the overall end of the clinical performance study.

Amendment

If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. **Information on the reasons for the early termination of the clinical performance study shall also be provided to all Member States, so that all Member States can inform sponsors conducting similar clinical performance studies, at the same time within the Union, of the results of that the clinical performance study.** That notification shall be made within 15 days from the overall end of the clinical performance study.

## Amendment 175

## Proposal for a regulation

## Article 55 — paragraphs 3 and 3 a (new)

Text proposed by the Commission

3. **Within** one year from the end of the clinical performance study, the sponsor shall submit to the Member States concerned **a summary of** the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with **an explanation**.

Amendment

3. **Irrespective of the outcome of the clinical performance study, within** one year from the end of the clinical performance study **or from its early termination**, the sponsor shall submit to the Member States concerned the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII.. **It shall be accompanied by a summary presented in terms that are easily understandable to a layperson. Both the report and the summary shall be submitted by the sponsor by means of the electronic system referred to in Article 51.**

Where, for **justified** scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with **a justification**.

**3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to define the content and structure of the layperson's summary.**

**The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to establish rules for the communication of the clinical performance study report.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of that data.*

## Amendment 176

## Proposal for a regulation

## Article 56 — paragraph 2

Text proposed by the Commission

Amendment

2. *In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadlines referred to in Article 49(2) shall start on the day following the acceptance.*

2. The Member States concerned shall agree, within six days of submission of the single application, **which** Member State shall be the coordinating Member State. Member **States and the Commission shall agree, in the framework of the attributions of the Medical Devices Coordination Group, on clear rules for designating the** coordinating Member State.

## Amendment 177

## Proposal for a regulation

## Article 56 — paragraph 5

Text proposed by the Commission

Amendment

5. *For the purpose of Article 55(3), the sponsor shall submit the clinical performance study report to the Member States concerned by means of the electronic system referred to in Article 51.*

*deleted*

## Amendment 178

## Proposal for a regulation

## Article 57 — paragraph 2 — subparagraph 1 — point a

Text proposed by the Commission

Amendment

(a) **a serious** adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible;

(a) **any** adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible;

Tuesday 22 October 2013

**Amendment 179**  
**Proposal for a regulation**  
**Chapter VII — title**

Text proposed by the Commission

## Chapter VII

Vigilance and market surveillance

Amendment

## Chapter VIII (\*)

Vigilance and market surveillance

(\*) As a consequence of this amendment, this Chapter will cover Articles 59 to 73.

**Amendment 180**  
**Proposal for a regulation**  
**Article 59**

Text proposed by the Commission

1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following::

- (a) any **serious** incident in respect of devices made available on the Union market;
- (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

Amendment

1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following::

- (a) any incident, **including date and place of incident, with an indication of whether it is serious in accordance with the definition under Article 2,** in respect of devices made available on the Union market; **where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident;**
- (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

Tuesday 22 October 2013

## Text proposed by the Commission

2. For similar **serious** incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected **serious** incidents referred to in point (a) of paragraph 1.

They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall **take the necessary steps to ensure that** the manufacturer of the device concerned **is informed of the incident**. The manufacturer shall ensure the appropriate follow-up.

The Member States shall **coordinate between them the development of** standard **web-based structured** forms for reporting of **serious** incidents by healthcare professionals, users and patients.

4. Health institutions manufacturing and using devices referred to in Article 4(4) shall report any **serious** incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.

## Amendment

2. For similar incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures, **including targeted information campaigns**, to encourage **and enable** healthcare professionals, **including doctors and pharmacists**, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They **shall inform the Commission of those measures**.

**The competent authorities of the Member States** shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall **inform** the manufacturer of the device concerned **without delay**. The manufacturer shall ensure the appropriate follow-up.

**The competent authority of a Member State shall notify the reports referred to in the first subparagraph to the electronic system referred to in Article 60 without delay, unless the same incident has already been reported by the manufacturer.**

**The Commission, in cooperation with the Member States and in consultation with the relevant stakeholders**, shall **develop** standard forms for **electronic and non-electronic** reporting of incidents by healthcare professionals, users and patients.

4. Health institutions manufacturing and using devices referred to in Article 4(4) shall **immediately** report any incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.

## Amendment 181

## Proposal for a regulation

## Article 60

## Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on **serious** incidents and field safety corrective actions referred to in Article 59(1);

## Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on incidents and field safety corrective actions referred to in Article 59(1);

Tuesday 22 October 2013

Text proposed by the Commission	Amendment
(b) the periodic summary reports by manufacturers referred to in Article 59(2);	(b) the periodic summary reports by manufacturers referred to in Article 59(2);
(c) the reports by competent authorities on <b>serious</b> incidents referred to in the second subparagraph of Article 61(1)	(c) the reports by competent authorities on incidents referred to in the second subparagraph of Article 61(1)
(d) the reports by manufacturers on trends referred to in Article 62;	(d) the reports by manufacturers on trends referred to in Article 62;
(e) the field safety notices by manufacturers referred to in Article 61(4);	(e) the field safety notices by manufacturers referred to in Article 61(4);
(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (6).	(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (6).
	<b>(f a) the reports by competent authorities on serious incidents and field safety corrective actions taken within health institutions involving devices referred to in Article 4(4)</b>
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.	2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, to the notified bodies, <b>to healthcare professionals and also to manufacturers where the information pertains to their own product.</b>
3. The Commission shall ensure that <b>healthcare professionals and</b> the public <b>have</b> appropriate <b>levels</b> of access to the electronic system.	3. The Commission shall ensure that the public <b>has an</b> appropriate <b>level</b> of access to the electronic system. <b>Where information is requested on a specific in vitro diagnostic medical device, that information shall be made available without delay and within 15 days at the latest.</b>
4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.	4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.
5. The reports on <b>serious</b> incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on <b>serious</b> incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States	5. The reports on incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States
(a) the Member State where the incident occurred;	(a) the Member State where the incident occurred;
(b) the Member State where the field safety corrective action is being or is to be undertaken;	(b) the Member State where the field safety corrective action is being or is to be undertaken;

Tuesday 22 October 2013

*Text proposed by the Commission*

- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.

*Amendment*

- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.

**5a. The reports and information referred to in Article 60 (5), shall also be automatically transmitted for the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 43.**

**Amendment 182****Proposal for a regulation****Article 61 — paragraph 1 — subparagraph 1***Text proposed by the Commission*

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.

*Amendment*

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. **The competent authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.**

**Amendment 183****Proposal for a regulation****Article 61 — paragraph 1 — subparagraph 2***Text proposed by the Commission*

**If in the case of reports received in accordance with Article 59 (3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 60, unless the same incident has already been reported by the manufacturer.**

*Amendment*

**deleted**

Tuesday 22 October 2013

## Amendment 184

## Proposal for a regulation

## Article 61 — paragraph 2

*Text proposed by the Commission*

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the incident.

*Amendment*

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the **serious** incident.

## Amendment 185

## Proposal for a regulation

## Article 65 — paragraphs 1, 1 a to 1 e (new) and 2

*Text proposed by the Commission*

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, **where necessary and justified**, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a **serious** risk where they deem it necessary.

*Amendment*

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and enter **and inspect** the premises of economic operators and take the necessary samples of devices **for analysis by an official laboratory**. They may destroy or otherwise render inoperable devices presenting a risk where they deem it necessary.

**1a. The competent authorities shall designate inspectors who shall be empowered to carry out the checks referred to in paragraph 1. The checks shall be carried out by the inspectors of the Member State in which the economic operator is located. Those inspectors may be assisted by experts appointed by the competent authorities.**

**1b. Unannounced inspections may also be carried out. The organisation and implementation of such inspections must always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**1c. Following each inspection carried out under paragraph 1, the competent authority shall draw up a report on compliance by the economic operator inspected with the legal and technical requirements applicable under this Regulation and any corrective actions needed.**

**1d. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 66.**

**1e. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 can also take place in the premises of an economic operator located in a third country, if the device is intended to be made available on the Union market.**

2. The Member States shall periodically review and assess the **functioning** of their surveillance **activities**. Such reviews and assessments shall be carried out at least every **four** years and the results thereof shall be communicated to the other Member States and the Commission. The Member **State concerned** shall make a summary of the results accessible to the public.

2. The Member States shall **draw up strategic surveillance plans covering their planned surveillance activities, as well as the human and material resources needed to carry those activities out. Member States shall** periodically review and assess the **implementaion** of their surveillance **plans**. Such reviews and assessments shall be carried out at least every **two** years and the results thereof shall be communicated to the other Member States and the Commission. **The Commission may make recommendations for adjustments to the surveillance plans.** The Member **States** shall make a summary of the results **and of the Commission's recommendations** accessible to the public.

Tuesday 22 October 2013

**Amendment 186****Proposal for a regulation****Article 66 — paragraph 2***Text proposed by the Commission*

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.

*Amendment*

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States, **to the Commission, to the Agency** and to **healthcare professionals. The Commission shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, where information is requested on a specific in vitro diagnostic medical device, it is made available without delay and within 15 days. The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank referred to in Article 25.**

**Amendment 187****Proposal for a regulation****Chapter VIII — title***Text proposed by the Commission***Chapter VIII**

Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

*Amendment***Chapter IX (\*)**

Cooperation between Member States, Medical Device Coordination Group, **Medical Device Advisory Committee**, EU reference laboratories, device registers

(\*) As a consequence of this amendment, this Chapter will cover Articles 74 to 79.

**Amendment 188****Proposal for a regulation****Article 76 a (new)***Text proposed by the Commission**Amendment***Article 76a****Medical Device Advisory Committee**

**The Medical Device Advisory Committee (MDAC) established in accordance with the conditions and modalities defined in Article 78a of Regulation (EU) No ... (\*) shall carry out, with the support of the Commission the tasks assigned to it by this Regulation.**

(\*) Reference and date.

Tuesday 22 October 2013

**Amendment 260**  
**Proposal for a regulation**  
**Article 76 b (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 76b**

**Assessment Committee for Medical Devices**

1. An ACMD is hereby established, under the principles of highest scientific competence, impartiality, transparency and to avoid potential conflicts of interest.

2. When undertaking a clinical assessment for a specific device, the ACMD shall be composed of:

- a minimum of 5 clinical experts in the field of which a clinical assessment and recommendation have been requested;
- one representative of the EMA;
- one representative of the Commission;
- one representative of patients' organisations appointed by the Commission in a transparent manner after a call for interest, for a three-year term which may be renewed.

The ACMD shall meet on request from the MDCG and Commission, and its meetings shall be chaired by a Commission representative.

The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of its clinical assessment and recommendation.

The Commission shall be responsible for providing the secretariat of this Committee.

3. The Commission shall establish a pool of clinical experts in the medical fields relevant to in vitro diagnostic medical devices being assessed by the ACMD.

In order to undertake the clinical assessment and recommendation procedure, each Member State may propose one expert, following a Union-wide call for expression of interest with a clear definition by the Commission of the requested profile. The publication of the call shall be widely advertised. Each expert shall be approved by the Commission and listed for a three-year term which may be renewed.

The Members of the ACMD shall be chosen for their competence and experience in the corresponding field. They shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the fields referred to in the first subparagraph of this paragraph.*

**4. The ACMD shall fulfil the tasks defined in Article 44a. When adopting its clinical assessment and recommendation, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of their members. Any diverging opinion shall be annexed to the ACMD opinion.**

**5. The ACMD shall establish its rules of procedure which shall, in particular, lay down procedures for the following:**

- **the adoption of opinions, including in case of urgency;**
- **the delegation of tasks to reporting and co-reporting members.**

#### Amendment 261

#### Proposal for a regulation

#### Article 77 — point a

Text proposed by the Commission

Amendment

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

**(-a) to provide regulatory opinions on the basis of a scientific assessment on certain types of in vitro diagnostic medical devices pursuant to Article 44a;**

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

**(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation;**

**(ab) to review and approve the criteria of the competent authorities of Member States in respect of point (aa);**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

(ac) *to oversee the coordination group of Notified Bodies as specified in Article 37;*

(ad) *to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 25;*

## Amendments 190

## Proposal for a regulation

## Article 77 — point b

Text proposed by the Commission

Amendment

(b) *to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;*

*deleted*

## Amendment 191

## Proposal for a regulation

## Article 78 — paragraph 2 — point b

Text proposed by the Commission

Amendment

(b) to carry out appropriate tests on samples of manufactured class D devices **or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;**

(b) to carry out appropriate **laboratory** tests on samples of manufactured class D devices **on request of competent authorities on samples collected during market surveillance activities under Article 65 and of notified bodies on samples collected during unannounced inspections under Annex VIII section 4.4;**

## Amendment 192

## Proposal for a regulation

## Article 78 — paragraph 2 — point d

Text proposed by the Commission

Amendment

(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

(d) to provide scientific advice **and technical assistance** regarding **the definition of** the state of the art in relation to specific devices, or a category or group of devices;

Tuesday 22 October 2013

## Amendment 193

## Proposal for a regulation

## Article 78 — paragraph 2 — point f

*Text proposed by the Commission*

- (f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures **and** market surveillance;

*Amendment*

- (f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures, **in particular for batch verification of class D devices and for** market surveillance;

## Amendment 194

## Proposal for a regulation

## Article 78 — paragraph 2 — point i

*Text proposed by the Commission*

- (i) to contribute to the development of **standards at** international **level**;

*Amendment*

- (i) to contribute to the development of **common technical specifications (CTS) and of** international **standards**

## Amendment 195

## Proposal for a regulation

## Article 78 — paragraph 3 — point a

*Text proposed by the Commission*

- (a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated;

*Amendment*

- (a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated; **appropriate knowledge and experience shall be based on:**

- (i) **experience of assessing high-risk IVDs and of carrying out the relevant laboratory tests;**

- (ii) **in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies;**

- (iii) **proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or institution, national reference laboratory for class D devices, quality control of in-vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house;**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- (iv) **knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs;**
- (v) **knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs;**
- (vi) **knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the Common Technical Specifications (CTS), applicable harmonized standards, product-specific requirements and relevant guidance documents;**
- (vii) **participation in relevant external and internal quality assessment schemes organised by international or national organisations.**

## Amendment 196

## Proposal for a regulation

## Article 78 — paragraph 5

Text proposed by the Commission

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they **may** be required to pay fees to wholly **or partially** cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

Amendment

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they **shall** be required to pay fees to wholly cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

## Amendment 197

## Proposal for a regulation

## Article 79 — paragraph 1

Text proposed by the Commission

The Commission and the Member States shall take all appropriate measures to **encourage** the establishment of registers for **specific types of** devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Amendment

The Commission and the Member States shall take all appropriate measures to **ensure** the establishment of registers for **in vitro diagnostic** devices to gather post-market experience related to the use of such devices. **Registers for class C and D devices shall be systematically established.** Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Tuesday 22 October 2013

**Amendment 200**  
**Proposal for a regulation**  
**Chapter IX — title**

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*Text proposed by the Commission*

**Chapter IX**

Confidentiality, data protection, funding, penalties

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*Amendment*

**Chapter X (\*)**

Confidentiality, data protection, funding, penalties

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(\*) As a consequence of this amendment, this Chapter will cover Articles 80 to 83.

**Amendment 198**  
**Proposal for a regulation**  
**Article 82 — paragraph 1**

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*Text proposed by the Commission*

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

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*Amendment*

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is **comparable and** set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

**Amendment 199**  
**Proposal for a regulation**  
**Article 83 — paragraph 1**

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*Text proposed by the Commission*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.

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*Amendment*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. **The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement.** The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Tuesday 22 October 2013

**Amendment 201**  
**Proposal for a regulation**  
**Chapter X — title**

Text proposed by the Commission

Chapter **X**

Final provisions

Amendment

Chapter **XI** (\*)

Final provisions

(\*) As a consequence of this amendment, this Chapter will cover Articles 84 to 90.

**Amendment 202**  
**Proposal for a regulation**  
**Article 90 — paragraphs 2 and 3**

Text proposed by the Commission

2. It shall apply from [**five** years after entry into force].
3. By way of derogation from paragraph 2, the following shall apply:
- (a) Article 23(2) and (3) and Article 43(4) shall apply from [**18 months** after **date of application referred to in paragraph 2**];
- (b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.

Amendment

2. It shall apply from [**three** years after entry into force].
3. By way of derogation from paragraph 2, the following shall apply:
- (a) Article 23(1) shall apply from [**30 months** after **entry into force**];
- (b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.

(ba) Article 74 shall apply from ... (\*);

(\*) Six months after the entry into force of this Regulation.

(bb) Articles 75 to 77 shall apply from... (\*);

(\*) 12 months after the entry into force of this Regulation.

(bc) Article 59 to 64 shall apply from... (\*);

(\*) 24 months after the entry into force of this Regulation.

(bd) Article 78 shall apply from ... (\*).

(\*) 24 months after the entry into force of this Regulation

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**3a. The implementing acts referred to in Articles 31(4), 40 (9), 42(8), 46(2) and Articles 58 and 64 shall be adopted within ... (\*)**

**(\*) 12 months after the entry into force of this Regulation.**

### Amendment 203

#### Proposal for a regulation

#### Annex I — part II — point 6.1 — point b

Text proposed by the Commission

(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations.

Amendment

(b) the clinical performance, **including measures of clinical validity** such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations; **and, where appropriate, measures of clinical utility. In the case of companion diagnostics, evidence of the clinical utility of the device for the intended purpose (selection of patients with a previously diagnosed condition or predisposition eligible for a targeted therapy) is required. For a companion diagnostic, the manufacturer should supply clinical evidence relating to the impact of a positive or negative test on (1) patient care; and (2) health outcomes, when used as directed with the stated therapeutic intervention.**

### Amendment 204

#### Proposal for a regulation

#### Annex I — part II — point 16

Text proposed by the Commission

16. Protection against the risks posed by devices intended by the manufacturer for self-testing **or near-patient testing**

16.1 The devices intended for self-testing **or near-patient testing** shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

Amendment

16. Protection against the risks posed by devices intended by the manufacturer for self-testing

16.1 The devices intended for self-testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

Tuesday 22 October 2013

*Text proposed by the Commission*

16.2 The devices intended for self-testing **or near-patient testing** shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure; and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

16.3 The devices intended for self-testing **and near-patient testing** shall, where reasonably possible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

*Amendment*

16.2 The devices intended for self-testing shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure; and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

16.3 The devices intended for self-testing shall, where reasonably possible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

**Amendment 206****Proposal for a regulation****Annex I — part III — point 17.1 — introductory part***Text proposed by the Commission*

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:

*Amendment*

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, **and must be made available on the manufacturer's website** taking into account the following:

**Amendment 207****Proposal for a regulation****Annex I — point 17.1 — point (vi)***Text proposed by the Commission*

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, **contraindications**, precautions or warnings in the information supplied by the manufacturer.

*Amendment*

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, precautions or warnings in the information supplied by the manufacturer.

Tuesday 22 October 2013

## Amendment 208

## Proposal for a regulation

## Annex I — part III — point 17.2 — point (xv)

Text proposed by the Commission

Amendment

(xv) *If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;*

*deleted*

## Amendment 209

## Proposal for a regulation

## Annex I — part III — point 17.3.1 — point (ii) — introductory part

Text proposed by the Commission

Amendment

(ii) The device's intended purpose:

(ii) The device's intended purpose **which may include:**

## Amendment 210

## Proposal for a regulation

## Annex I — part III — point 17.3.1 — point ii — indent 2

Text proposed by the Commission

Amendment

— its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);

— its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, **prognosis, companion diagnostic**);

## Amendment 211

## Proposal for a regulation

## Annex I — part III — point 17.3.1 — point ii — indent 7 a (new)

Text proposed by the Commission

Amendment

— **for companion diagnostics, the relevant target population and directions for use with associated therapeutic(s).**

Tuesday 22 October 2013

## Amendment 212

## Proposal for a regulation

## Annex I — part III — point 17.3.2 — point i a (new)

Text proposed by the Commission

Amendment

(ia) *The instruction for use shall be understandable to a layperson and reviewed by the representatives of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.*

## Amendment 213

## Proposal for a regulation

## Annex II — point 1.1 — point c — point ii

Text proposed by the Commission

Amendment

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, **prognosis, companion diagnosis**);

## Amendment 214

## Proposal for a regulation

## Annex II — point 1.1 — point c — point viii a (new)

Text proposed by the Commission

Amendment

(viii) *for companion diagnostics, the relevant target population and directions for use with the associated therapeutic(s).*

## Amendment 265

## Proposal for a regulation

## Annex II — point 3.2 — point b

Text proposed by the Commission

Amendment

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

(b) identification of all sites, including suppliers and sub-contractors, where **critical** manufacturing activities are performed.

Tuesday 22 October 2013

## Amendment 215

## Proposal for a regulation

## Annex II — point 6.2 — paragraph 2

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*Text proposed by the Commission*

The clinical evidence report referred to in Section 3 of Annex XII shall be included and/or fully referenced in the technical documentation.

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*Amendment*

The clinical evidence report referred to in Section 3 of Annex XII shall be included and fully referenced in the technical documentation.

## Amendment 266

## Proposal for a regulation

## Annex III — point 7

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*Text proposed by the Commission*

**7. References to the relevant harmonised standards or CTS used in relation to which conformity is declared;**

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*Amendment*

**deleted**

## Amendment 216

## Proposal for a regulation

## Annex V— part A — point 15

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*Text proposed by the Commission*

15. in case of devices classified as class C or D, the summary of safety and performance,

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*Amendment*

15. in case of devices classified as class C or D, the summary of safety and performance, **and the full dataset collected during the clinical study and the post-market clinical follow-up.**

## Amendment 217

## Proposal for a regulation

## Annex V — part A — point 18 a (new)

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*Text proposed by the Commission*

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*Amendment*

**18a. Full technical documentation and the clinical performance report.**

Tuesday 22 October 2013

## Amendment 218

## Proposal for a regulation

## Annex VI — points 1.1.4 and 1.2 to 1.6

*Text proposed by the Commission*

## 1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.

## 1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

*Amendment*

## 1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.  
***This information shall be made publicly available.***

## 1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. ***This does not preclude the notified body from performing conformity assessment activities for different economic operators producing different or similar products.***

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

Tuesday 22 October 2013

## Text proposed by the Commission

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;
- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

1.2.4. The impartiality of the notified bodies, of their top level management **and** of the assessment personnel shall be guaranteed. The remuneration of the top level management **and** assessment personnel of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

## Amendment

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;
- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

***The notified body shall make publicly available the declarations of interest of its top-level management and the personnel responsible for carrying out the conformity assessment tasks. The national authority shall verify the compliance of the notified body with the provisions under this point and shall report to the Commission twice a year in full transparency.***

1.2.4. The impartiality of the notified bodies, of their top level management, of the assessment personnel **and subcontractors** shall be guaranteed. The remuneration of the top level management, assessment personnel **and subcontractors** of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities. ***The notified body shall provide evidence to the national authority of compliance with this point.***

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

Tuesday 22 October 2013

## Text proposed by the Commission

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

## 1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

## 1.4. Liability

The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

## 1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

## 1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

## Amendment

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

## 1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to information obtained in carrying out their tasks under this Regulation, **only in justified cases and** except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

**Where information and data are requested from the notified body by public or healthcare professionals and where such a request is declined, the notified body shall justify the reasons for non-disclosure and shall make publicly available its justification.**

## 1.4. Liability

The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

## 1.5. Financial requirements

The notified body, **including its subsidiaries**, shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

## 1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel **including subcontractors**, is informed of **and trained on** the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, **standards**, guidance and best practice documents adopted in the framework of this Regulation. **The notified body shall keep a record of the actions it takes to inform its personnel.**

Tuesday 22 October 2013

*Text proposed by the Commission*

1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of in vitro diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.

*Amendment*

1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of in vitro diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.

**Amendment 219****Proposal for a regulation****Annex VI — point 2***Text proposed by the Commission***2. QUALITY MANAGEMENT REQUIREMENTS**

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.2. The quality management system of the notified body shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of — the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals.

*Amendment***2. QUALITY MANAGEMENT REQUIREMENTS**

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.2. The quality management system of the notified body **and its subcontractors** shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of — the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals;
- **continuous training.**

Tuesday 22 October 2013

**Amendment 220**  
**Proposal for a regulation**  
**Annex VI — point 3.1**

*Text proposed by the Commission*

3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

*Amendment*

3.1.1. A notified body **and its subcontractors** shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility. **In accordance with Article 35, this requirement shall be monitored to ensure that it is of the requisite quality.**

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical, **scientific** and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the **permanent** availability within its organisation of sufficient scientific personnel who possess experience, **a university degree** and **the** knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

**Permanent ‘in house’ staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as their declarations of interest and the specific tasks for which they are responsible.**

**Notified bodies shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured.**

**The notified body responsible for carrying out the assessment tasks shall notify the other Member States of the findings of the annual inspections carried out. Those findings shall be set out in a report.**

**It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.**

Tuesday 22 October 2013

Text proposed by the Commission

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to *in vitro* diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.

Amendment

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with **medical**, technical **and where needed pharmacological** knowledge and sufficient and appropriate experience relating to *in vitro* diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data **or the evaluation of an assessment made by a subcontractor**.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel, **including any subcontractors, subsidiaries and external experts**, involved in conformity assessment activities and inform the personnel concerned about it.

**3.1.3a. The notified body shall make available the list of its personnel involved in conformity assessment activities and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date.**

## Amendment 221

### Proposal for a regulation

#### Annex VI — point 3.2

Text proposed by the Commission

3.2.1. The notified body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.

Amendment

3.2.1. The **MDCG** shall establish and document **the principles of high level competence and** qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, **safety**, clinical evaluation and the different types of sterilisation processes.

Tuesday 22 October 2013

## Text proposed by the Commission

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. This personnel altogether shall have proven knowledge and experience in the following:

- Union *in vitro* diagnostic medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of *in vitro* diagnostic medical device technologies, the *in vitro* diagnostic medical device industry and the design and manufacture of *in vitro* diagnostic medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to *in vitro* diagnostic medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to *in vitro* diagnostic medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

3.2.4. Notified bodies shall have available personnel with **clinical** expertise. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

## Amendment

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. This personnel altogether shall have proven knowledge and experience in the following:

- Union *in vitro* diagnostic medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of *in vitro* diagnostic medical device technologies, the *in vitro* diagnostic medical device industry and the design and manufacture of *in vitro* diagnostic medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to *in vitro* diagnostic medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to *in vitro* diagnostic medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.
- ***at least three years' appropriate experience in the field of conformity assessments within a notified body,***
- ***adequate seniority/experience in conformity assessments under this Regulation or previously applicable law during a period of at least three years within a notified body. The notified body staff involved in certification decisions shall not have been involved in the conformity assessment on which a certification decision needs to be taken.***

3.2.4. ***Clinical experts:*** notified bodies shall have available personnel with expertise ***in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations. Permanent 'in house' staff shall be used. However, in accordance with Article 28, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as the specific tasks for which they are responsible.*** This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

Tuesday 22 October 2013

## Text proposed by the Commission

- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to discuss **the clinical data contained within the manufacturer's clinical evaluation** with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;
- be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;
- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;
- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;

## Amendment

- identify when specialist input is required for the assessment of **the clinical investigation plans and** the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to discuss **the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention** with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;
- be able to scientifically challenge **the clinical investigation plans and** the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;
- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;
- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

- **ensure independence and objectivity and disclose potential conflicts of interest.**

3.2.5. **Product assessors:** the personnel responsible for carrying out product related **reviews** (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have **specialist qualifications which should include:**

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device (**as defined within a generic device group**) or technology to be assessed or related to the scientific aspects to be assessed;

Tuesday 22 October 2013

## Text proposed by the Commission

## Amendment

— appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

— appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

— appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

— ***qualification based on technical or scientific fields (e.g. sterilization, biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging);***

— appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments

— ***appropriate knowledge and experience of clinical evaluation;***

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality **management** system shall have the following proven qualification:

3.2.6. **Auditor:** The personnel responsible for carrying out audits of the manufacturer's quality **assurance** system shall have **specialist qualifications, which should include:**

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering

— four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management

— four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management

— ***appropriate knowledge of technologies such as those defined by IAF/EAC coding or equivalent;***

— appropriate knowledge of the *in vitro* diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

— appropriate knowledge of the *in vitro* diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

— appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

— appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

— appropriate knowledge of quality management systems and related standards and guidance documents;

— appropriate knowledge of quality management systems and related standards and guidance documents;

Tuesday 22 October 2013

<i>Text proposed by the Commission</i>	<i>Amendment</i>
— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out the audits;	— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out the audits;
— training in auditing techniques enabling them to challenge quality management systems.	— training in auditing techniques enabling them to challenge quality management systems.

### Amendment 222

#### Proposal for a regulation

#### Annex VI — point 3.4

<i>Text proposed by the Commission</i>	<i>Amendment</i>
3.4. Subcontractors and external experts	3.4. Subcontractors and external experts
3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.	3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities <b>in particular where clinical expertise is limited</b> . The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.
3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.	3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented, <b>be publicly available</b> and be subject to a written agreement covering, among others, confidentiality and conflict of interests.
3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.	3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area, <b>each treatment or medical speciality</b> for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.
3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used	3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**3.4.4a.** *The policy and procedures under points 3.4.2 and 3.4.4 shall be communicated to the national authority before any subcontracting takes place.*

#### Amendment 223

##### Proposal for a regulation

##### Annex VI — point 3.5.2

Text proposed by the Commission

Amendment

3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.

3.5.2. It shall review the competence of its personnel and identify training needs **and ensure that necessary measures are taken accordingly**, in order to maintain the required level of qualification and knowledge.

#### Amendment 224

##### Proposal for a regulation

##### Annex VI — point 3.5 a — title and point 3.5 a.1 (new)

Text proposed by the Commission

Amendment

##### **3.5a. Additional requirements for Special Notified Bodies**

##### **3.5a.1. Clinical Experts for Special Notified Bodies**

**Notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations and pharmacology. Permanent ‘in house’ staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as the specific tasks for which they are responsible. That personnel shall be integrated in the notified body’s decision-making process in a steady way in order to:**

- **identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- *appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;*
- *be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;*
- *be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;*
- *be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;*
- *be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.*
- *have an understanding of active substances.*
- *ensure independence and objectivity and disclose potential conflicts of interest*

## Amendment 267

## Proposal for a regulation

## Annex VI — point 3.5 a.2. (new)

Text proposed by the Commission

Amendment

## 3.5a.2. Product Specialists for Special Notified Bodies

*The personnel responsible for carrying out product related reviews (e.g. design dossier review, technical documentation review or type examination) for devices referred to in Article 41 a shall have the following proven Product Specialist qualification:*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- 
- *Meet the requirement for Product Assessors;*
  
  - *Have an advanced academic degree in a field relevant to medical devices, or alternatively have six years of relevant experience in in vitro diagnostic medical devices or related sectors;*
  
  - *Have an ability to identify key risks of products within the specialist's product categories without prior reference to manufacturer's specifications or risk analyses;*
  
  - *Have an ability to assess the essential requirements in the absence of harmonised or established national standards;*
  
  - *The professional experience should be gained in the first product category their qualification is based on, relevant to the product category of designation of the notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use, with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;*
  
  - *Missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;*
  
  - *For product specialists with qualifications in specific technology, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.*

*For each designated product category, the Special notify body shall have a minimum of two product specialists of which at least one in house, to review devices referred to in Article 41a (1). For those devices, product specialists shall be available in house for the designated technology fields covered by the scope of notification.*

Tuesday 22 October 2013

## Amendment 226

## Proposal for a regulation

## Annex VI — Point 3.5 a.3. (new)

Text proposed by the Commission

Amendment

**3.5a.3. Training for Product Specialists**

*Product Specialists shall receive a minimum of 36 hours of training in in vitro diagnostic medical devices, in vitro diagnostic medical device regulations, and assessment and certification principles, including training in the verification of manufactured product.*

*The Notified Body shall ensure that in order for a product specialist to be qualified, he or she obtains adequate training in the relevant procedures of the Notified Body's quality management system and is taken through a training plan consisting of sufficient design dossier reviews witnessed, performed under supervision and peer reviewed before doing a qualifying full independent review.*

*For each product category for which qualification is sought, the Notified Body must show evidence of appropriate knowledge in the product category. A minimum of five design dossiers (at least two of them initial applications or significant extensions of certification) shall be conducted for the first product category. For subsequent qualification in additional product categories evidence of adequate product knowledge and experience needs to be demonstrated.*

## Amendment 227

## Proposal for a regulation

## Annex VI — Point 3.5 a. 4. (new)

Text proposed by the Commission

Amendment

**3.5a.4. Maintenance Qualification for Product Specialists**

*Qualifications of product specialists shall be reviewed on an annual basis; a minimum of four design dossier reviews, independent of the number of product categories qualified for shall be demonstrated as a four-year rolling average. Reviews of significant changes to the approved design (not full design examinations) shall count for 50 %, as shall reviews supervised.*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*On an ongoing basis, the product specialist shall be required to show evidence of state-of-art product knowledge, review experience in each product category for which qualification exists. Annual training with regard to latest status of Regulations, harmonized standards, relevant guidance documents, clinical evaluation, performance evaluation, CTS requirements must be demonstrated.*

*If the requirements for renewal of qualification are not met, the qualification shall be suspended. Then the first upcoming design dossier review shall be done under supervision, and re-qualification confirmed based on the outcome of that review.*

#### Amendment 228

#### Proposal for a regulation

#### Annex VI — point 4

Text proposed by the Commission

Amendment

4.1. The notified body's decision-making process shall be clearly documented, including the **process for the** issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.1. The notified body's decision-making process shall be **transparent and** clearly documented **and its outcome publicly available**, including the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

4.3. The notified body shall have in place documented procedures covering at least:

4.3. The notified body shall have in place documented procedures **that are publicly available** covering at least:

- the application for conformity assessment by a manufacturer or by an authorised representative,
- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification,

- the application for conformity assessment by a manufacturer or by an authorised representative,
- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification, **as well as the recommended duration for conducting its conformity assessment,**

Tuesday 22 October 2013

<i>Text proposed by the Commission</i>	<i>Amendment</i>
— the language of the application, of the correspondence and of the documentation to be submitted.	— the language of the application, of the correspondence and of the documentation to be submitted.
— the terms of the agreement with the manufacturer or authorised representative,	— the terms of the agreement with the manufacturer or authorised representative,
— the fees to be charged for conformity assessment activities,	— the fees to be charged for conformity assessment activities,
— the assessment of relevant changes to be submitted for prior approval,	— the assessment of relevant changes to be submitted for prior approval,
— the planning of surveillance,	— the planning of surveillance,
— the renewal of certificates.	— the renewal of certificates.

**Amendment 229****Proposal for a regulation****Annex VI — point 4 a (new)**

<i>Text proposed by the Commission</i>	<i>Amendment</i>
	<b>4a. A RECOMMENDED DURATION FOR CONFORMITY ASSESSMENTS CONDUCTED BY NOTIFIED BODIES</b>
	<b>4.1. Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client</b>
	<b>4.2. An audit duration shall be based, inter alia, on the effective number of personnel of the organisation, the complexity of the processes within the organisation, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration may be adjusted based on any significant factors that uniquely apply to the organisation to be audited. The notified body shall ensure that any variation in audit duration does not compromise the effectiveness of audits.</b>
	<b>4.3. The duration of any scheduled on site audit shall not be less than one auditor/day.</b>
	<b>4.4. Certification of multiple sites under one quality assurance system shall not be based on a sampling system.</b>

Tuesday 22 October 2013

**Amendment 230**  
**Proposal for a regulation**  
**Annex VII — point 1.1**

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*Text proposed by the Commission*

1.1. Application of the classification rules shall be governed by the intended purpose of the devices.

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*Amendment*

1.1. Application of the classification rules shall be governed by the intended purpose, **novelty, complexity and inherent risk** of the devices.

**Amendment 231**  
**Proposal for a regulation**  
**Annex VII — point 2.3 — point c**

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*Text proposed by the Commission*

c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring;

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*Amendment*

c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or **embryo** being tested, or to the individual's offspring;

**Amendment 232**  
**Proposal for a regulation**  
**Annex VII — point 2.3 — point f — point ii**

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*Text proposed by the Commission*

(ii) Devices intended to be used for disease staging; or

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*Amendment*

(ii) Devices intended to be used for disease staging **or prognosis**; or

**Amendment 233**  
**Proposal for a regulation**  
**Annex VII — point 2.3 — point j**

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*Text proposed by the Commission*

(j) screening for congenital disorders in the foetus.

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*Amendment*

(j) screening for congenital disorders in the foetus **or embryo**.

Tuesday 22 October 2013

## Amendment 235

## Proposal for a regulation

## Annex VIII — point 3.2 — point d — indent 2

*Text proposed by the Commission*

- 
- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

*Amendment*

- 
- the product identification **and traceability** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

## Amendment 236

## Proposal for a regulation

## Annex VIII — point 4.4 — subparagraph 1

*Text proposed by the Commission*


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The notified body shall randomly perform unannounced **factory** inspections **to the manufacturer** and, if appropriate, **at the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.** The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.

*Amendment*


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The notified body shall randomly perform **for each manufacturer and generic device group** unannounced inspections **at the relevant manufacturing sites** and, if appropriate, at the manufacturer's suppliers and/or subcontractors. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer. **At the time of such inspections, the notified body shall carry out tests or ask to carry them out in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report. The notified body shall carry out such inspections at least once every three years.**

## Amendment 237

## Proposal for a regulation

## Annex VIII — point 5.3

*Text proposed by the Commission*


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5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

*Amendment*


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5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. **The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation. The notified body shall comment on the conformity of the following:**

- 
- **general description of the product,**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- *design specifications, including a description of the solutions adopted to fulfil the essential requirements,*
- *systematic procedures used for the design process and techniques used to control, monitor and verify the design of the device.*

The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

#### Amendment 238

#### Proposal for a regulation

#### Annex VIII — point 5.7

Text proposed by the Commission

Amendment

5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, **in regular intervals**, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.

5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.

#### Amendment 239

#### Proposal for a regulation

#### Annex VIII — point 6.1 — title

Text proposed by the Commission

Amendment

6.1. Examination of the design of devices for self-testing **and near-patient testing** classified as class A, B or C

6.1 Examination of the design of devices for self-testing classified as class A, B or C **and of devices for near patient testing classified as class C**

Tuesday 22 October 2013

## Amendment 240

## Proposal for a regulation

## Annex VIII — point 6.1 — point a

Text proposed by the Commission

- (a) The manufacturer of devices for self-testing **or near-patient testing** classified as class A, B and C shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

Amendment

- (a) The manufacturer of devices for self-testing classified as class A, B and C **and of devices for near patient testing classified as class C** shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

## Amendment 241

## Proposal for a regulation

## Annex VIII — point 6.2 — point e

Text proposed by the Commission

- (e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall **convey its final** decision to the medicinal products competent authority concerned or to the EMA. The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.

Amendment

- (e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA **on the scientific suitability of the companion diagnostic** when making its decision. **If the notified body deviates from that position,** it shall **justify its** decision to the medicinal products competent authority concerned or to the EMA. **If no agreement is reached, the notified body shall inform the MDCG thereof.** The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.

## Amendment 242

## Proposal for a regulation

## Annex IX — point 3.5

Text proposed by the Commission

3.5. in the case of devices classified as class D, request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;

Amendment

3.5. in the case of devices classified as class D, **or for companion diagnostics,** request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;

Tuesday 22 October 2013

**Amendment 243**  
**Proposal for a regulation**  
**Annex IX — point 3.6**

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*Text proposed by the Commission*

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*Amendment*

3.6. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of a one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as ‘medicinal products competent authority’) or the European Medicines Agency (hereinafter referred to as ‘EMA’) on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. The medicinal products authority or the European Medicines Agency shall deliver its opinion, if any, within 60 days upon receipt of the valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

*deleted*

**Amendment 244**  
**Proposal for a regulation**  
**Annex IX — point 5.4**

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*Text proposed by the Commission*

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*Amendment*

5.4. Where the changes affect a companion diagnostic approved through the EU type-examination certificate with regard to its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

*deleted*

Tuesday 22 October 2013

## Amendment 245

## Proposal for a regulation

## Annex X — point 5.1

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Text proposed by the Commission

5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, **in regular intervals**, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings

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Amendment

5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate **laboratory** tests. The reference laboratory shall inform the notified body about its findings

## Amendment 246

## Proposal for a regulation

## Annex XII — Part A — point 1.2.1.4

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Text proposed by the Commission

1.2.1.4 The analytical performance **data** shall be summarised as part of **the clinical evidence report**.

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Amendment

1.2.1.4 The analytical performance **full dataset** shall **accompany the clinical evidence report and may** be summarised as part of **it**.

## Amendment 247

## Proposal for a regulation

## Annex XII — Part A — point 1.2.2.5

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Text proposed by the Commission

1.2.2.5 Clinical performance **data** shall be summarised as part of **the clinical evidence report**.

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Amendment

1.2.2.5 Clinical performance **full dataset** shall **accompany the clinical evidence report and may** be summarised as part of **it**.

Tuesday 22 October 2013

**Amendment 248****Proposal for a regulation****Annex XII — Part A — point 1.2.2.6 — indent 2***Text proposed by the Commission*

- 
- For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol;

*Amendment*

- 
- For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol **and the full dataset**;

**Amendment 249****Proposal for a regulation****Annex XII — Part A — point 1.2.2.6 — indent 3***Text proposed by the Commission*

- 
- For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the **individual data points**.

*Amendment*

- 
- For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the **full dataset**.

**Amendment 250****Proposal for a regulation****Annex XII — Part A — point 2.2 — paragraph 1***Text proposed by the Commission*


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Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18<sup>th</sup> World Medical Assembly in Helsinki, Finland, in 1964 and last amended by the 59<sup>th</sup> World Medical Association General Assembly in Seoul, Korea, in 2008.

*Amendment*


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Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18<sup>th</sup> World Medical Assembly in Helsinki, Finland, in 1964 and last amended by the 59<sup>th</sup> World Medical Association General Assembly in Seoul, Korea, in 2008. **Conformity with the above principles shall be granted after an examination by the Ethics Committee concerned.**

Tuesday 22 October 2013

## Amendment 251

## Proposal for a regulation

## Annex XII — Part A — point 2.3.3 — paragraph 1

*Text proposed by the Commission*

A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

*Amendment*

A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale. ***The report shall be accompanied by the clinical evidence report as described in point 3.1 and be accessible through the electronic system referred to in Article 51.***

## Amendment 252

## Proposal for a regulation

## Annex XII — Part A — point 3.3

*Text proposed by the Commission*

3.3 The clinical evidence and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex.

*Amendment*

3.3 The clinical evidence ***data*** and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex. ***The clinical evidence data and its subsequent updates through post-market follow-up shall be accessible through the electronic systems referred to in Articles 51 and 60.***

## Amendment 253

## Proposal for a regulation

## Annex XIII — Part I a (new) — point 1 (new)

*Text proposed by the Commission**Amendment****Ia. Incapacitated subjects and minors******1. Incapacitated subjects***

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies may be conducted only where, in addition to the general conditions, all of the following conditions are met:*

- the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;*
- the incapacitated subject has received adequate information in relation to his or her capacity for understanding regarding the study and its risks and benefits from the investigator or his/her representative, in accordance with the national law of the Member State concerned;*
- the explicit wish of an incapacitated subject, who is capable of forming an opinion and assessing this information, to refuse participation in, or to be withdrawn from, the clinical performance study at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal representative as a result shall be followed by the investigator;*
- no incentives or financial inducements are given except compensation for participation in the clinical performance study;*
- such research is essential to validate data obtained in a clinical performance study on persons able to give informed consent or by other research methods;*
- such research relates directly to a medical condition from which the person concerned suffers;*
- the clinical performance study has been designed to minimise pain, discomfort, fear, and any other foreseeable risk in relation to the disease and the developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;*
- the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subjects;*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- *there are grounds for expecting that participation in the clinical performance study will produce a benefit for the incapacitated subject outweighing the risks or will produce only a minimal risk;*
- *an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;*

*The test subject shall as far as possible take part in the consent procedure.*

#### Amendment 254

#### Proposal for a regulation

#### Annex XIII — Part I a (new) — point 2 (new)

Text proposed by the Commission

Amendment

#### 2. Minors

*An interventional clinical performance study and other clinical performance studies involving risks for the minor may be conducted only where, in addition to the general conditions, all of the following conditions are met:*

- *the written informed consent of the legal representative or representatives has been obtained, whereby consent shall represent the minor's presumed will;*
- *the informed and express consent of the minor has been obtained, where the minor is able to give consent according to national law,*
- *the minor has received all relevant information in a way adapted to his or her age and maturity, from a medical doctor (either the investigator or member of the study team) trained or experienced in working with children, regarding the study, the risks and the benefits;*
- *without prejudice to second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical performance study at any time, is duly taken into consideration by the investigator;*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- 
- *no incentives or financial inducements are given except payment for participation in the clinical performance study*
  - *such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;*
  - *the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;*
  - *there are grounds to expect that some direct benefit for the category of patients concerned by the study may be obtained from the clinical performance study;*
  - *the corresponding scientific guidelines of the Agency have been followed;*
  - *the interests of the patient shall always prevail over those of science and society;*
  - *the clinical performance study does not replicate other studies based on the same hypothesis and age-appropriate technology is used;*
  - *an ethics committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol.*

*The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.*

*If during a clinical performance study the minor reaches the age of majority as defined in the national law of the Member State concerned, his/her express informed consent shall be obtained before the study may continue.*

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Tuesday 22 October 2013

P7\_TA(2013)0428

## Medical devices \*\*\*I

**Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 — C7-0318/2012 — 2012/0266(COD)) <sup>(1)</sup>**

(Ordinary legislative procedure: first reading)

(2016/C 208/20)

### Amendment 1

#### Proposal for a regulation

##### Recital 1 a (new)

*Text proposed by the Commission*

*Amendment*

- (1a) ***The desire to provide swift access to new medical devices for patients should never take precedence over the need to ensure patient safety.***

### Amendment 2

#### Proposal for a regulation

##### Recital 2

*Text proposed by the Commission*

*Amendment*

- (2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

- (2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health ***for patients, users and operators***. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

<sup>(1)</sup> The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0324/2013).

Tuesday 22 October 2013

**Amendment 3****Proposal for a regulation****Recital 2 a (new) — sentence 1 (new)***Text proposed by the Commission**Amendment*

(2a) **Council Directive 2010/32/EU <sup>(1)</sup> guarantees safety not just for patients but also for users of sharp needles.**

<sup>(1)</sup> Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU (OJ L 134, 1.6.2010, p. 66).

**Amendment 4****Proposal for a regulation****Recital 2 a (new) — sentence 2 (new)***Text proposed by the Commission**Amendment*

**Directive 2010/63/EU of the European Parliament and of the Council <sup>(1)</sup> states that tests on vertebrate animals must be replaced, restricted or refined.**

<sup>(1)</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

**Amendment 5****Proposal for a regulation****Recital 3***Text proposed by the Commission**Amendment*

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety **for health professionals, patients, users and operators, including in the waste disposal chain.**

Tuesday 22 October 2013

**Amendment 6**  
**Proposal for a regulation**  
**Recital 3 a (new)**

Text proposed by the Commission

Amendment

- (3a) ***In the area of medical devices many SMEs are active. This should be taken into account when regulating the sector without compromising the safety and health aspects.***

**Amendment 7**  
**Proposal for a regulation**  
**Recital 7**

Text proposed by the Commission

Amendment

- (7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as in vitro diagnostic medical devices, medicinal products, cosmetics and food. ***Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety should be amended to exclude medical devices from its scope.***

- (7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as in vitro diagnostic medical devices, medicinal products, cosmetics and food. ***Since in some cases it is difficult to distinguish between medical devices and cosmetic, medicinal or food products, the possibility to take an Union-wide decision regarding the regulatory status of a product should be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council<sup>(28)</sup>, Directive 2004/27/EC of the European Parliament and of the Council<sup>(29)</sup>, Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>(30)</sup> and Directive 2002/46/EC of the European Parliament and of the Council<sup>(31)</sup>. Those Union acts should therefore be amended.***

<sup>(28)</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

<sup>(29)</sup> Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34).

<sup>(30)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(31)</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

Tuesday 22 October 2013

**Amendment 8**  
**Proposal for a regulation**  
**Recital 7 a (new)**

Text proposed by the Commission

Amendment

- (7a) **A multidisciplinary Medical Device Advisory Committee (MDAC) composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, regulatory status of devices and other aspects of implementation of this Regulation as necessary.**

**Amendment 9**  
**Proposal for a regulation**  
**Recital 8**

Text proposed by the Commission

Amendment

- (8) **It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.**

- (8) **In order to ensure consistent classification across all Member States, particularly with regards to borderline cases, it should be the responsibility of the Commission, having consulted the MDCG and the MDAC, to decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation. Member States should also have the possibility to request the Commission to take a decision on the appropriate regulatory status of a product, or category or group of products.**

**Amendment 10**  
**Proposal for a regulation**  
**Recital 11 a (new)**

Text proposed by the Commission

Amendment

- (11a) **Unregulated non-intrusive devices, such as non-corrective contact lenses for cosmetic purposes, can cause health complications — such as Microbial Keratitis — when manufactured or used incorrectly. Appropriate safety standards must be in place to protect the safety of consumers who decide to use such products.**

Tuesday 22 October 2013

**Amendment 11**  
**Proposal for a regulation**  
**Recital 12**

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*Text proposed by the Commission*

- (12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain living biological substances of other origin are also not covered by this Regulation.

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*Amendment*

- (12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain living biological substances of other origin **that achieve their intended purpose by pharmacological, immunological or metabolic means** are also not covered by this Regulation.

**Amendment 12**  
**Proposal for a regulation**  
**Recital 12 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (12a) **Devices for use in blood donation and blood therapy should meet the requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council <sup>(1)</sup>.**

- <sup>(1)</sup> Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

**Amendment 13**  
**Proposal for a regulation**  
**Recital 12 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (12b) **The advertising of cosmetic surgery should be better regulated, in order to ensure that patients are fully aware of the risks as well as the benefits.**

Tuesday 22 October 2013

**Amendment 14**  
**Proposal for a regulation**  
**Recital 13**

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*Text proposed by the Commission*

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- (13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health protection, free movement of goods **and** legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles **that can be** released **to** the human body **and those devices** should be subject to the most severe conformity assessment procedure.

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*Amendment*

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- (13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health **and safety** protection **for health professionals, operators and patients, as well as** free movement of goods, legal certainty for manufacturers **and responsibility on their part**, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles **which are intended to be intentionally** released **in** the human body should be subject to the most severe conformity assessment procedure.

**Amendment 15**  
**Proposal for a regulation**  
**Recital 13 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (13a) **Medical devices used in the donation of substances of human origin and their subsequent use for treatment must conform to Union public health legislation ensuring minimum standards for quality and safety, including Directive 2002/98/EC on minimum standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and its additional directives.**

**Amendment 16**  
**Proposal for a regulation**  
**Recital 15 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (15a) **This Regulation includes requirements regarding the design, safety and performance characteristics of medical devices intended to prevent occupational injuries as laid down in Directive 2010/32/EU.**

Tuesday 22 October 2013

**Amendment 17**  
**Proposal for a regulation**  
**Recital 19**

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*Text proposed by the Commission*

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- (19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No [...] on European standardisation should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

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*Amendment*

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- (19) To recognise the important role of standardisation **and traceability** in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No **1025/2012 of the European Parliament and of the Council** <sup>(42)</sup> should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

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<sup>(42)</sup> **Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).**

**Amendment 18**  
**Proposal for a regulation**  
**Recital 19 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (19a) **With devices that consist of more than one implantable part, such as hip implants, compatibility of the parts of different manufacturers should be ensured in order to avoid the replacement of the functional part of the device and thus unnecessary risks and inconvenience for patients. The Commission should investigate the need for further measures to ensure the compatibility of the equivalent parts of hip implants from different manufacturers, bearing in mind that the hip operations are most often made on older people for whom the health risks of operations are higher.**

Tuesday 22 October 2013

**Amendment 19**  
**Proposal for a regulation**  
**Recital 21 a (new)**

Text proposed by the Commission

Amendment

(21a) **Directive 2013/35/EU of the European Parliament and of the Council<sup>(1)</sup> should be the reference text for ensuring that people working in the vicinity of magnetic resonance imaging equipment when it is functioning are properly protected.**

<sup>(1)</sup> Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC (OJ L 179, 29.6.2013, p. 1).

**Amendment 20**  
**Proposal for a regulation**  
**Recital 24**

Text proposed by the Commission

Amendment

(24) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors as laid down in the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators.

(24) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors as laid down in the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators. **Conditions enabling small and medium-sized enterprises with smart specialisation to have easier access to that market should be established.**

**Amendment 21**  
**Proposal for a regulation**  
**Recital 25 a (new)**

Text proposed by the Commission

Amendment

(25a) **To ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty medical device, that the risk of damage as well as the risk of the manufacturer's insolvency are not shifted to patients harmed by a faulty medical device, manufacturers should be obliged to take liability insurance with sufficient minimum coverage.**

Tuesday 22 October 2013

**Amendment 22**  
**Proposal for a regulation**  
**Recital 27**

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*Text proposed by the Commission*

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- (27) It should be ensured that supervision and control of the manufacture of medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification.

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*Amendment*

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- (27) It should be ensured that supervision and control of the manufacture of medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification. ***In addition to regulatory compliance, that person could also be responsible for compliance in other fields such as manufacturing processes and quality assessment. The required qualifications of the person responsible for the regulatory compliance should be without prejudice to national provisions regarding professional qualifications, in particular for manufacturers of custom-made devices where such requirements could be met through different educational and professional training systems at national level.***

**Amendment 24**  
**Proposal for a regulation**  
**Recital 31 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (31a) ***The current possibility to reprocess medical devices labelled as single-use is not acceptable from a safety point of view. Only devices labelled as reusable should therefore be reprocessed. Consequently, medical devices labelled as single-use should be real single-use and there should be only two possibilities: single-use or reusable. In order to avoid any systematic labelling of devices as single-use, all devices should be reusable as a rule, except if they are included in a list established by the Commission, after consultation of the MDAC, of categories and groups of medical devices which are unsuitable for reprocessing. The reprocessing of devices encompasses various activities to ensure that a medical device can be safely reused, ranging from decontamination, sterilisation, cleaning, disassembly, repair, component replacement and packaging. These activities should be subject to comparable and transparent standards.***

Tuesday 22 October 2013

**Amendment 25**  
**Proposal for a regulation**  
**Recital 32**

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*Text proposed by the Commission*

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- (32) Patients who are implanted with a device should be given essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

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*Amendment*

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- (32) Patients who are implanted with a device should be given **clear and easily accessible** essential information related to the implanted device allowing it to be identified and containing **information about the principal characteristics of the device, and** any necessary **health risk** warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

**Amendment 26**  
**Proposal for a regulation**  
**Recital 33**

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*Text proposed by the Commission*

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- (33) Medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation.

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*Amendment*

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- (33) Medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. **However Member States should be allowed to decide whether to restrict the use of any specific type of medical device in relation to aspects that are not covered by this Regulation.**

Tuesday 22 October 2013

**Amendment 27**  
**Proposal for a regulation**  
**Recital 34**

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*Text proposed by the Commission*

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- (34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals.

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*Amendment*

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- (34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals, **wholesalers and pharmacists and be compatible with the safety features as referred to in Directive 2011/62/EU of the European Parliament and of the Council <sup>(1)</sup> and other authentication systems already in place in those settings.**

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<sup>(1)</sup> Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74).

**Amendment 28**  
**Proposal for a regulation**  
**Recital 35**

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*Text proposed by the Commission*

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- (35) Transparency and **better** information are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

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*Amendment*

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- (35) Transparency and **adequate access to** information, **appropriately presented for the intended user**, are essential to empower patients, **users** and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Tuesday 22 October 2013

**Amendment 29**  
**Proposal for a regulation**  
**Recital 36**

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*Text proposed by the Commission*

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- (36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

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*Amendment*

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- (36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency ***through better access to information for the public and healthcare professionals***, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Tuesday 22 October 2013

**Amendment 30**  
**Proposal for a regulation**  
**Recital 37**

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*Text proposed by the Commission*

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- (37) Eudamed's electronic systems **regarding devices on the market, the relevant economic operators and certificates** should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

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*Amendment*

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- (37) Eudamed's electronic systems should enable the public and healthcare professionals to be adequately informed about devices on the Union market. **Adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on medical devices that may pose a risk to public health and safety is essential. Where such access is limited, it should be possible, upon a reasoned request, to disclose the existing information on medical devices, unless the limitation of access is justified on grounds of confidentiality.** The electronic system on clinical investigations should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities. **A regular overview of vigilance and market surveillance information should be made available to healthcare professionals and the public.**

**Amendment 31**  
**Proposal for a regulation**  
**Recital 39**

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*Text proposed by the Commission*

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- (39) For high-risk medical devices, manufacturers should **summarise the main** safety and performance aspects of the device and the outcome of the clinical evaluation **in a document that** should be publicly available.

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*Amendment*

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- (39) For high-risk medical devices, **in the interests of increased transparency,** manufacturers should **draw up a report of the** safety and performance aspects of the device and the outcome of the clinical evaluation. **A summary of the safety and performance report** should be publicly available **via Eudamed.**

Tuesday 22 October 2013

**Amendment 32**  
**Proposal for a regulation**  
**Recital 39a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (39a) According to the policy of the European Medicines Agency (EMA) on access to documents, the EMA releases documents submitted as part of applications for marketing authorisation for medicinal products, including clinical trial reports, on request once the decision-making process for the medicinal product in question has been completed. Corresponding standards on transparency and access to documents should be upheld and reinforced for high-risk medical devices, in particular as they are not subject to pre-market approval. For the purposes of this Regulation, in general the data included in clinical investigations should not be considered commercially sensitive once compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure. This should be without prejudice to intellectual property rights concerning the data in clinical investigations by the manufacturer with regard to the use of these data by other manufacturers.

**Amendment 33**  
**Proposal for a regulation**  
**Recital 39 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (39b) As regards invasive devices with a diagnostic and measuring function, Member States should take all necessary measures to prevent the risk of infection and microbial contamination between patients. To this end, the Member States should eliminate the known or foreseeable risks to patient safety by advocating inter alia the safest levels of and guidelines for disinfection and ensure their effective implementation by users and health establishments. In accordance with this Regulation, the Commission should ensure that these preventive health protection measures are appropriate.

Tuesday 22 October 2013

**Amendment 34**  
**Proposal for a regulation**  
**Recital 40**

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*Text proposed by the Commission*

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- (40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

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*Amendment*

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- (40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection **for health professionals, users and operators, including in the waste disposal chain,** and **for ensuring** citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, **and where applicable by the EMA,** in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

**Amendment 35**  
**Proposal for a regulation**  
**Recital 42**

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*Text proposed by the Commission*

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- (42) **For high risk medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding novel devices, devices for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.**

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*Amendment*

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**deleted**

Tuesday 22 October 2013

## Amendments 363 and 370

## Proposal for a regulation

## Recital 42 a (new)

Text proposed by the Commission

Amendment

- (42a) *For high-risk medical devices, such as devices in class III, implantable devices and devices intended to administer medicinal products when failure or malfunctioning of these devices would have a major impact on health and safety, the conformity assessment should be the responsibility of special notified bodies. Those special notified bodies should be designated by the EMA on the basis of the reinforced requirements on staff qualification and training as referred to in Section 3.5a of Annex VI. These special notified bodies should meet in a Network in order in particular to exchange good practice and ensure convergence in their work. The Assessment Committee for Medical Devices (ACMD) shall provide an opinion on the robustness of the clinical data by way on an assessment in specific cases. The need for such additional assessment should decrease once the new rules have been fully implemented and applied in particular to all notified bodies and as common technical standards are developed. The Commission should therefore review the functioning of and the experience with the additional assessment procedure after five years with a view to assessing whether it can be further restricted.*

## Amendment 379

## Proposal for a regulation

## Recital 42 b (new)

Text proposed by the Commission

Amendment

- (42b) *As this Regulation now combines active implantable medical devices covered by Directive 90/385/EEC, and implantable medical devices covered by Directive 93/42/EEC, and places all active implantable medical devices and implantable devices of public health concern in the highest risk class III category attracting the strictest controls, and as the vast majority of class IIb implantable medical devices such as pins, bone-screws, plates, staples etc., have a long history of safe implantation within the human body, and as special notified bodies will be specifically designated for such class IIb implantable devices, class IIb implantable devices need not be subjected to the scrutiny procedure.*

Tuesday 22 October 2013

**Amendment 364**  
**Proposal for a regulation**  
**Recital 42 c (new)**

Text proposed by the Commission

Amendment

- (42c) *The ACMD should be composed of clinical experts in the medical fields relevant to the medical device being assessed, one representative of the EMA and one representative of patients' organisations. The ACMD should meet on request from the MDCG or the Commission and its meetings should be chaired by a Commission representative. The Commission should provide logistic support to the secretariat and operations of the ACMD.*

**Amendment 38**  
**Proposal for a regulation**  
**Recital 45**

Text proposed by the Commission

Amendment

- (45) The conformity assessment procedures should be **simplified** and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.
- (45) The conformity assessment procedures should be **strengthened** and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

**Amendment 39**  
**Proposal for a regulation**  
**Recital 47**

Text proposed by the Commission

Amendment

- (47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects and the most recent (2008) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.
- (47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 **or any subsequent version of it** on good clinical practice for clinical investigations of medical devices for human subjects and the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.

Tuesday 22 October 2013

**Amendment 40**  
**Proposal for a regulation**  
**Recital 47 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(47a) *The Declaration of Helsinki of the World Medical Association<sup>(1)</sup> states in Article 15 that ‘the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins’. Clinical investigations involving risk for the subject should only be allowed after assessment and approval by an ethics committee. The reporting Member State and the other concerned Member States need to organise themselves in a way that the competent authority concerned receives approval by an ethics committee on the clinical performance study protocol.*

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<sup>(1)</sup> WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and lastly amended by the 59<sup>th</sup> WMA General Assembly, Seoul, Korea, October 2008  
[http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage])

**Amendment 41**  
**Proposal for a regulation**  
**Recital 48 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(48a) *For the sake of transparency, sponsors should submit the results of a clinical investigation together with a layperson summary within the deadlines specified by the regulation. The Commission should be empowered to adopt delegated acts on the preparation of the layperson’s summary and the communication of the clinical investigation report. The Commission should provide guidelines for managing and facilitating the sharing of raw data from all clinical investigations.*

Tuesday 22 October 2013

**Amendment 43**  
**Proposal for a regulation**  
**Recital 50**

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*Text proposed by the Commission*

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- (50) Sponsors should report **certain** adverse events occurring during clinical investigations to the Member States concerned, which **should** have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information **should** be communicated to the other Member States.

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*Amendment*

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- (50) Sponsors should report adverse events occurring during clinical investigations to the Member States concerned, which **shall** have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information **shall** be communicated to the other Member States, **the MDCG and the Commission**.

**Amendment 44**  
**Proposal for a regulation**  
**Recital 51 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (51a) **Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC of the European Parliament and of the Council<sup>(1)</sup>.**

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<sup>(1)</sup> Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

**Amendment 45**  
**Proposal for a regulation**  
**Recital 52**

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*Text proposed by the Commission*

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- (52) In order to better protect health and safety regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

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*Amendment*

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- (52) In order to better protect **the** health and safety **of health professionals, patients, users and operators, including in the waste disposal chain**, regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

Tuesday 22 October 2013

**Amendment 46**  
**Proposal for a regulation**  
**Recital 53**

Text proposed by the Commission

- (53) Healthcare professionals and patients should be empowered to report suspected serious incidents at national level using harmonised formats. **The** national competent authorities should inform manufacturers and **share** the information **with their peers** when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.

Amendment

- (53) **Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents.** Healthcare professionals, **users** and patients should be empowered **and enabled** to report such incidents at national level using harmonised formats **and guaranteeing anonymity, where appropriate. In order to minimise the recurrence of such incidents, the** national competent authorities should inform manufacturers, **and, if appropriate, their subsidiaries and sub-contractors,** and **report** the information **via the respective electronic system in Eudamed** when they confirm that an incident has occurred.

**Amendment 47**  
**Proposal for a regulation**  
**Recital 54**

Text proposed by the Commission

- (54) The assessment of reported serious incidents and field safety corrective actions should be conducted at national level but **coordination should be ensured** where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State with the objective of sharing resources and ensuring consistency regarding the corrective action.

Amendment

- (54) The assessment of reported serious incidents and field safety corrective actions should be conducted at national level but where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State **coordination**, with the objective of sharing resources and ensuring consistency regarding the corrective action, **and transparency of procedures should be ensured.**

**Amendment 48**  
**Proposal for a regulation**  
**Recital 54 a (new)**

Text proposed by the Commission

Amendment

- (54a) **Manufacturers should report periodically on medical devices classified as class III as regards the data relevant to the risk benefit ratio and the exposition of the population in order to evaluate whether any action concerning the medical device concerned is necessary.**

Tuesday 22 October 2013

**Amendment 49**  
**Proposal for a regulation**  
**Recital 56**

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*Text proposed by the Commission*

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- (56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

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*Amendment*

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- (56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures. ***The Commission should clearly define the way these inspections should be conducted in order to ensure a full and harmonised implementation within the Union.***

**Amendment 50**  
**Proposal for a regulation**  
**Recital 57**

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*Text proposed by the Commission*

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- (57) The Member States ***shall*** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.

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*Amendment*

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- (57) The Member States ***should*** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies. ***These fees should be comparable across Member States and should be made public.***

**Amendment 51**  
**Proposal for a regulation**  
**Recital 57 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (57a) ***Member States are invited to set and enforce serious penalties for manufacturers that commit fraud and cheat with regard to medical devices. Those penalties should be at least as large as the revenue gains from fraud or cheating. Penalties may include imprisonment.***

Tuesday 22 October 2013

**Amendment 52**  
**Proposal for a regulation**  
**Recital 58**

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*Text proposed by the Commission*

- (58) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency.

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*Amendment*

- (58) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt **a comparable** level and structure of the fees to ensure transparency.

**Amendment 53**  
**Proposal for a regulation**  
**Recital 58 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (58a) **Member States should adopt provisions on standard fees for notified bodies, which should be comparable across Member States. The Commission should provide guidelines to facilitate the comparability of those fees. Member States should transmit their list of standard fees to the Commission and ensure that the notified bodies registered on their territory make the lists of standard fees for their conformity assessment activities publicly available.**

**Amendment 54**  
**Proposal for a regulation**  
**Recital 59**

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*Text proposed by the Commission*

- (59) **An expert committee, the Medical Device Coordination Group (MDCG)**, composed of persons designated by the Member States based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [...] on in vitro diagnostic medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

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*Amendment*

- (59) **A** MDCG, composed of persons designated by the Member States based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [...] on in vitro diagnostic medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

Tuesday 22 October 2013

**Amendment 55**  
**Proposal for a regulation**  
**Recital 61**

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*Text proposed by the Commission*

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- (61) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for medical devices is effectively implemented at Union level based on sound scientific evidence.

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*Amendment*

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- (61) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for medical devices is effectively **and uniformly** implemented at Union level based on sound scientific evidence.

**Amendment 56**  
**Proposal for a regulation**  
**Recital 63**

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*Text proposed by the Commission*

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- (63) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

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*Amendment*

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- (63) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the **principle of free and informed consent, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property, as well as the European Convention on Human Rights**. This Regulation should be applied by the Member States in accordance with those rights and principles.

Tuesday 22 October 2013

**Amendment 57**  
**Proposal for a regulation**  
**Recital 64**

*Text proposed by the Commission*

- (64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies, of the **minimum** requirements to be met by notified bodies, of the classification rules, of the conformity assessment procedures, and of the documentation to be submitted for the approval of clinical investigations; the establishment of the UDI system; the information to be submitted for the registration of medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical investigations; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

*Amendment*

- (64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies, of the requirements to be met by notified bodies, of the classification rules, of the conformity assessment procedures, and of the documentation to be submitted for the approval of clinical investigations; the establishment of the UDI system the information to be submitted for the registration of medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical investigations; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. **However, basic aspects of this Regulation such as general safety and performance requirements, stipulations on technical documentation and the requirements for CE marking certification, as well as any amendments or additions to it, should be provided for only through the ordinary legislative procedure.** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Tuesday 22 October 2013

**Amendment 58**  
**Proposal for a regulation**  
**Recital 68**

Text proposed by the Commission

(68) To allow economic operators, **notified bodies, Member States and the Commission** to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period **for that adaptation and** for the organisational arrangements to be taken **for its proper application**. It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of medical devices on the market.

Amendment

(68) To allow economic operators, **especially SMEs**, to adapt to the changes introduced by this Regulation **and to ensure its proper application**, it is appropriate to provide for a sufficient transitional period for the organisational arrangements to be taken. **However, parts of the Regulation that affect directly Member States and the Commission should be implemented as soon as possible.** It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of medical devices on the market. **Also at the date of application, existing notified bodies that handle class III devices, shall be subject to an application for notification in accordance with this Regulation.**

**Amendment 59**  
**Proposal for a regulation**  
**Article 1 — paragraph 1 — subparagraph 1**

Text proposed by the Commission

This Regulation establishes rules to be complied with by medical devices **and** accessories to medical devices that are placed on the market or put into service in the Union **for human use**.

Amendment

This Regulation establishes rules to be complied with by medical devices **for human use**, accessories to medical devices **and medical devices for aesthetic purposes** that are placed on the market or put into service in the Union.

**Amendment 60**  
**Proposal for a regulation**  
**Article 1 — paragraph 1 — subparagraph 2**

Text proposed by the Commission

For the purposes of this Regulation, medical devices **and** accessories to medical devices shall hereinafter be referred to as 'devices'.

Amendment

For the purposes of this Regulation, medical devices, accessories to medical devices **and devices for aesthetic purposes** shall hereinafter be referred to as 'devices'.

Tuesday 22 October 2013

## Amendment 61

## Proposal for a regulation

## Article 1 — paragraph 2 — point f

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*Text proposed by the Commission*

- (f) products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable, including living micro-organisms, bacteria, fungi or virus;

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*Amendment*

- (f) **all** products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable **and that achieve their intended purpose by pharmacological, immunological or metabolic means**, including **certain** living micro-organisms, bacteria, fungi or virus;

## Amendment 62

## Proposal for a regulation

## Article 1 — paragraph 4 — subparagraph 1

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*Text proposed by the Commission*

Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1 (2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation.

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*Amendment*

Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1 (2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation **following consultation with the national medicine agency or with the EMA.**

## Amendment 63

## Proposal for a regulation

## Article 1 — paragraph 5 a (new)

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*Text proposed by the Commission*

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*Amendment*

**5a. This Regulation shall not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.**

**Articles 10 (Personnel), 14 (Traceability), 15 (Notification of serious adverse events and reactions), 19 (Examination of donors) and 29 (Technical requirements and their adaptation to technical and scientific progress) of Directive 2002/98/EC ensure donor and patient safety and as such those existing standards shall be maintained.**

Tuesday 22 October 2013

## Amendment 64

## Proposal for a regulation

## Article 1 — paragraph 7 a (new)

Text proposed by the Commission

Amendment

**7a. The regulation of medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.**

## Amendment 65

## Proposal for a regulation

## Article 2 — paragraph 1 — point 1 — introductory part

Text proposed by the Commission

Amendment

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific **direct or indirect** medical purposes of:

## Amendment 66

## Proposal for a regulation

## Article 2 — paragraph 1 — point 1 — indent 1

Text proposed by the Commission

Amendment

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, prevention, monitoring, **prediction**, treatment or alleviation of disease,

## Amendment 67

## Proposal for a regulation

## Article 2 — paragraph 1 — point 1 — paragraph 2

Text proposed by the Commission

Amendment

The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

The implantable or other invasive products, **as well as products using external physical agents**, intended to be used for human beings, which are listed **on a non-exhaustive basis** in Annex XV, shall be considered medical devices **for the purposes of this Regulation**, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

Tuesday 22 October 2013

## Amendment 68

## Proposal for a regulation

## Article 2 — paragraph 1 — point 2

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*Text proposed by the Commission*

- (2) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable **or assist** the device(s) to be used in accordance with its/their intended purpose(s);

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*Amendment*

- (2) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the device(s) to be used in accordance with its/their intended purpose(s); **or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s);**

## Amendment 69

## Proposal for a regulation

## Article 2 — paragraph 1 — point 2 a (new)

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*Text proposed by the Commission*

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*Amendment*

- (2a) 'device for aesthetic purposes' means any instrument, apparatus, appliance, software, implant, material, substance or other article, intended by the manufacturer to be used, alone or in combination, for the purposes of modifying the physical appearance of human beings, without any therapeutic or reconstructive intent, by implanting it in the human body, attaching it to the surface of the eye or using it to induce a tissue or cell reaction on external or non-external parts of the human body.

**Tattooing products and piercings shall not be considered devices for aesthetic purposes.**

Tuesday 22 October 2013

## Amendment 70

## Proposal for a regulation

## Article 2 — paragraph 1 — point 3

Text proposed by the Commission

- (3) 'custom-made device' means any device specifically made **in accordance with** a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, **and is intended for the sole use of a particular patient.**

*However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;*

Amendment

- (3) 'custom-made device' means any device specifically made **by an appropriately qualified person exclusively to meet a specific patient's individual requirements and needs. In particular a 'custom-made device' may be produced on the basis of** a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics. **However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;**

## Amendment 71

## Proposal for a regulation

## Article 2 — paragraph 1 — point 4 — paragraph 1

Text proposed by the Commission

- (4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.

Amendment

- (4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated **by the human body or** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.

Tuesday 22 October 2013

## Amendment 72

## Proposal for a regulation

## Article 2 — paragraph 1 — point 4 — paragraph 2

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Text proposed by the Commission

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*Stand alone software shall be considered an active device;*

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Amendment

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*deleted*

## Amendment 73

## Proposal for a regulation

## Article 2 — paragraph 1 — point 8 — paragraph 1

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Text proposed by the Commission

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(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure.

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Amendment

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(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure **and which has been tested and demonstrated to be impossible to reuse.**

## Amendment 357

## Proposal for a regulation

## Article 2 — paragraph 1 — point 8 a (new)

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Text proposed by the Commission

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Amendment

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(8a) 'reusable device' means a device that is suitable for reprocessing and that is intended to be used on multiple patients or during multiple procedures;

## Amendment 75

## Proposal for a regulation

## Article 2 — paragraph 1 — point 9

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Text proposed by the Commission

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(9) 'single-use device for critical use' means a single-use device intended to be used for surgically invasive medical procedures;

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Amendment

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*deleted*

Tuesday 22 October 2013

## Amendment 354

## Proposal for a regulation

## Article 2 — paragraph 1 — point 10

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*Text proposed by the Commission*

- (10) ‘intended purpose’ means the use for which the device is intended according to the **data supplied by the manufacturer on the** label, in the instructions for use **or** in promotional or sales materials or statements;

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*Amendment*

- (10) ‘intended purpose’ means the use for which the device is intended according to the **clinical evaluation, to be reflected in the conformity certificate, the product** label, in the instructions for use **and if applicable** in promotional or sales materials or statements;

## Amendment 76

## Proposal for a regulation

## Article 2 — paragraph 1 — point 16

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*Text proposed by the Commission*

- (16) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market **in the course of a commercial activity**, whether in return for payment or free of charge;

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*Amendment*

- (16) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market, whether in return for payment or free of charge;

## Amendment 77

## Proposal for a regulation

## Article 2 — paragraph 1 — point 24

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*Text proposed by the Commission*

- (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients **or the promotion of public health**;

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*Amendment*

- (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients;

## Amendment 78

## Proposal for a regulation

## Article 2 — paragraph 1 — point 27

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*Text proposed by the Commission*

- (27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device;

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*Amendment*

- (27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device; **routine device maintenance service activities are not included in this definition**;

Tuesday 22 October 2013

**Amendment 79****Proposal for a regulation****Article 2 — paragraph 1 — point 31 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(31a) ‘performance’ means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use;**

**Amendment 80****Proposal for a regulation****Article 2 — paragraph 1 — point 31 b (new)**

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*Text proposed by the Commission*

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*Amendment*

**(31b) ‘benefit’ means the positive health impact of a medical device based on clinical and non-clinical data;**

**Amendment 82****Proposal for a regulation****Article 2 — paragraph 1 — point 32**

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*Text proposed by the Commission*

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*Amendment*

(32) ‘clinical evaluation’ means the assessment and analysis of clinical data pertaining to a device in order to verify the safety **and** performance of the device when used as intended by the manufacturer;

(32) ‘clinical evaluation’ means the assessment and analysis of clinical data pertaining to a device in order to verify the safety, performance **and clinical benefits** of the device when used as intended by the manufacturer;

**Amendment 83****Proposal for a regulation****Article 2 — paragraph 1 — point 33 — paragraph 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**Clinical investigations for medical devices, where made compulsory in accordance with this Regulation, shall include clinical investigations in the appropriate target population and well-controlled investigations.**

Tuesday 22 October 2013

**Amendment 84****Proposal for a regulation****Article 2 — paragraph 1 — point 36 — introductory part***Text proposed by the Commission*

(36) 'clinical data' means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:

*Amendment*

(36) 'clinical data' means **all** the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:

**Amendment 86****Proposal for a regulation****Article 2 — paragraph 1 — point 37***Text proposed by the Commission*

(37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical investigation;

*Amendment*

(37) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation and management, **conduct or financing** of a clinical investigation;

**Amendment 87****Proposal for a regulation****Article 2 — paragraph 1 — point 37 a (new)***Text proposed by the Commission**Amendment*

(37a) '**conformity assessment**' means, in relation to a clinical study, the checking by the authorities responsible of the relevant official documentation, facilities and records and of the existence of sufficient insurance cover. Such checking may be carried out on the premises of the sponsor and/or the research establishment or wherever the authority responsible may deem checks to be necessary.

Tuesday 22 October 2013

## Amendment 88

## Proposal for a regulation

## Article 2 — paragraph 1 — point 37 b (new)

Text proposed by the Commission

Amendment

(37b) *'ethics committee' means an independent body in a Member State, consisting of health-care professionals and non-medical members including at least one well-experienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in clinical investigations and to provide public assurance of that protection in full transparency. In cases of such investigations involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise;*

## Amendment 89

## Proposal for a regulation

## Article 2 — paragraph 1 — point 39 — indent 2 — point iii

Text proposed by the Commission

Amendment

(iii) hospitalisation or ***extending the duration of*** hospitalisation,

(iii) hospitalisation or ***prolongation of patient*** hospitalisation,

## Amendment 90

## Proposal for a regulation

## Article 2 — paragraph 1 — point 39 — indent 3

Text proposed by the Commission

Amendment

— foetal distress, foetal death or a congenital ***abnormality*** or birth defect;

— foetal distress, foetal death or a congenital ***physical or mental impairments*** or birth defect;

Tuesday 22 October 2013

## Amendment 91

## Proposal for a regulation

## Article 2 — paragraph 1 — point 40

Text proposed by the Commission

(40) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of **an investigational** device, including malfunction, **use errors** or inadequacy in the information supplied by the manufacturer;

Amendment

(40) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of **a** device, **as defined in points 1 to 6 of this paragraph**, including malfunction, or inadequacy in the information supplied by the manufacturer;

## Amendment 92

## Proposal for a regulation

## Article 2 — paragraph 1 — point 48 a (new)

Text proposed by the Commission

Amendment

(48a) '**unannounced inspection**' means an inspection conducted without advance notice;

## Amendment 93

## Proposal for a regulation

## Article 3

Text proposed by the Commission

Amendment

1. The Commission may, at the request of a Member State **or on its own initiative**, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

1. The Commission may **on its own initiative or shall** at the request of a Member State, by means of implementing acts **on the basis of the opinions of the MDCG and the MDAC referred to in Articles 78 and 78a respectively**, determine whether or not a specific product, or category or group of products, **including borderline products**, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

2. **The Commission shall ensure the sharing of expertise between Member States in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.**

Tuesday 22 October 2013

**Amendment 256**  
**Proposal for a regulation**  
**Chapter II — title**

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*Text proposed by the Commission*

**Chapter II**

Making available of devices, obligations of economic operators,  
 reprocessing, CE marking, free movement

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*Amendment*

**Chapter VI (\*)**

Making available of devices, obligations of economic operators,  
 reprocessing, CE marking, free movement

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(\*) As a consequence of this amendment, this Chapter will cover Articles 4 to 14 and 16 to 22

**Amendment 94**  
**Proposal for a regulation**  
**Article 4 — paragraph 4**

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*Text proposed by the Commission*

4. Devices that are manufactured and used within a single health institution shall be considered as being put into service. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 **to** 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.

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*Amendment*

4. Devices that are manufactured and used within a single health institution shall be considered as being put into service. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23, **26 and** 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.

**Amendment 95**  
**Proposal for a regulation**  
**Article 4 — paragraph 5**

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*Text proposed by the Commission*

**5. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.**

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*Amendment*

**deleted**

Tuesday 22 October 2013

## Amendment 96

## Proposal for a regulation

## Article 5 — paragraph 1

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*Text proposed by the Commission*

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest **when** the device is placed on the market.

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*Amendment*

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest **by the day on which the** device is placed on the market.

## Amendment 97

## Proposal for a regulation

## Article 5 — paragraph 2 a (new)

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*Text proposed by the Commission*

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*Amendment*

2a. *Service providers providing means of distance communication shall be obliged, upon receiving a request from the competent authority, to disclose the details of entities engaging in distance selling.*

## Amendment 98

## Proposal for a regulation

## Article 5 — paragraph 2 b (new)

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*Text proposed by the Commission*

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*Amendment*

2b. *There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by:*

(a) *ascribing characteristics, functions and effects to the product which the product does not have;*

(b) *creating the false impression that treatment or diagnosis using the product is sure to be successful, or failing to inform of a likely risk associated with the use of the product in line with its intended use or for a longer-than-anticipated period;*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

(c) **suggesting uses or characteristics of the product other than those declared when the conformity assessment was carried out.**

**Promotional materials, presentations and information about the products may not mislead in the manner referred to in the first subparagraph.**

#### Amendment 99

##### Proposal for a regulation

##### Article 7 — paragraph 1

Text proposed by the Commission

1. Where no harmonised standards exist or where **relevant harmonised standards are not sufficient**, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

Amendment

1. Where no harmonised standards exist or where **there is a need to address public health concerns**, the Commission, **after having consulted the MDCG and the MDAC**, shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

**1a. Before adopting CTS referred to in paragraph 1, the Commission shall ensure that the CTS have been developed with the appropriate support of the relevant stakeholders and that they are coherent with the European and international standardisation system. CTS are coherent if they do not conflict with European standards, meaning they cover areas where no harmonised standards exist, the adoption of new European standards is not envisaged within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not envisaged within a reasonable period.**

#### Amendment 100

##### Proposal for a regulation

##### Article 8 — paragraph 2 — subparagraph 2

Text proposed by the Commission

**The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.**

Amendment

**deleted**

Tuesday 22 October 2013

## Amendment 101

## Proposal for a regulation

## Article 8 — paragraph 6 — subparagraph 2

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*Text proposed by the Commission*

If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.

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*Amendment*

If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures, **including immediate notification to Eudamed as established by Article 27.**

## Amendment 102

## Proposal for a regulation

## Article 8 — paragraph 8

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*Text proposed by the Commission*

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative accordingly.

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*Amendment*

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors, **the importers** and, where applicable, the authorised representative accordingly.

## Amendment 103

## Proposal for a regulation

## Article 8 — paragraph 9 — subparagraph 1 a (new)

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*Text proposed by the Commission*

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*Amendment*

**If a competent authority considers or has reason to believe that a device has caused damages, it shall ensure, where this is not already foreseen by national litigation or judicial proceedings, that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to in the first subparagraph from the manufacturer or his authorised representative while ensuring due respect to the intellectual property rights.**

Tuesday 22 October 2013

**Amendment 104****Proposal for a regulation****Article 8 — paragraph 10 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**10a.** Before placing a medical device on the market, manufacturers shall ensure they are covered by an appropriate liability insurance covering any damages to patients or users that can be directly attributed to a manufacturing defect of the same medical device, with a level of coverage proportionate to the potential risk associated with the medical device produced, and in accordance with Council Directive 85/374/EEC <sup>(1)</sup>.

<sup>(1)</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

**Amendment 105****Proposal for a regulation****Article 11 — paragraph 2 — subparagraph 1 — point -a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(-a)** that the manufacturer is identifiable and has the technical, scientific and financial capacity to produce a medical device compliant with this Regulation, and that importers make available to the national authorities and on their website a report on the investigation procedures attesting to the expertise of the manufacturer.

**Amendment 106****Proposal for a regulation****Article 11 — paragraph 2 — subparagraph 1 — point f a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(fa)** that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8(10a), unless the importer himself ensures sufficient coverage that meets the requirements of that paragraph.

Tuesday 22 October 2013

**Amendment 107****Proposal for a regulation****Article 11 — paragraph 7***Text proposed by the Commission*

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, **take** the necessary corrective action to bring that device **into** conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action **taken**.

*Amendment*

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, **ensure that** the necessary corrective action to bring that device **in** conformity, withdraw or recall it, **is taken and, implement that action**. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action **they have implemented**.

**Amendment 108****Proposal for a regulation****Article 12 — paragraph 2 — subparagraph 1 — point c***Text proposed by the Commission*

(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article **24 and Article 11(3) respectively**.

*Amendment*

(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 11(3).

**Amendment 109****Proposal for a regulation****Article 12 — paragraph 4***Text proposed by the Commission*

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

*Amendment*

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure, **within the scope of their respective activities**, that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Tuesday 22 October 2013

**Amendment 110**  
**Proposal for a regulation**  
**Article 13**

*Text proposed by the Commission*

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one **qualified** person who possesses **expert knowledge** in the field of medical devices. The **expert knowledge** shall be demonstrated by either of the following qualifications:

- (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;**
- (b) **five** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC.

2. The **qualified** person shall at least be responsible for ensuring the following matters:

- (a) that the conformity of the devices is appropriately assessed before a batch is released;
- (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
- (c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
- (d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

*Amendment*

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person **responsible for regulatory compliance** who possesses **the requisite expertise** in the field of medical devices. The **requisite expertise** shall be demonstrated by either of the following qualifications:

- (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in **law**, natural sciences, medicine, pharmacy, engineering or another relevant discipline;
- (b) **three** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC.

2. The person **responsible for regulatory compliance** shall at least be responsible for ensuring the following matters:

- (a) that the conformity of the devices is appropriately assessed before a batch is released;
- (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
- (c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
- (d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

***If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.***

Tuesday 22 October 2013

Text proposed by the Commission

3. The **qualified** person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one **qualified** person who possesses **expert knowledge** regarding the regulatory requirements for medical devices in the Union. The **expert knowledge** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices**;

(b) **five** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Amendment

3. The person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one person **responsible for regulatory compliance** who possesses **the requisite expertise** regarding the regulatory requirements for medical devices in the Union. The **requisite expertise** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

(b) **three** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

## Amendment 111

## Proposal for a regulation

## Article 14 — paragraph 1 — subparagraph 1 a (new)

Text proposed by the Commission

Amendment

**A distributor, importer or other natural or legal person shall assume the obligations incumbent on the manufacturer under paragraph 1(a) only if the device in question was manufactured outside the Union. In the case of devices manufactured within the Union, the manufacturer's proof of compliance with this Regulation shall suffice.**

Tuesday 22 October 2013

**Amendment 112**  
**Proposal for a regulation**  
**Article 14 — paragraph 4**

Text proposed by the Commission

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample **or a mock-up** of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

Amendment

4. **At least 28 calendar days** prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample of the relabelled or repackaged device, including any translated label and instructions for use. **Within the same period of 28 calendar days**, he shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

**Amendment 113**  
**Proposal for a regulation**  
**Article 15**

Text proposed by the Commission

Article 15

Amendment

deleted

**Single-use devices and their reprocessing**

1. **Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.**

2. **Only single-use devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.**

3. **In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

5. The name and address of the legal or natural person referred to in paragraph 1 and the other relevant information in accordance with Section 19 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

6. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that Member State the following:

- (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
- (b) the making available of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them. The Commission shall keep the information publicly available.

#### Amendment 257

#### Proposal for a regulation

#### Chapter VI a (new)

Text proposed by the Commission

Amendment

#### Chapter VIa (\*)

#### Labelling and safe reprocessing of medical devices

(\*) As a consequence of this amendment, this Chapter will cover Articles 15a to 15d

Tuesday 22 October 2013

**Amendment 358**  
**Proposal for a regulation**  
**Article 15 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 15a**

**General principles on safe reprocessing**

1. Any natural or legal person, including health institutions as specified in Article 4(4), who wishes to reprocess a single-use device to make it suitable for further use within the Union, and who can provide scientific evidence that such a device could be safely reprocessed shall be considered to be the manufacturer of its reprocessed device and shall be held liable for its reprocessing activities. The natural or legal person shall ensure the traceability of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, with the exception of obligations linked to the conformity assessment procedure.
2. Only reusable devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.
3. Unless they are placed on the list of single-use devices referred to in Article 15b, medical devices shall be considered as suitable for reprocessing and reusable devices in accordance with the provisions laid down in Article 15c, and providing the highest level of patient safety is guaranteed.
4. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that Member State the following:
  - (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
  - (b) the making available of reprocessed single-use devices.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them. The Commission shall keep the information publicly available.**

**Amendment 359****Proposal for a regulation****Article 15 b (new)**

Text proposed by the Commission

Amendment

**Article 15b****List of single-use devices unsuitable for reprocessing**

**1. In accordance with Article 15a(3), the Commission, after the mandatory consultation of the MDAC shall establish, by means of delegated acts, a list of medical devices or types of medical device which are unsuitable for reprocessing. The Commission shall regularly update that list, including by adding or removing items. A first list shall be established no later than six months before the date of entry into force of this Regulation.**

**2. The decision to include or remove any device or type of device from the list shall be made in particular by taking into account:**

- their intended use in or on the human body and the body parts they will be in contact with;**
- the conditions of their use;**
- their intended purpose;**
- the material which of which they are composed;**
- the severity of the disease that is being treated;**
- a genuine safety risk; and**
- the latest scientific and technological advancements in the relevant fields and disciplines.**

**3. The delegated acts referred to in paragraph 1 shall be adopted in accordance with Article 89.**

Tuesday 22 October 2013

**Amendment 118**  
**Proposal for a regulation**  
**Article 15 c (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 15c**

***Reprocessing of medical devices labelled as reusable***

**1. Any natural or legal person, including health institutions as specified in Article 4(4), who reprocesses a device labelled as 'reusable' shall:**

— ***comply with the EU standards referred to in paragraph 2;***

— ***ensure that, where a single-use device is removed from the list referred to in Article 15b, the reusable device is reprocessed in accordance with the opinion of the EU reference laboratory;***

— ***ensure that the reusable device is not reprocessed beyond the maximum number of times specified for that device;***

**2. The Commission shall, by means of implementing acts, and in collaboration with the International Medical Devices Regulatory Forum and international standardisation bodies, define a clear set of high quality and safety standards for reprocessing of single use devices, including specific requirements for the manufacturers of reprocessed devices.**

**3. In drawing up these quality and safety standards, the Commission shall notably include:**

— ***cleaning, disinfection and sterilisation processes in line with the risk assessment for the respective devices,***

— ***requirements in relation to systems for hygiene, infection-prevention, quality management and documentation applicable to the natural or legal persons reprocessing the medical devices,***

— ***functionality testing of the devices after reprocessing.***

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*These standards shall be consistent with the latest scientific evidence and guarantee the highest level of quality and safety, in accordance with the severity of the condition, as reflected in European standards from the European standardisation organisations, where the latter take into account the provisions of relevant international standards, in particular those of ISO and IEC, or any other international technical standards able to guarantee, at the very least, a higher level of quality, safety and performance than ISO and IEC standards.*

**3. The natural or legal person referred to in paragraph 1 shall comply with EU standards referred to in paragraph 1 to ensure the quality of the reprocessing of medical devices labelled as 'reusable' and the safety of reprocessed devices.**

**4. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt CTS, as referred to in Article 7(1).**

## Amendment 377

## Proposal for a regulation

## Article 15 d (new)

Text proposed by the Commission

Amendment

## Article 15d

**Report on the functioning of the system**

**No later than four years after the date of application of this Regulation, the Commission shall assess and draw up an evaluation report. The report shall be submitted to the European Parliament and the Council. Where appropriate, the report shall be accompanied by a legislative proposal.**

## Amendment 120

## Proposal for a regulation

## Article 16

Text proposed by the Commission

Amendment

Implant card

Implant card **and information about implantable devices**

1. The manufacturer of an implantable device shall provide together with the device an implant card which shall be made available to the **particular patient who has been implanted with the device.**

1. The manufacturer of an implantable device shall provide together with the device an implant card which shall be made available to **the healthcare professional implanting the device who shall be responsible for:**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

— **submitting the implant card to the patient, and**

— **recording all the information contained on the implant card in the patient's medical records;**

**The implant card shall also be made available by the manufacturer in an electronic format and Member States shall ensure that hospitals and clinics keep an electronic version on record.**

**The following implants shall be exempted from this obligation: sutures, staples, dentals implants, screws and plates.**

**The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing this list of exempted implants.**

2. This card shall contain the following:

(a) the information allowing identification of the device, including the Unique Device Identification;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;

(c) any information about the expected lifetime of the device and any necessary follow-up.

2. This card shall contain the following:

(a) the information allowing identification of the device, including the Unique Device Identification;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;

**(ba) description of potential adverse effects;**

(c) any information about the expected lifetime of the device and any necessary follow-up.

**(ca) principal characteristics of the device, including the materials used;**

**Member States may introduce national provisions requiring that the implant card includes also information on post-operative follow-up care measures.**

The information shall be written in a way that is readily understood by a lay person.

The information shall be written in a way that is readily understood by a lay person.

Tuesday 22 October 2013

**Amendment 121****Proposal for a regulation****Article 21 — paragraph 1***Text proposed by the Commission*

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without **significantly** changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

*Amendment*

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. **When the article is a part of an implantable device, the natural or legal person who makes it available on the market shall cooperate with the manufacturer of the device to ensure its compatibility with the functioning part of the device in order to avoid the replacement of the whole device and its consequences for patient safety.** Substantiating evidence shall be kept available to the competent authorities of the Member States.

**Amendment 122****Proposal for a regulation****Article 21 — paragraph 2***Text proposed by the Commission*

2. An article that is intended specifically to replace a part or component of a device and that **significantly** changes the performance or safety characteristics of the device shall be considered a device.

*Amendment*

2. An article that is intended specifically to replace a part or component of a device and that changes the performance or safety characteristics of the device shall be considered **as a device and shall meet the requirements laid down in this Regulation.**

**Amendment 258****Proposal for a regulation****Chapter III — title***Text proposed by the Commission***Chapter III**

Identification and traceability of devices, registration of devices and of economic operators, **summary of safety and clinical performance**, European databank on medical devices

*Amendment***Chapter VIII (\*)**

Identification and traceability of devices, registration of devices and of economic operators, European databank on medical devices

(\*) As a consequence of this amendment, this Chapter will cover Articles 23, 24, 25, 27

Tuesday 22 October 2013

## Amendment 123

## Proposal for a regulation

## Article 24 — paragraph 1 — introductory part

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*Text proposed by the Commission*

1. For devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:

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*Amendment*

1. For devices, other than custom-made and investigational devices, a **single** system for Unique Device Identification (UDI) shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices, **be coherent if possible with the global regulatory approach for UDI in medical devices**, and shall consist of the following:

## Amendment 124

## Proposal for a regulation

## Article 24 — paragraph 1 a (new)

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*Text proposed by the Commission*

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*Amendment*

**1a. The UDI system shall be updated with the results of the post-market clinical follow-up evaluation report referred to in Section 3 of Part B of Annex XIII.**

## Amendment 125

## Proposal for a regulation

## Article 24 — paragraph 2 — point e — point i

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*Text proposed by the Commission*

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **three** years after its designation;

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*Amendment*

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **five** years after its designation;

## Amendment 126

## Proposal for a regulation

## Article 24 — paragraph 8 — point b

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*Text proposed by the Commission*

(b) the legitimate interest in protecting commercially sensitive information;

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*Amendment*

(b) the legitimate interest in protecting commercially sensitive information, **providing that it does not conflict with public health protection**;

Tuesday 22 October 2013

**Amendment 127**

**Proposal for a regulation**

**Article 24 — paragraph 8 — point e a (new)**

*Text proposed by the Commission*

*Amendment*

**(ea) compatibility with other traceability systems used by the stakeholders involved with medical devices**

**Amendment 128**

**Proposal for a regulation**

**Article 24 — paragraph 8 — point e b (new)**

*Text proposed by the Commission*

*Amendment*

**(eb) the compatibility of the UDI systems with the safety features established under Directive 2011/62/EU.**

**Amendment 129**

**Proposal for a regulation**

**Article 25 — paragraph 2 — subparagraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**Steps shall be taken to ensure that no additional national registration procedures are necessary.**

**Amendment 261**

**Proposal for a regulation**

**Chapter II a (new)**

*Text proposed by the Commission*

*Amendment*

**Chapter IIa (\*)**

**Conformity assessment**

(\*) As a consequence of this amendment, this Chapter will cover Articles 26, 42, 44a, 45, 46, 47, 48

Tuesday 22 October 2013

**Amendment 130**  
**Proposal for a regulation**  
**Article 26**

Text proposed by the Commission

**Summary of safety and clinical performance**

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up **a summary of** safety and clinical performance. **It** shall be written in a way that is **clear to the intended user**. The draft of this **summary** shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 **and shall be validated by that body**.

2. The Commission may, by means of implementing acts, set out **the form and the** presentation of the data elements to be included in the summary **of safety and clinical performance**. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

Amendment

**Safety and clinical performance report**

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a **report on the** safety and clinical performance **of the device based on the full information collected during the clinical investigation**. **The manufacturer shall also draw up a summary of that report which** shall be written in a way that is **easy for a lay person to understand in the official language(s) of the country where the medical device is made available on the market**. The draft report shall be part of the documentation to be submitted to **and validated by the special** notified body involved in the conformity assessment in accordance with Article 43a.

**1a. The summary referred to in paragraph 1 shall be made available to the public through Eudamed in accordance with provisions under point (b) of Article 27(2) and point 18 of Annex V Part A.**

2. The Commission may, by means of implementing acts, set out **the format of** the presentation of the data elements to be included in both the **report and the summary referred to in paragraph 1**. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88 (2).

**Amendment 131**  
**Proposal for a regulation**  
**Article 27**

Text proposed by the Commission

1. The Commission shall develop and manage the European databank on medical devices (Eudamed) for the following purposes:

(a) to enable the public to be adequately informed about devices placed on the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators;

Amendment

1. The Commission shall develop, and manage the European databank on medical devices (Eudamed) for the following purposes:

(a) to enable the public to be adequately informed about devices placed on **or removed from** the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators, **with due regard to commercial confidentiality where justified**;

Tuesday 22 October 2013

## Text proposed by the Commission

- (b) to enable traceability of devices within the internal market;
- (c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to be conducted in more than one Member State to comply with information obligations under Articles 50 to 60;
- (d) to enable manufacturers to comply with information obligations under Articles 61 to 66;
- (e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following as integral parts:

- (a) the electronic system on UDI referred to in Article 24;
- (b) the electronic system on registration of devices and economic operators referred to in Article 25;
- (c) the electronic system on information on certificates referred to in Article 45(4);
- (d) the electronic system on clinical investigations referred to in Article 53,
- (e) the electronic system on vigilance referred to in Article 62;
- (f) the electronic system on market surveillance referred to in Article 68.

## Amendment

- (b) to enable traceability of devices within the internal market;
- (c) to enable the public to be adequately informed about clinical investigations, **and to have an overview of vigilance data and market surveillance activities as well as to enable healthcare professionals to have adequate access to the results of clinical investigations**, and to enable sponsors of clinical investigations to be conducted in more than one Member State to comply with information obligations under Articles 50 to 60;
- (d) to enable manufacturers to comply with information obligations under Articles 61 to 66;
- (e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following as integral parts:

- (a) the electronic system on UDI referred to in Article 24;
- (b) the electronic system on registration of devices and economic operators referred to in Article 25;
- (c) the electronic system on information on certificates referred to in Article 45(4);
- (d) the electronic system on clinical investigations referred to in Article 53,
- (e) the electronic system on vigilance referred to in Article 62;
- (f) the electronic system on market surveillance referred to in Article 68;
- (fa) **the electronic system on registration of subsidiaries and subcontracting referred to in Article 30a;**
- (fb) **the electronic system on special notified bodies referred to in Article 43b .**

Tuesday 22 October 2013

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Text proposed by the Commission

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3. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators **and** sponsors as specified in the provisions concerning the electronic systems referred to in paragraph 2.

4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent defined in the provisions referred to in paragraph 2.

5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).

6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.

7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

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Amendment

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3. The data shall be entered into Eudamed by **the Commission**, the Member States, notified bodies, economic operators, sponsors **and healthcare professionals** as specified in the provisions concerning the electronic systems referred to in paragraph 2.

4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors, **healthcare professionals** and the public to the extent defined in the provisions referred to in paragraph 2.

5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).

6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.

7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

**7a. The information contained in the European Databank shall be robust, transparent and user-friendly, enabling the public and healthcare professionals to compare information on registered devices, economic operators, clinical investigations, vigilance data and market-surveillance activities.**

**When developing and managing Eudamed, the Commission shall, in consultation with relevant stakeholders including patient and consumer organisations, ensure that all publicly accessible parts of Eudamed are presented in a user-friendly format.**

Tuesday 22 October 2013

*Text proposed by the Commission*

8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

*Amendment*

8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

**Amendment 259****Proposal for a regulation****Chapter IV — title***Text proposed by the Commission*

Chapter IV

Notified bodies

*Amendment*

Chapter IV (\*)

Notified bodies

(\*) As a consequence of this amendment, this Chapter will cover Articles 28 to 40a and 43 to 43c

**Amendment 132****Proposal for a regulation****Article 28 — paragraphs 5 to 8***Text proposed by the Commission*

5. The national authority responsible for notified bodies shall safeguard the **confidentiality** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel **at its disposal** for the proper performance of its tasks.

*Amendment*

5. The national authority responsible for notified bodies shall safeguard the **confidential aspects** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

6. The national authority responsible for notified bodies shall have a sufficient number of **permanent** and competent personnel **‘in house’**, for the proper performance of its tasks. **Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8.**

**In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI.**

**Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer’s quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**Without prejudice to Article 33(3)**, where a national authority is responsible for the designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall be consulted on all aspects specifically related to medical devices.

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission **may** participate in the review. The outcome of the peer-review shall be communicated to all Member States **and to the Commission** and a summary of the outcome shall be made publicly available.

Where a national authority is responsible for the designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall be consulted on all aspects specifically related to medical devices.

7. **The ultimate responsibility for the notified bodies and the national authority responsible for notified bodies lies with the Member State in which they are located. The Member State is required to check that the designated national authority responsible for notified bodies performs its work on the assessment, designation and notification of conformity assessment bodies and for the monitoring of the notified bodies properly and that the designated national authority responsible for notified bodies works impartially and objectively.** Member States shall provide the Commission and the other Member States with **all** information **they request** on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto. **Such information shall be publicly available subject to provisions under Article 84.**

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission **shall** participate in the review. The outcome of the peer-review shall be communicated to all Member States and a summary of the outcome shall be made publicly available.

Tuesday 22 October 2013

## Amendment 133

## Proposal for a regulation

## Article 29 — paragraph 1

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Text proposed by the Commission

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. Minimum requirements to be met by notified bodies are set out in Annex VI.

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Amendment

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. **In this respect, permanent in-house administrative, technical and scientific personnel, with medical, technical and where needed pharmacological knowledge shall be ensured. Permanent in-house personnel shall be used, but notified bodies may hire external experts on an ad hoc and temporary basis as and when needed.** Minimum requirements to be met by notified bodies are set out in Annex VI. **In particular, in accordance with point 1.2. of Annex VI, the notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities and avoid conflict of interests.**

**The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices. This list shall at least contain the qualifications, curriculum vitae and declaration of interests for each member of staff. The list shall be sent to the national authority responsible for notified bodies which shall check that the staff satisfies the requirements of this Regulation. The list shall also be sent to the Commission.**

## Amendment 134

## Proposal for a regulation

## Article 30

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Text proposed by the Commission

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Amendment

**-1. Notified bodies shall have permanent in-house competent personnel and expertise, both in technical fields linked with the assessment of the performance of the devices, and in the medical field. They shall have the capacity to evaluate in house the quality of subcontractors.**

**Contracts may be awarded to external experts for the assessment of medical devices or technologies in particular where clinical expertise is limited.**

Tuesday 22 October 2013

*Text proposed by the Commission*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.

4. Notified bodies shall **keep at the disposal of** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

*Amendment*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

**2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.**

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the **explicit** agreement of the legal or natural person that applied for conformity assessment.

4. **At least once a year**, notified bodies shall **submit to** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

**4a. The annual assessment of notified bodies as provided for in Article 35(3) shall include verification of the compliance of the subcontractor(s) or the subsidiary/ies of notified bodies with the requirements set out in Annex VI.**

**Amendment 135****Proposal for a regulation****Article 30 a (new)***Text proposed by the Commission**Amendment***Article 30a****Electronic system on registration of subsidiaries and subcontractors**

**1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on subcontractors and subsidiaries, as well as on the specific tasks for which they are responsible.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

2. Before subcontracting can effectively take place, the notified body which intends to subcontract specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, shall register their name(s) together with their specific tasks.

3. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.

4. The data contained in the electronic system shall be accessible to the public.

## Amendment 136

## Proposal for a regulation

## Article 31 — paragraph 1 — subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In case a conformity assessment body wants to be notified for devices referred to in Article 43a(1), it shall indicate so and submit an application for notification to the EMA in accordance with Article 43a.

## Amendment 137

## Proposal for a regulation

## Article 32 — paragraphs 3 to 6

Text proposed by the Commission

Amendment

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **two** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission **who** shall lead the joint assessment team.

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **three** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies **and free of conflicts of interest with the applicant conformity assessment body**. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission, **and at least one other shall come from a Member State other than the one in which the applicant conformity assessment body is established. The Commission representative shall lead the joint assessment team. In case the conformity assessment body has asked to be notified for devices referred to in Article 43a(1), the EMA shall also be part of the joint assessment team.**

Tuesday 22 October 2013

## Text proposed by the Commission

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 31 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.

Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team **with a view to finding common agreement with respect to the assessment of the application. Divergent opinions shall be identified in the assessment report of the national authority responsible.**

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

6. The joint assessment team shall provide its opinion regarding the assessment report **and** the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification **which the** relevant national authority **shall duly take into consideration for** its decision on the designation of the notified body.

## Amendment

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 31 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.

Findings regarding non-compliance of **an applicant conformity assessment** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team. **The national authority shall set out in the assessment report the measures that the notify body shall take to ensure compliance of that applicant conformity assessment body with the requirements set out in Annex VI. In the event of a disagreement, a separate opinion drawn up by the assessment team setting out its reservations regarding notification shall be appended to the assessment report of the national authority responsible.**

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. **If the assessment team draws up a separate opinion, this too shall be submitted to the Commission for forwarding to the MDCG.** Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

6. The joint assessment team shall provide its **final** opinion regarding the assessment report, the draft notification **and, where appropriate, the separate opinion drawn up by the assessment team**, within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification. **The** relevant national authority shall **base** its decision on the designation of the notified body **on the recommendation by the MDCG. In case where its decision differs from the MDCG recommendation, the relevant national authority shall provide the MDCG in writing with all the necessary justification for its decision.**

Tuesday 22 October 2013

## Amendment 138

## Proposal for a regulation

## Article 33 — paragraphs 2 to 4 and 8 to 9

## Text proposed by the Commission

2. Member States **may** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.

3. *Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.*

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.

The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully **or partially**, the Commission shall publish the notification accordingly.

## Amendment

2. Member States **shall** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI **and for which the application assessment procedure has been completed in accordance with Article 32.**

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, the **risk class and the** type of devices which the notified body is authorised to assess.

The Commission may, by means of implementing acts, set up a list of codes and the corresponding **risk-classes** and types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be **immediately** suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully, the Commission shall publish the notification accordingly.

**The Commission shall also enter information on the notification of the notified body into the electronic system referred to in Article 27(2). That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG, as referred to in this article.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

***The full details of the notification, including the class and the typology of devices, as well as the annexes, shall be made publicly available.***

**Amendment 139****Proposal for a regulation****Article 34 — paragraph 1**

Text proposed by the Commission

1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 33. It shall assign a single identification number even when the body is notified under several Union acts.

Amendment

1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 33. It shall assign a single identification number even when the body is notified under several Union acts. ***If they are successfully renotified, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them.***

**Amendment 140****Proposal for a regulation****Article 34 — paragraph 2**

Text proposed by the Commission

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified, accessible to the public. The Commission shall ensure that the list is kept up to date.

Amendment

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified, ***easily*** accessible to the public. The Commission shall ensure that the list is kept up to date

**Amendment 141****Proposal for a regulation****Article 35**

Text proposed by the Commission

1. The national authority responsible for notified bodies shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Amendment

1. The national authority responsible for notified bodies, ***and where applicable the EMA***, shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission **unless** there is a legitimate reason for not doing so **in which case both sides may** consult the MDCG. **The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI. This assessment shall include an on-site visit to each notified body.

4. **Three** years after notification of a notified body, and again every **third** year thereafter, the assessment to determine whether the notified body still **satisfies** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.

Notified bodies shall, without delay, **and within 15 days at the latest**, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay, **and within 15 days at the latest, to** requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission. **Where** there is a legitimate reason for not doing so, **the notified bodies shall explain these reasons in writing and shall** consult the MDCG, **which shall then issue a recommendation. The national authority responsible for notified bodies shall comply with the MDCG's recommendation.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI, **including an assessment of whether its subcontractor(s) and subsidiary/-ies satisfy these requirements.** This assessment shall include an **unannounced inspection through an** on-site visit to each notified body, **and to each subsidiary or subcontractor within or outside the Union, if relevant.**

**The assessment shall also include a review of samples of the design dossier assessments carried out by the notified body to determine the ongoing competence of the notified body and quality of its assessments, in particular the notified body's ability to evaluate and assess clinical evidence.**

4. **Two** years after notification of a notified body, and again every **second** year thereafter, the assessment to determine whether the notified body **and its subsidiaries and subcontractors** still **satisfy** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body, **or a subsidiary or subcontractor of a notified body**, with the requirements set out in Annex VI.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

***For special notified bodies under Article 43a, the assessment referred to in this paragraph shall be performed every year.***

***The comprehensive results of the assessments shall be published.***

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

***5a. Every year, the notified bodies shall forward an annual activity report setting out the information referred to in point 3.5 of Annex VI to the competent authority and to the Commission, which shall forward it to the MDCG.***

#### Amendment 142

#### Proposal for a regulation

#### Article 35 a (new)

Text proposed by the Commission

Amendment

#### Article 35a

#### Penalties

***Member States shall ensure they have a system of penalties in place in case notified bodies do not fulfil the minimum requirements. This system should be transparent and proportionate to the nature and level of the non-compliance.***

#### Amendment 143

#### Proposal for a regulation

#### Article 36

Text proposed by the Commission

Amendment

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 32(2) to (6) and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 32(2) to (6) and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

Tuesday 22 October 2013

Text proposed by the Commission

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. **A suspension shall not exceed a period of one year, renewable once for the same period.** Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission **and** the other Member States of any suspension, restriction or withdrawal of a notification.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the **change to** the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

Amendment

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. **Suspension shall apply until a decision to annul the suspension has been reached by the MDCG, which shall follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 32(3).** Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately **and within 10 days at the latest**, inform the Commission, the other Member States **and the relevant manufacturers and health professionals** of any suspension, restriction or withdrawal of a notification.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall **inform the Commission and shall** take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the **suspension, restriction or withdrawal of** the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, **and at the latest 30 days after the publication of the report**, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

**With a view to verifying whether the reasons for the suspension, restriction or withdrawal of the notification have implications for the certificates issued, the national authority responsible shall ask the relevant manufacturers to supply evidence of conformity at notification, and the manufacturers shall have 30 days in which to respond to that request.**

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

Tuesday 22 October 2013

## Text proposed by the Commission

- (a) in the case of suspension of a notification: on condition that, within three months of the suspension, ***either the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or*** another notified body confirm in writing that it is assuming the functions of the notified body during the period of suspension;
- (b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

## Amendment

- (a) in the case of suspension of a notification: on condition that, within three months of the suspension another notified body confirm in writing that it is assuming the functions of the notified body during the period of suspension;
- (b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately ***and within 10 days at the latest,*** inform the Commission, the other Member States and the other notified bodies thereof.

***The Commission shall immediately and within 10 days at the latest enter information on the changes to the notification of the notified body into the electronic system referred to in Article 27(2).***

## Amendment 144

## Proposal for a regulation

## Article 37 — paragraph 3 — subparagraph 1

## Text proposed by the Commission

Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary.

## Amendment

Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary. ***The Commission shall make a report with the opinions of Member States publicly available after the assessment.***

Tuesday 22 October 2013

**Amendment 145**  
**Proposal for a regulation**  
**Article 39 — paragraph 1**

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*Text proposed by the Commission*

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices.

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*Amendment*

The Commission, **in consultation with the MDCG**, shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices. ***This group shall meet on a regular basis and at least twice a year.***

**Amendment 146**  
**Proposal for a regulation**  
**Article 39 — paragraph 2 a (new)**

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*Text proposed by the Commission*

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*Amendment*

***The Commission or the MDCG may request the participation of any notified body.***

**Amendment 147**  
**Proposal for a regulation**  
**Article 39 — paragraph 2 b (new)**

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*Text proposed by the Commission*

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*Amendment*

***The Commission may, by means of implementing acts, adopt measures setting out the modalities for the functioning of the coordination group of notified bodies as set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).***

**Amendment 148**  
**Proposal for a regulation**  
**Article 40**

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*Text proposed by the Commission*

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*Amendment*

Fees

***Fees for the activities of national authorities***

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

Tuesday 22 October 2013

Text proposed by the Commission

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation **and** cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation, cost-effectiveness **and the need to create a level-playing field across Member States.** Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

***These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made public.***

#### Amendment 149

#### Proposal for a regulation

#### Article 40 a (new)

Text proposed by the Commission

Amendment

#### Article 40 a

#### ***Transparency on fees charged by notified bodies for conformity assessment activities***

***1. Member States shall adopt provisions on standard fees for notified bodies.***

***2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees within 24 months from the date of entry into force of this Regulation.***

***3. Member States shall transmit their list of standard fees to the Commission.***

***4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available.***

Tuesday 22 October 2013

**Amendment 260**  
**Proposal for a regulation**  
**Chapter V — title**

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*Text proposed by the Commission*

**Chapter V**

Classification **and conformity assessment**

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*Amendment*

**Chapter II (\*)**

Classification **of medical devices**

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(\*) As a consequence of this amendment, this Chapter will cover Article 41

**Amendment 150**  
**Proposal for a regulation**  
**Article 41 — paragraph 2 — subparagraph 2**

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*Text proposed by the Commission*

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.

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*Amendment*

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. **The final decision shall be made publically available in the Eudamed.**

**Amendment 151**  
**Proposal for a regulation**  
**Article 41 — paragraph 3 — subparagraph 1**

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*Text proposed by the Commission*

The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification.

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*Amendment*

The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification. **Such decision should in particular be taken in order to resolve diverging decisions between Member States.**

**Amendment 152**  
**Proposal for a regulation**  
**Article 41 — paragraph 3 — subparagraph 2**

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*Text proposed by the Commission*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

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*Amendment*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). **Before adopting implementing acts, the Commission shall consult with relevant stakeholders and take into account their suggestions.**

Tuesday 22 October 2013

## Amendment 153

## Proposal for a regulation

## Article 41 — paragraph 4 — introductory part

*Text proposed by the Commission*

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following:

*Amendment*

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission, **having consulted relevant stakeholders, including organisations of healthcare professionals**, shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following:

## Amendment 154

## Proposal for a regulation

## Article 42 — paragraph 4

*Text proposed by the Commission*

4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annex II coupled with a conformity assessment based on product conformity verification as specified in Section 7 of Part A or Section 8 of Part B of Annex X.

*Amendment*

4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the **prototype and the** design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annex II coupled with a conformity assessment based on product conformity verification as specified in Section 7 of Part A or Section 8 of Part B of Annex X.

## Amendment 155

## Proposal for a regulation

## Article 42 — paragraph 10 — subparagraph 1 — introductory part

*Text proposed by the Commission*

The Commission **may**, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

*Amendment*

The Commission **shall**, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

Tuesday 22 October 2013

## Amendment 156

## Proposal for a regulation

## Article 42 — paragraph 10 — subparagraph 1 — indent 2

Text proposed by the Commission

- 
- *the minimum frequency of unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;*

Amendment

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*deleted*

## Amendment 157

## Proposal for a regulation

## Article 42 — paragraph 10 a (new)

Text proposed by the Commission

Amendment

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*10a. Unannounced inspections, in terms of their nature and extent, may be counted as regular inspections, with offsetting of economic operators' costs resulting from unannounced inspections, provided that no significant non-conformities are recorded during unannounced inspections. Account must be taken at all times, when ordering unannounced inspections and carrying them out, of the proportionality principle, with due regard, in particular, for the risk potential of each individual product.*

## Amendment 158

## Proposal for a regulation

## Article 42 — paragraph 11

Text proposed by the Commission

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*11. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the conformity assessment procedures set out in Annexes VIII to XI.*

Amendment

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*deleted*

Tuesday 22 October 2013

## Amendment 159

## Proposal for a regulation

## Article 43 — title and paragraph 1

Text proposed by the Commission

Involvement of notified bodies

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

Amendment

Involvement of notified bodies **in conformity assessment procedures**

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer **of devices other than those listed in Article 43a(1)** may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. **Where a manufacturer applies to a notified body located in a Member State other than the one where it is registered, the manufacturer shall inform its national authority responsible for the notified bodies of the application.** An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

## Amendment 160

## Proposal for a regulation

## Article 43 — paragraph 2

Text proposed by the Commission

2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment.

Amendment

2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment. **It shall also inform all of the competent national bodies without delay.**

## Amendment 161

## Proposal for a regulation

## Chapter V — Section 2 a (new) — title (new)

Text proposed by the Commission

Amendment

**Section 2a — Additional provisions for the conformity assessment of high-risk devices: Involvement of special notified bodies**

Tuesday 22 October 2013

## Amendments 360 and 371

## Proposal for a regulation

## Article 43 a (new)

Text proposed by the Commission

Amendment

## Article 43a

*Involvement of the special notified bodies in the conformity assessment procedures of high-risk devices*

1. Only special notified bodies shall be entitled to conduct conformity assessments for the following devices:

- (a) implantable devices;
- (b) devices incorporating a substance, as referred to in Article 1(4) and point 6.1. of Annex VII (Rule 13);
- (c) Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3. of Annex VII (Rule 11);
- (d) devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable; or
- (e) all other class III devices.

2. Applicant special notified bodies which consider they fulfil the requirements for special notified bodies referred to in Annex VI, point 3.6, shall submit their application to the EMA.

3. The application shall be accompanied by the fee payable to the EMA to cover the costs relating to the examination of the application.

4. The EMA shall designate the special notified body or bodies in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices listed in paragraph 1 within 90 days and send it to the Commission.

5. The Commission shall then publish the notification accordingly and the name of the special notified body or bodies.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

6. This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the special notified body.

This notification shall be valid for five years and subject to renewal every five years, following a new application to the EMA.

7. The manufacturer of devices listed in paragraph 1 may apply to a special notified body of his choice, whose name appears in the electronic system of Article 43b (new).

8. An application may not be lodged in parallel with more than one special notified body for the same conformity assessment activity.

9. The special notified body shall notify the Commission of applications for conformity assessments for devices listed in paragraph 1.

10. Article 43 (2), (3) and (4) apply to special notified bodies.

#### Amendment 372

#### Proposal for a regulation

#### Article 43 b (new)

Text proposed by the Commission

Amendment

#### Article 43b

#### Electronic system on special notified bodies

1. The Commission shall establish and regularly update an electronic registration system for:

- the registration of applications and granted authorisations to perform conformity assessments as special notified bodies under this Section and to collate and process information on the name of the special notified bodies;
- the exchange of information with national authorities; and
- the publication of assessment reports.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

2. The information collated and processed in the electronic system which relates to the application process for special notified bodies shall be entered into the electronic registration system by the EMA.

3. The information collated and processed in the electronic system and which relates to special notified bodies shall be accessible to the public.

4. The Commission shall regularly update the system.

#### Amendments 361 and 373

#### Proposal for a regulation

#### Article 43 c (new)

Text proposed by the Commission

Amendment

#### Article 43c

#### Network of special notified bodies

1. The Commission and the MDCG shall establish, host, coordinate and manage the network of special notified bodies.

2. The network shall have the following objectives:

(a) to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of medical devices;

(b) to contribute to the pooling of knowledge regarding medical devices;

(c) to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network;

(d) to help identify the experts in innovative fields;

(e) to develop and update rules on conflicts of interest;

(f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies; and

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

(g) to identify and notify significant discrepancies in the conformity assessments carried out by different Special notified bodies on substantially similar devices and to communicate these to the MDCG.

3. Meetings of the network shall be convened whenever requested by at least two of its members or by the EMA. It shall meet at least twice a year.

## Amendment 165

## Proposal for a regulation

## Article 44

Text proposed by the Commission

Amendment

Article 44

deleted

*Mechanism for scrutiny of certain conformity assessments*

1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class III, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.

2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4). In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.*

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.

5. Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific categories or groups of devices, other than devices of class III, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Measures pursuant to this paragraph may be justified only by one or more of the following criteria:

- (a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;
- (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

(c) *an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;*

(d) *significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;*

(e) *public health concerns regarding a specific category or group of devices or the technology on which they are based.*

6. *The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.*

7. *The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.*

8. *The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

Tuesday 22 October 2013

**Amendment 374/REV**  
**Proposal for a regulation**  
**Article 44 a (new)**

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Text proposed by the Commission

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Amendment

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**Article 44a**

*Assessment procedure in specific cases*

1. Special notified bodies shall notify the Commission of applications for conformity assessments for implantable Class III devices, Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3. of Annex VII (Rule 11), and devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable with the exception of applications to renew or supplement existing certificates and devices for which specifications referred to in Articles 6 and 7 have been published for the clinical evaluation and the post-market clinical follow-up. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 78.

2. Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:

- the clinical evaluation report as referred to in Annex XIII, including the clinical investigations report as referred to in Annex XIV,
- the post market clinical follow-up plan referred to in Annex XIII, and
- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*The members of the MDCG shall decide on making such a request only on the basis of the following criteria:*

- (a) the novelty of the device with possible major clinical or health impact;*
- (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure;*
- (c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices.*

*In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.*

*In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.*

*In the absence of request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the special notified body may continue with the conformity assessment procedure.*

*3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.*

*4. In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

5. The MDCG shall immediately inform the Commission, the special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the ACMD and the Commission.

Within 30 days following receipt of the grounds for the request, the MCDG shall re-examine its opinion, after consultation of the ACMD where necessary. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MCDG shall send its final opinion to the Commission, the special notified body and the manufacturer.

8. In the case of a favourable opinion MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on the conditions that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device or group of devices concerned and adopt them where possible (in accordance with Article 7).

In the case of an unfavourable MDCG opinion, the special notified body shall not yet deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraph 6 and 7 accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the special notified bodies and the ACMD, and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

13. The company concerned shall not be charged for the additional cost due to this assessment.

#### Amendment 369

#### Proposal for a regulation

#### Article 44 b (new)

Text proposed by the Commission

Amendment

#### Article 44b

Five years after the entry into force of this Regulation, the Commission shall publish a report on the experience acquired as a result of the operation of the procedure referred to in Article 44a. The report shall assess in particular how many products were subject to an additional assessment, what factors triggered the assessment and what was the final decision on the products. It shall also analyse the effects of the full impact of the new rules on special notified bodies vis-a-vis the additional assessments.

Tuesday 22 October 2013

## Amendment 167

## Proposal for a regulation

## Article 45 — paragraph 1

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*Text proposed by the Commission*

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XII.

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*Amendment*

1. ***Before issuing a certificate, the notified conformity assessment body shall take into account any findings set out in the clinical investigation report referred to in Article 59(4).*** The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XII.

## Amendment 168

## Proposal for a regulation

## Article 45 — paragraph 3

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*Text proposed by the Commission*

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

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*Amendment*

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision ***and shall notify them to the competent authorities of the Member States in which the medical device is manufactured and placed on the market, the Commission and the MDCG.***

## Amendment 169

## Proposal for a regulation

## Article 46 — paragraph 2 a (new)

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*Text proposed by the Commission*

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*Amendment*

2a. ***It shall notify the competent authorities of the Member States affected by the manufacture and placing on the market of the relevant medical device, the Commission and the MDCG.***

Tuesday 22 October 2013

**Amendment 170****Proposal for a regulation****Article 47 — paragraph 1***Text proposed by the Commission*

1. By way of derogation from Article 42, any competent authority may authorise, on duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient safety.

*Amendment*

1. By way of derogation from Article 42, any competent authority may authorise, on duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient safety, ***provided that the MDCG has authorised it. This derogation shall be possible only if the manufacturer submits the requisite clinical data to the competent authority within the prescribed period.***

**Amendment 171****Proposal for a regulation****Article 47 — paragraph 2***Text proposed by the Commission*

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

*Amendment*

2. The Member State shall inform the Commission, ***the notified body responsible for assessing the relevant medical device, the MDCG*** and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

**Amendment 262****Proposal for a regulation****Chapter VI — title***Text proposed by the Commission***Chapter VI**

Clinical evaluation and clinical investigations

*Amendment***Chapter V (\*)**

Clinical evaluation and clinical investigations

(\*) As a consequence of this amendment, this Chapter will cover Articles 49 to 60

Tuesday 22 October 2013

## Amendment 172

## Proposal for a regulation

## Article 49 — paragraph 3

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Text proposed by the Commission

3. Where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.

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Amendment

3. **Except for class III devices**, where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.

**Exemption from demonstration of conformity with general safety and performance requirements based on clinical data under the first subparagraph shall be subject to prior approval by the competent authority.**

## Amendment 173

## Proposal for a regulation

## Article 49 — paragraph 5 — subparagraph 1 a (new)

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Text proposed by the Commission

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Amendment

**For devices classified as class III and implantable devices, the summary of safety and clinical performance referred to in Article 26(1) shall be updated at least annually with clinical evaluation reports.**

## Amendment 174

## Proposal for a regulation

## Article 50 — paragraph 1 — point a

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Text proposed by the Commission

(a) to verify that, under normal conditions of use, devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of a medical device referred to in number (1) of Article 2(1), and achieve the performances intended as specified by the manufacturer;

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Amendment

(a) to verify that, under normal conditions of use, devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of a medical device referred to in number (1) of Article 2(1), and achieve the performances intended as specified by the manufacturer **or sponsor**;

Tuesday 22 October 2013

## Amendment 175

## Proposal for a regulation

## Article 50 — paragraph 1 — point b

Text proposed by the Commission

(b) to verify **that devices achieve the intended benefits to the patient as specified by the manufacturer;**

Amendment

(b) to verify **the clinical safety and efficacy of the device, including the intended benefits to the patient, when used for the intended purpose, in the target population and in accordance with the instructions of use;**

## Amendment 177

## Proposal for a regulation

## Article 51 — paragraph 2

Text proposed by the Commission

2. The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. Within **six** days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical investigation falls within the scope of this Regulation and whether the application is complete.

Amendment

2. The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. Within **14** days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

**In case of more than one Member State concerned, where a Member State disagrees with the coordinating Member State on whether the clinical investigation should be approved, on grounds other than intrinsically national, local or ethical concerns, the Member States concerned shall make an attempt to agree on a conclusion. If no conclusion is found, the Commission shall take a decision after having consulted the Member States concerned, and if appropriate, having taken advice from the MDCG. In case where the concerned Member States object the clinical investigation for intrinsically national, local or ethical concerns the clinical investigation should not take place in the Member States concerned.**

Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Tuesday 22 October 2013

**Amendment 178****Proposal for a regulation****Article 51 — paragraph 3 — subparagraph 3***Text proposed by the Commission*

Where the Member State has not notified the sponsor according to paragraph 2 within **three** days following receipt of the comments or of the completed application, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

*Amendment*

Where the Member State has not notified the sponsor according to paragraph 2 within **six** days following receipt of the comments or of the completed application, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

**Amendment 179****Proposal for a regulation****Article 51 — paragraph 5 — point c***Text proposed by the Commission*

(c) after the expiry of **35** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

*Amendment*

(c) after the expiry of **60** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

**Amendment 180****Proposal for a regulation****Article 51 — paragraph 6***Text proposed by the Commission*

6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of **at least one patient** shall be taken into account.

*Amendment*

6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of **patients** shall be taken into account.

***The list of the reviewers should be made available to the sponsor***

Tuesday 22 October 2013

## Amendment 181

## Proposal for a regulation

## Article 51 — paragraphs 6 a to 6 e (new)

Text proposed by the Commission

Amendment

6a. Every step in the clinical investigation, from first consideration of the need and justification for the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, such as those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul in 2008.

6b. Authorisation by the concerned Member State for conducting a clinical investigation under this Article shall be granted only after examination and approval by an independent ethics committee in accordance with the World Medical Association's Declaration of Helsinki.

6c. The examination of the Ethics Committee shall cover in particular the medical justification for the clinical investigation, the consent of the test subjects participating in the clinical investigation following the provision of full information about the clinical investigation and the suitability of the investigators and investigation facilities.

The ethics committee shall act in accordance with the respective laws and regulations of the country or countries in which the investigation is to be conducted and must abide by all relevant international norms and standards. It shall also work with such efficiency as to enable the Member State concerned to comply with the procedural deadlines set out in this Chapter.

The ethics committee shall be made up of an appropriate number of members, who together are in possession of the relevant qualifications and experience in order to be able to assess the scientific, medical and ethical aspects of the clinical investigation under scrutiny.

The members of the Ethics Committee assessing the application for a clinical investigation shall be independent from the sponsor, the institution of the investigation site, and the investigators involved, as well as free of any other undue influence. Names, qualifications, and declaration of interest of the assessors of the application shall be made publicly available.

6d. Member States shall take the necessary measures to establish Ethics Committees in the field of clinical investigations where such committees do not exist, and to facilitate their work.

Tuesday 22 October 2013

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Text proposed by the Commission

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Amendment

***6e. The Commission shall facilitate cooperation of ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment.***

***The Commission shall develop guidelines on patient involvement in ethics committees, drawing upon existing good practices.***

**Amendment 182****Proposal for a regulation****Article 52 — paragraph 1 — point g a (new)**

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Text proposed by the Commission

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Amendment

***(ga) the methodology to be used, the number of subjects involved and the intended result of the study.***

**Amendment 183****Proposal for a regulation****Article 52 — paragraph 2 a (new)**

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Text proposed by the Commission

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Amendment

***2a. Upon completion of the clinical investigation, the sponsor shall enter in the electronic system referred to in Article 53a summary of its results drawn up in a way that is easy for a lay person to understand.***

**Amendment 184****Proposal for a regulation****Article 52 — paragraph 3 — point b**

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Text proposed by the Commission

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Amendment

(b) protection of commercially sensitive information;

(b) protection of commercially sensitive information; ***data on adverse events and safety data shall not be considered commercially sensitive information;***

Tuesday 22 October 2013

## Amendment 185

## Proposal for a regulation

## Article 53 — paragraphs 1, 2 and 2a (new)

*Text proposed by the Commission*

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to create the single identification numbers for on clinical investigations referred to in Article 51(1) and to collate and process the following information:

- (a) the registration of on clinical investigations in accordance with Article 52;
- (b) the exchange of information between the Member States and between them and the Commission in accordance with Article 56;
- (c) the information related to on clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;
- (d) the reports on serious adverse events and device deficiencies referred to in Article 59(2) in case of single application in accordance with Article 58.

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 52, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.

*Amendment*

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to create the single identification numbers for on clinical investigations referred to in Article 51(1) and to collate and process the following information:

- (a) the registration of on clinical investigations in accordance with Article 52;
- (b) the exchange of information between the Member States and between them and the Commission in accordance with Article 56;
- (c) the information related to on clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;
- (d) the reports on serious adverse events and device deficiencies referred to in Article 59(2) in case of single application in accordance with Article 58.

**(da) the clinical investigation report and summary submitted by the sponsor in accordance with Article 57(3)**

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 52 **and in points (d) and (da) of Article 53**, the information collated and processed in the electronic system shall be accessible only to the Member States and to the **Commission. The Commission shall also ensure that healthcare professionals have access to the electronic system.**

**The information referred to in points (d) and (da) of Article 53 shall be accessible to the public in accordance with Article 52 (3) and (4).**

**2a. Upon a reasoned request, all information on a specific medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified in accordance with Article 52(3).**

Tuesday 22 October 2013

## Amendment 186

## Proposal for a regulation

## Article 55 — paragraph 2 a (new)

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Text proposed by the Commission

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Amendment

**2a. Assessment by the Member State of the request by the sponsor for a substantial modification to a clinical investigation shall be in accordance with Article 51(6).**

## Amendment 187

## Proposal for a regulation

## Article 56 — paragraph 1

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Text proposed by the Commission

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Amendment

1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate its decision and the grounds **therefor** to all Member States and the Commission by means of the electronic system referred to in Article 53.

1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety **or efficacy** grounds, that Member State shall communicate **such facts and** its decision and the grounds **for that decision** to all Member States and the Commission by means of the electronic system referred to in Article 53.

## Amendment 188

## Proposal for a regulation

## Article 57 — paragraph 1

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Text proposed by the Commission

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Amendment

1. If the sponsor has temporarily halted a clinical investigation on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

1. If the sponsor has temporarily halted a clinical investigation on safety **or efficacy** grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

## Amendment 189

## Proposal for a regulation

## Article 57 — paragraph 2

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Text proposed by the Commission

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Amendment

2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, providing a justification in the event of early termination. That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.

2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, providing a justification in the event of early termination, **so that all Member States can inform sponsors conducting similar clinical investigations at the same time within the Union of the results of that clinical investigation.** That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.

Tuesday 22 October 2013

*Text proposed by the Commission*

If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the overall end of the clinical investigation. That notification shall be made within 15 days from the **overall** end of the clinical investigation.

*Amendment*

If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the **early termination in one Member State and of the** overall end of the clinical investigation. **Information on the reasons for the early termination of the clinical investigation shall also be provided to all Member States, so that all Member States can inform sponsors conducting similar clinical investigations at the same time within the Union of the results of that clinical investigation.** That notification shall be made within 15 days from the end of the clinical investigation **in one or more Member States.**

**Amendment 190****Proposal for a regulation****Article 57 — paragraph 3***Text proposed by the Commission*

3. **Within** one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned **a summary of** the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with **an explanation.**

*Amendment*

3. **Irrespective of the outcome of the clinical investigation, within** one year from the end of the clinical performance study **or from its early termination**, the sponsor shall submit to the Member States concerned the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. **It shall be accompanied by a summary presented in terms that are easily understandable to a layperson. Both the report and the summary shall be submitted by the sponsor by means of the electronic system referred to in Article 53.** Where, for **justified** scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with **a justification.**

**3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to define the content and structure of the layperson's summary.**

**The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to establish rules for the communication of the clinical investigation report.**

**For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of the data.**

Tuesday 22 October 2013

## Amendment 191

## Proposal for a regulation

## Article 58 — paragraph 1

*Text proposed by the Commission*

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation **to be conducted in more than one Member State** may submit, for the purpose of Article 51, **a single** application that, upon receipt, is transmitted electronically to the Member States concerned.

*Amendment*

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation may submit, for the purpose of Article 51, **the** application that, upon receipt, is transmitted electronically to the Member States concerned.

## Amendment 192

## Proposal for a regulation

## Article 58 — paragraph 2

*Text proposed by the Commission*

2. **In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadline referred to in Article 51(2) shall start on the day following the acceptance.**

*Amendment*

2. Concerned Member **States** shall agree, within six days of submission of the single application, **which** Member State shall be the coordinating Member State. Member **States and the Commission shall agree, in the framework of the attributions of the MDCG, on clear rules for designating the** coordinating Member State.

## Amendment 193

## Proposal for a regulation

## Article 58 — paragraph 3 — subparagraph 2 — point b

*Text proposed by the Commission*

(b) establish the results of the coordinated assessment in a report to be **taken into account** by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5).

*Amendment*

(b) establish the results of the coordinated assessment in a report to be **approved** by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5).

Tuesday 22 October 2013

**Amendment 194**  
**Proposal for a regulation**  
**Article 58 — paragraph 5**

Text proposed by the Commission

Amendment

**5. For the purpose of Article 57(3), the sponsor shall submit the clinical performance study report to the Member States concerned by means of the electronic system referred to in Article 53.**

**deleted**

**Amendment 195**  
**Proposal for a regulation**  
**Article 59 — paragraph 1 — subparagraph 1 a (new)**

Text proposed by the Commission

Amendment

**Information regarding incidents that are caused by user errors shall also be collected, as they are a major source of incidents with medical devices. This information shall contribute to improve the safety and knowledge of the device.**

**Amendment 196**  
**Proposal for a regulation**  
**Article 59 — paragraph 1 — subparagraph 1 b (new)**

Text proposed by the Commission

Amendment

**Member States shall put in place non-electronic formats of reporting to ensure that patients who do not have online access are able to report.**

**Amendment 197**  
**Proposal for a regulation**  
**Article 59 — paragraph 4 — subparagraph 1**

Text proposed by the Commission

Amendment

In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in **paragraph 2** by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in **paragraphs 1 and 2** by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Tuesday 22 October 2013

**Amendment 263**  
**Proposal for a regulation**  
**Chapter VII — title**

Text proposed by the Commission

## Chapter VII

Vigilance and market surveillance

Amendment

## Chapter IX (\*)

Vigilance and market surveillance

(\*) As a consequence of this amendment, this Chapter will cover Articles 61 to 75

**Amendment 198**  
**Proposal for a regulation**  
**Article 61**

Text proposed by the Commission

1. Manufacturers of devices other than custom-made or investigational devices, shall report through the electronic system referred to in Article 62 the following:

(a) any **serious** incident in respect of devices made available on the Union market;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

Amendment

1. Manufacturers of devices other than custom-made or investigational devices, shall report through the electronic system referred to in Article 62 the following:

(a) any incident, **including date and place of incident, with an indication of whether it is serious in accordance with the definition under Article 2,** in respect of devices made available on the Union market; **where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident;**

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

Tuesday 22 October 2013

## Text proposed by the Commission

2. For similar **serious** incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 62(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected **serious** incidents referred to in point (a) of paragraph 1.

They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall **take the necessary steps to ensure that** the manufacturer of the device concerned **is informed of the incident**. The manufacturer shall ensure the appropriate follow-up.

The Member States shall **coordinate between them the development of** standard **web-based structured** forms for reporting of **serious** incidents by healthcare professionals, users and patients.

4. Manufacturers of custom-made devices shall report any **serious** incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.

## Amendment

2. For similar incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 62(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures, **including targeted information campaigns**, to encourage **and enable** healthcare professionals, **including doctors and pharmacists**, users and patients to report to their competent authorities suspected incidents referred to in point (a) of paragraph 1. They **shall inform the Commission of those measures**.

**The competent authorities of the Member States** shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall **inform** the manufacturer of the device concerned **without delay**. The manufacturer shall ensure the appropriate follow-up.

**The competent authority of a Member State shall notify the reports referred to in the first subparagraph to the electronic system referred to in Article 62 without delay, unless the same incident has already been reported by the manufacturer.**

The **Commission, in cooperation with the Member States and in consultation with the relevant stakeholders**, shall **develop** standard forms for **electronic and non-electronic** reporting of incidents by healthcare professionals, users and patients.

4. Manufacturers of custom-made devices shall **immediately** report any incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.

## Amendment 199

## Proposal for a regulation

## Article 62

## Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

## Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

Tuesday 22 October 2013

## Text proposed by the Commission

- (a) the reports by manufacturers on **serious** incidents and field safety corrective actions referred to in Article 61(1);
- (b) the periodic summary reports by manufacturers referred to in Article 61(2);
- (c) the reports by competent authorities on **serious** incidents referred to in the second subparagraph of Article 63(1)
- (d) the reports by manufacturers on trends referred to in Article 64;
- (e) the field safety notices by manufacturers referred to in Article 63(5);
- (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.

3. The Commission shall ensure that **healthcare professionals and** the public **have** appropriate **levels** of access to the electronic system.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on **serious** incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:

- (a) the Member State where the incident occurred;

## Amendment

- (a) the reports by manufacturers on incidents and field safety corrective actions referred to in Article 61(1);
- (b) the periodic summary reports by manufacturers referred to in Article 61(2);
- (c) the reports by competent authorities on incidents referred to in the second subparagraph of Article 63(1)
- (d) the reports by manufacturers on trends referred to in Article 64;
- (da) the periodic safety update reports drawn up by manufacturers, as referred to in Article 63a;**
- (e) the field safety notices by manufacturers referred to in Article 63(5);
- (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, to the notified bodies, **to healthcare professionals and also to manufacturers where the information pertains to their own product.**

3. The Commission shall ensure that the public **has an** appropriate **level** of access to the electronic system. **In case where information is requested on a specific medical device, that information shall be made available without delay and within 15 days at the latest.**

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:

- (a) the Member State where the incident occurred;

Tuesday 22 October 2013

*Text proposed by the Commission*

- (b) the Member State where the field safety corrective action is being or is to be undertaken;
- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.

*Amendment*

- (b) the Member State where the field safety corrective action is being or is to be undertaken;
- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.

**5a. The reports and information referred to in Article 62 (5), shall also be automatically transmitted for the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 45.**

**Amendment 200****Proposal for a regulation****Article 63 — paragraph 1 — subparagraph 1***Text proposed by the Commission*

Member States shall take the necessary steps to ensure that any information regarding **a serious** incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.

*Amendment*

Member States shall take the necessary steps to ensure that any information regarding **an** incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. **The competent authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations.**

**Amendment 201****Proposal for a regulation****Article 63 — paragraph 1 — subparagraph 2***Text proposed by the Commission*

**If in the case of reports received in accordance with Article 61 (3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 62, unless the same incident has already been reported by the manufacturer.**

*Amendment*

**deleted**

Tuesday 22 October 2013

## Amendment 202

## Proposal for a regulation

## Article 63 — paragraph 2

*Text proposed by the Commission*

2. The national competent authorities shall carry out a risk assessment with regard to reported **serious** incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the incident.

*Amendment*

2. The national competent authorities shall carry out a risk assessment with regard to reported incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the incident, **as well as they shall take into account patients' opinions**.

## Amendment 203

## Proposal for a regulation

## Article 63 — paragraph 3 — subparagraph 1

*Text proposed by the Commission*

In the case of devices referred to in the first subparagraph of Article 1(4) and where the **serious** incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the second subparagraph of Article 42 (2).

*Amendment*

In the case of devices referred to in the first subparagraph of Article 1(4) and where the incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the EMA, that was consulted by the notified body in accordance with the second subparagraph of Article 42(2).

## Amendment 204

## Proposal for a regulation

## Article 63 — paragraph 3 — subparagraph 2

*Text proposed by the Commission*

In the case of devices covered by this Regulation in accordance with point (e) of Article 1(2) and where the **serious** incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with the third subparagraph of Article 42(2).

*Amendment*

In the case of devices covered by this Regulation in accordance with point (e) of Article 1(2) and where the incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with the third subparagraph of Article 42(2).

Tuesday 22 October 2013

**Amendment 205****Proposal for a regulation****Article 63 — paragraph 4***Text proposed by the Commission*

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 62, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence **of a serious incident**, including information on the underlying events and the outcome of its assessment.

*Amendment*

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 62, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence, including information on the underlying events and the outcome of its assessment.

**Amendment 206****Proposal for a regulation****Article 63 — paragraph 6 — subparagraph 1 — point a***Text proposed by the Commission*

(a) where similar **serious** incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;

*Amendment*

(a) where similar incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;

**Amendment 207****Proposal for a regulation****Article 63 — paragraph 7 — subparagraph 1 — point a***Text proposed by the Commission*

(a) to monitor the investigation of the **serious** incident by the manufacturer and the corrective action to be taken;

*Amendment*

(a) to monitor the investigation of the incident by the manufacturer and the corrective action to be taken;

**Amendment 208****Proposal for a regulation****Article 63 — paragraph 7 — subparagraph 1 — point b***Text proposed by the Commission*

(b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the **serious** incident on the certificate;

*Amendment*

(b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the incident on the certificate;

Tuesday 22 October 2013

**Amendment 209**  
**Proposal for a regulation**  
**Article 63 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 63 a**

***Periodic safety update reports***

**1. Manufacturers of medical devices classified as class III shall report to the electronic system referred to in Article 62:**

- (a) summaries of data relevant to the benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certification;**
- (b) a scientific evaluation of the risk-benefit ratio of the medical device;**
- (c) all data relating to the volume of sales of the medical devices including an estimate of the population exposed to the medical device.**

**2. Manufacturers shall submit periodic safety update reports to the competent authorities immediately upon request or at least once a year during the first 2 years following initial placing on the market of that medical device.**

**3. The MDCG shall assess the periodic safety update reports to determine whether there are new risks or whether risks have changed, or whether there are changes to the risk-benefit ratio of the medical device.**

**4. Following the assessment of the periodic safety update reports, the MDCG shall consider whether any action regarding the medical device concerned is necessary. The MDCG shall inform the notified body in case of unfavourable scientific assessment. In this case, the notified body shall maintain, vary, suspend or revoke the authorisation as appropriate.**

Tuesday 22 October 2013

**Amendment 210****Proposal for a regulation****Article 64 — paragraph 1***Text proposed by the Commission*

Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of **incidents that are not serious** incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.

*Amendment*

Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of **all** incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.

**Amendment 211****Proposal for a regulation****Article 64 a (new)***Text proposed by the Commission**Amendment***Article 64a**

***Medical devices which fall under legal acts of the European Union concerning the quality and safety of blood***

***1. This Regulation is without prejudice to existing and implemented provisions at European level relating to the collection, testing, processing, storage and distribution of blood and blood components.***

***2. This Regulation is without prejudice to national laws and Union legislation in the field of traceability and vigilance in the field of blood and blood components which have a higher standard than this Regulation. They should be retained in the interests of patients.***

Tuesday 22 October 2013

**Amendment 212****Proposal for a regulation****Article 66 — paragraph 1 — point a**

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*Text proposed by the Commission*

- (a) typology of **serious** incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

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*Amendment*

- (a) typology of incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

**Amendment 213****Proposal for a regulation****Article 66 — paragraph 1 — point b**

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*Text proposed by the Commission*

- (b) harmonised forms for the reporting of **serious** incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 61 and 64;

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*Amendment*

- (b) harmonised forms for the reporting of incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 61 and 64;

**Amendment 214****Proposal for a regulation****Article 66 — paragraph 1 — point c**

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*Text proposed by the Commission*

- (c) timelines for the reporting of **serious** incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;

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*Amendment*

- (c) timelines for the reporting of incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;

**Amendment 215****Proposal for a regulation****Article 66 — paragraph 2 — subparagraph 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

***In drafting the implementing acts, the Commission shall seek the prior advice of the MDAC***

Tuesday 22 October 2013

## Amendment 216

## Proposal for a regulation

## Article 67 — paragraphs 1 to 2

*Text proposed by the Commission*

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, **where necessary and justified**, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a **serious** risk where they deem it necessary.

*Amendment*

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and enter **and inspect** the premises of economic operators and take the necessary samples of devices **for analysis by an official laboratory**. They may destroy or otherwise render inoperable devices presenting a risk where they deem it necessary.

**1a. The competent authorities shall designate inspectors who shall be empowered to carry out the checks referred to in paragraph 1. The checks shall be carried out by the inspectors of the Member State in which the economic operator is located. These inspectors may be assisted by experts appointed by the competent authorities.**

**1b. Unannounced inspections may also be carried out. The organisation and implementation of such inspections shall always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product.**

**1c. Following each inspection carried out under paragraph 1, the competent authority shall draw up a report on compliance by the economic operator inspected with the legal and technical requirements applicable under this Regulation and any corrective actions needed.**

**1d. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 68.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

2. The Member States shall periodically review and assess the **functioning** of their surveillance **activities**. Such reviews and assessments shall be carried out at least every **four** years and the results thereof shall be communicated to the other Member States and the Commission. The Member **State concerned** shall make a summary of the results accessible to the public.

1e. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 may also take place in the premises of an economic operator located in a third country, if the device is intended to be made available on the Union market.

2. The Member States shall **draw up strategic surveillance plans covering their planned surveillance activities, as well as the human and material resources needed to carry these activities out. Member States shall** periodically review and assess the **implementaion** of their surveillance **plans**. Such reviews and assessments shall be carried out at least every **two** years and the results thereof shall be communicated to the other Member States and the Commission. **The Commission may make recommendations for adjustments to the surveillance plans.** The Member **States** shall make a summary of the results **and of the Commission's recommendations** accessible to the public.

## Amendment 217

## Proposal for a regulation

## Article 68 — paragraph 2

Text proposed by the Commission

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States **and to the Commission**.

Amendment

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States, **to the Commission, to the notified bodies, to the EMA and to healthcare professionals. The Commission shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, in case information is requested on a specific medical device, it is made available without delay and within 15 days. The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank in Article 27**

Tuesday 22 October 2013

## Amendment 218

## Proposal for a regulation

## Article 68 — paragraph 2 — subparagraph 1 a (new)

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Text proposed by the Commission

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Amendment

*The information in to relation to Article 68 paragraph 1, points a, b, c and d shall be made available to the MDCG who shall communicate it at the first meeting of the MDAC after the information becomes available.*

## Amendment 219

## Proposal for a regulation

## Article 69 — paragraph 1

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Text proposed by the Commission

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Amendment

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities. ***In connection with that evaluation, the competent authorities shall inform the notified assessment bodies, in the case of class IIa, IIb and III devices, and the other competent authorities of the findings of the evaluation and the measures that are to be taken on the basis of those findings.***

## Amendment 220

## Proposal for a regulation

## Article 69 — paragraph 1 a (new)

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Text proposed by the Commission

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Amendment

***1a. Where the competent authorities of a Member State, based on vigilance data or other information, have reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they may carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.***

Tuesday 22 October 2013

## Amendment 221

## Proposal for a regulation

## Article 70 — paragraph 1

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Text proposed by the Commission

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall **without delay** require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.

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Amendment

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall **immediately** require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period **that is clearly defined and communicated to the relevant economic operator**, proportionate to the nature of the risk.

## Amendment 222

## Proposal for a regulation

## Article 70 — paragraph 2

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Text proposed by the Commission

2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 68.

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Amendment

2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall **immediately** inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 68.

## Amendment 223

## Proposal for a regulation

## Article 70 — paragraph 3

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Text proposed by the Commission

3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

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Amendment

3. The economic operators shall **without delay** ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

Tuesday 22 October 2013

**Amendment 224****Proposal for a regulation****Article 70 — paragraph 3 — subparagraph 1 a (new)***Text proposed by the Commission**Amendment*

*Where the concerned devices are to be recalled, the economic operator shall make all reasonable efforts to complete the recall before the end of clearly defined period communicated to it by the competent authority as referred to in paragraph 1,*

**Amendment 225****Proposal for a regulation****Article 70 — paragraph 4 — subparagraph 2***Text proposed by the Commission**Amendment*

They shall notify the Commission and the other Member States, **without delay**, of those measures, by means of the electronic system referred to in Article 68.

They shall notify the Commission and the other Member States, **immediately**, of those measures, by means of the electronic system referred to in Article 68.

**Amendment 226****Proposal for a regulation****Article 70 — paragraph 6***Text proposed by the Commission**Amendment*

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall **without delay** inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 68.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall **immediately** inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 68.

**Amendment 227****Proposal for a regulation****Article 70 — paragraph 7***Text proposed by the Commission**Amendment*

7. Where, within **two months** of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

7. Where, within **one month** of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

Tuesday 22 October 2013

**Amendment 228****Proposal for a regulation****Article 70 — paragraph 8***Text proposed by the Commission*

8. All Member States shall ensure that appropriate restrictive measures are taken **without delay** in respect of the device concerned.

*Amendment*

8. All Member States shall ensure that appropriate restrictive measures are taken **immediately** in respect of the device concerned.

**Amendment 229****Proposal for a regulation****Article 71 — paragraph 1***Text proposed by the Commission*

1. Where, within **two months** of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

*Amendment*

1. Where, within **one month** of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

**Amendment 230****Proposal for a regulation****Article 72 — paragraph 1***Text proposed by the Commission*

1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

*Amendment*

1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall **immediately** require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

Tuesday 22 October 2013

## Amendment 231

## Proposal for a regulation

## Article 73 — paragraph 1 — introductory part

*Text proposed by the Commission*

1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:

*Amendment*

1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is **clearly defined and communicated and that is** proportionate to the non-compliance where it makes one of the following findings:

## Amendment 232

## Proposal for a regulation

## Article 73 — paragraph 2

*Text proposed by the Commission*

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States **without delay** of those measures, by means of the electronic system referred to in Article 68.

*Amendment*

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall **immediately** take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States **immediately** of those measures, by means of the electronic system referred to in Article 68.

## Amendment 233

## Proposal for a regulation

## Article 74 — paragraph 1

*Text proposed by the Commission*

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it **may** take any necessary and justified provisional measures.

*Amendment*

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it **shall** take any necessary and justified provisional measures.

Tuesday 22 October 2013

**Amendment 234****Proposal for a regulation****Article 75 — paragraph 2***Text proposed by the Commission*

2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

*Amendment*

2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time **that is clearly determined** before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

**Amendment 235****Proposal for a regulation****Article 75 — paragraph 3***Text proposed by the Commission*

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.

*Amendment*

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's **satisfactorily** demonstrating that he has taken effective corrective action.

**Amendment 264****Proposal for a regulation****Chapter VIII — title***Text proposed by the Commission***Chapter VIII**

Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

*Amendment***Chapter X (\*)**

Cooperation between Member States, Medical Device Coordination Group, **Medical Device Advisory Committee**, EU reference laboratories, device registers

(\*) As a consequence of this amendment, this Chapter will cover Articles 76 to 83

Tuesday 22 October 2013

**Amendment 236****Proposal for a regulation****Article 76 — paragraph 1***Text proposed by the Commission*

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities.

*Amendment*

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities **and their contact details**.

**Amendment 237****Proposal for a regulation****Article 77 — paragraph 1***Text proposed by the Commission*

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information necessary to enable this Regulation to be applied uniformly.

*Amendment*

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and **with the MDCG as appropriate and** exchange with each other **and the Commission** the information necessary to enable this Regulation to be applied uniformly.

**Amendment 238****Proposal for a regulation****Article 78 — paragraph 2 — subparagraph 2 a (new)***Text proposed by the Commission**Amendment*

**The Commission shall verify the competence of the members of the MDCG. The Commission shall make public the results of its verification in each instance and provide information about the competence of the members of the MDCG.**

**Amendment 239****Proposal for a regulation****Article 78 — paragraph 6***Text proposed by the Commission*

**6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.**

*Amendment***deleted**

Tuesday 22 October 2013

**Amendment 240**  
**Proposal for a regulation**  
**Article 78 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 78a**

**Medical Device Advisory Committee**

1. The Commission shall establish a multidisciplinary MDAC composed of experts and representatives of the relevant stakeholders in order to provide support, advice and expertise to the MDCG, the Commission and Member States on technical, scientific, social and economic aspects of regulating medical devices and in vitro diagnostic medical devices, such as in the field of medical technology, borderline cases involving medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, as well as further aspects of the implementation of this Regulation.
2. When establishing the MDAC, the Commission shall ensure a broad, appropriate and balanced representation of the disciplines relevant for medical devices. The MDAC may establish under its responsibility expert panels for specific medical disciplines.
3. The MDAC shall be chaired by a representative of the Commission. The Commission shall provide the logistic support to its operations.
4. The MDAC shall establish its rules of procedure which shall enter into force after receiving a favourable opinion from the Commission.
5. The MDAC shall ensure an appropriate level of consultation of the EMA and the EFSA when deliberating borderline cases involving medicinal and food products.
6. The MDAC shall disclose the declarations of interest of its members.

Tuesday 22 October 2013

**Amendment 367**  
**Proposal for a regulation**  
**Article 78 b (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 78b**

**Assessment Committee for Medical Devices**

1. An Assessment Committee for Medical Devices (ACMD) is hereby established, under the principles of the highest scientific competences, impartiality, and transparency and to avoid potential conflicts of interest.

2. The ACMD shall be composed of:

- at least one member representing each of the medical fields referred to in paragraph 3. This member shall be a recognised expert in his/her field and be able to draw on additional expertise where necessary. These experts shall be appointed by way of a Commission call for interest, for a 3 year term that maybe renewed once;
- one representative of the EMA;
- one representative of the European Commission;
- three representatives of patients 'organizations appointed by the European Commission by way of a Commission call for interest.

*The ACMD shall meet on request from the MDCG and the Commission, and its meetings shall be chaired by a Commission representative.*

*The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of the assessment procedure in specific cases.*

*The Commission shall ensure the secretariat of this Committee.*

3. The members of the ACMD shall be chosen for their competence and experience in the corresponding field.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- 
- Anaesthesiology;
  - Blood grouping or tissue typing;
  - Blood transfusion and transplantation;
  - Cardiology;
  - Communicable diseases;
  - Dentistry;
  - Dermatology;
  - Ear/Nose/Throat (ENT);
  - Endocrinology;
  - Gastroenterology;
  - General/Plastic surgery;
  - Medical genetics;
  - Nephrology/Urology;
  - Neurology;
  - Obstetrics/Gynaecology;
  - Oncology;
  - Ophthalmology;
  - Orthopaedics;
  - Physical medicine;
  - Pulmonology/Pneumology;
  - Radiology.

The Members of the ACMD shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending, deleting or supplementing the fields referred to in point a of this paragraph.

4. The ACMD shall fulfil the tasks defined in Article 44a. When adopting a clinical assessment, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of their members. In the case of the Coordination Group, the European Commission shall not take part in votes. Diverging opinion shall be annexed to the ACMD opinion.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**5. The ACMD shall establish its rules of procedure which shall, in particular lay down procedures for the following:**

- **the adoption of the clinical assessments including in case of urgency;**
- **the delegation of tasks to members.**

#### **Amendment 366 and 368**

#### **Proposal for a regulation**

#### **Article 80 — points a and b**

Text proposed by the Commission

Amendment

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

**(-a) to provide regulatory opinions on the basis of a clinical assessment delivered in accordance with Art 44a) (assessment procedure in specific cases);**

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

**(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation;**

**(ab) to review and approve the criteria of the competent authorities of Member States in respect of point (aa) of this Article;**

**(ac) to oversee the coordination group of Notified Bodies as specified in Article 39;**

**(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 27;**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

(b) *to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;*

**Amendment 243****Proposal for a regulation****Article 81 — paragraph 2 — point b**

Text proposed by the Commission

Amendment

(b) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

(b) to provide scientific advice **and technical assistance** regarding **the definition of** the state of the art in relation to specific devices, or a category or group of devices;

**Amendment 244****Proposal for a regulation****Article 81 — paragraph 2 — point f**

Text proposed by the Commission

Amendment

(f) to contribute to the development of **standards at** international **level**;

(f) to contribute to the development of **CTS as well as of** international **standards**

**Amendment 245****Proposal for a regulation****Article 81 — paragraph 2 — point g a (new)**

Text proposed by the Commission

Amendment

(ga) *to provide scientific opinions and technical assistance to the Commission in relation to the requalification of single-use devices as reusable devices.*

Tuesday 22 October 2013

## Amendment 246

## Proposal for a regulation

## Article 82 — paragraph 1

Text proposed by the Commission

1. Members of the MDCG and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. **Upon request**, the declaration of interests shall be **accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.**

Amendment

1. Members of the MDCG, **of the advisory panels to the MDCG** and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry **or in the supply chain** which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry **or in the supply chain** and update this declaration whenever a relevant change occurs. The declaration of interests shall be **made publicly available on the Commission website.**

## Amendment 247

## Proposal for a regulation

## Article 82 — paragraph 2

Text proposed by the Commission

2. Experts **and other third parties invited by the MDCG on a case-by-case basis** shall be requested to declare their interests in the issue in question.

Amendment

2. Experts **participating in the advisory committee referred to in Article 78a** shall be requested to declare their interests in the issue in question.

## Amendment 248

## Proposal for a regulation

## Article 83 — paragraph 1

Text proposed by the Commission

The Commission and the Member States shall take all appropriate measures to **encourage** the establishment of registers for **specific types of devices** to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Amendment

The Commission and the Member States shall take all appropriate measures to **ensure** the establishment of **coordinated and harmonised** registers for **medical** devices to gather post-market experience related to the use of such devices. **Registers for medical devices in classes IIb and III shall be systematically established.** Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Tuesday 22 October 2013

**Amendment 265**  
**Proposal for a regulation**  
**Chapter IX — title**

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*Text proposed by the Commission*

**Chapter IX**

Confidentiality, data protection, funding, penalties

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*Amendment*

**Chapter XI (\*)**

Confidentiality, data protection, funding, penalties

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(\*) As a consequence of this amendment, this Chapter will cover Articles 84 to 87

**Amendment 249**  
**Proposal for a regulation**  
**Article 86**

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*Text proposed by the Commission*

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

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*Amendment*

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. ***The structure and level of fees shall be publicly available on request.***

**Amendment 250**  
**Proposal for a regulation**  
**Article 87**

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*Text proposed by the Commission*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.

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*Amendment*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. ***The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement.*** The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Tuesday 22 October 2013

**Amendment 251****Proposal for a regulation****Article 89 — paragraph 1***Text proposed by the Commission*

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), **4(5), 8(2)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **42(11)**, 45(5), 51(7), 53(3), 74(4) and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

*Amendment*

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), **15b (1), 16 (1)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **44a (2), 44a(9)**, 45(5), 51(7), 53(3), **57(3a)**, 74(4), **78b(3)** and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

**Amendment 252****Proposal for a regulation****Article 89 — paragraph 2***Text proposed by the Commission*

2. The delegation of power referred to in Articles 2(2) and (3), **4(5), 8(2)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **42(11)**, 45(5), 51(7), 53(3), 74(4) and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

*Amendment*

2. The delegation of power referred to in Articles 2(2) and (3), **15b (1), 16 (1)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **44a (2), 44a(9)**, 45(5), 51(7), 53(3), **57(3a)**, 74(4), **78b(3)** and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Tuesday 22 October 2013

**Amendment 253****Proposal for a regulation****Article 89 — paragraph 3***Text proposed by the Commission*

3. The delegation of power referred to in Articles 2(2) and (3), **4(5), 8(2)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **42(11)**, 45(5), 51(7), 53(3), 74(4) and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

*Amendment*

3. The delegation of power referred to in Articles 2(2) and (3), **15b (1), 16 (1)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4) **44a (2), 44a(9)**, 45(5), 51(7), 53(3), **57(3a)**, 74(4), **78b(3)** and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

**Amendment 254****Proposal for a regulation****Article 89 — paragraph 1 — subparagraph 1 a (new)***Text proposed by the Commission**Amendment*

***The Commission shall, in drafting delegated acts, seek the advice of the MDCG.***

**Amendment 255****Proposal for a regulation****Article 94 — paragraph 4***Text proposed by the Commission*

4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

*Amendment*

4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application ***if the relevant delegated acts and implementing acts have been implemented.***

Tuesday 22 October 2013

## Amendment 266

## Proposal for a regulation

## Annex I — part I — point 2 — point c

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Text proposed by the Commission

(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and

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Amendment

(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; **hence, it should take into consideration the latest tools and concepts developed in hazard and risk assessment based on human-relevant models, pathways of toxicity, adverse outcome pathways and evidence-based toxicology;** and

## Amendment 267

## Proposal for a regulation

## Annex I — part I — point 2 — subparagraph 1 a (new)

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Text proposed by the Commission

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Amendment

**Points (a), (b), (c) and (d) of this point shall not reduce the necessity for clinical investigation and post-market clinical follow up to adequately address the risks, hazards and performance of devices.**

## Amendment 378

## Proposal for a regulation

## Annex I — Part I — point 6 a (new)

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Text proposed by the Commission

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Amendment

**6a. This Regulation now combines active implantable medical devices covered by Directive 90/385/EEC, and implantable medical devices covered by Directive 93/42/EEC, and places all active implantable medical devices and implantable devices of public health concern in the highest risk class III category attracting the strictest controls, and as the vast majority of class IIb implantable medical devices such as pins, bone-screws, plates, staples etc., have a long history of safe implantation within the human body, and as special notified bodies will be specifically designated for such class IIb implantable devices, class IIb implantable devices need not be subjected to the scrutiny procedure.**

Tuesday 22 October 2013

## Amendment 268

## Proposal for a regulation

## Annex I — part II — point 7 — point 7.1 — point b a (new)

Text proposed by the Commission

Amendment

(ba) *the physical compatibility between the different manufacturers' parts of the devices which consist of more than one implantable part;*

## Amendment 355

## Proposal for a regulation

## Annex I — part II — point 7 — point 7.4

Text proposed by the Commission

Amendment

7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. **Special attention shall be given to** substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, **and to** substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health **and** which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .

7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. **Medical devices or parts thereof that are invasive or come into contact with the body of patients, or (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances , including gases, to be (re)administered to the body, shall not contain, in concentrations above 0,1 % by weight in homogeneous materials, substances** which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , **or** substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health **or** which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) , **or are endocrine disrupters pursuant to Commission Recommendation (.../.../EU) on criteria for the identification of endocrine disrupters.**

**The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to allow the use of such substances for a period not exceeding four years where any of the following conditions is fulfilled:**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- *their elimination or substitution via design changes or materials and components which do not require any of these substances is technically impracticable,*
- *the reliability of substitutes is not ensured,*
- *the combined negative health or patient safety impact caused by substitution is likely to outweigh the combined health or patient safety benefits thereof.*

*The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to renew the derogation if the criteria of the second subparagraph continue to be fulfilled.*

*Manufacturers wishing to apply for a derogation, a renewal of a derogation or the revoking of a derogation shall submit the following information to the Commission:*

- (a) the name, address and contact details of the applicant;*
- (b) information on the medical device and the specific uses of the substance in the material and components of the medical device for which an exemption, or its revocation, is requested and its particular characteristics;*
- (c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in the second subparagraph;*
- (d) an analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;*
- (e) other relevant information;*
- (f) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;*
- (g) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification.*

If devices, or parts thereof, *that are intended*

- *to be invasive devices and to come into contact with the body of the patient for short- or long-term, or*

If devices or parts thereof, *as referred to in the first subparagraph,*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- to (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

contain, in a concentration of 0,1 % by mass **of the plasticised material or above, phthalates** which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, **these** devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing **phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women**, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

contain, in a concentration of 0,1 % by mass **or above, in a homogeneous material, substances** which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, **or substances identified as endocrine disrupters pursuant to the first subparagraph, and were granted a derogation pursuant to the second or third subparagraph, the** devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing **such substances**. The manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

## Amendment 271

## Proposal for a regulation

## Annex I — part II — point 8 — point 8.1 — point a (new)

Text proposed by the Commission

Amendment

- (aa) **fully comply with the requirements of applicable Union Directives concerning occupational safety, such as Directive 2010/32/EU,**

## Amendment 272

## Proposal for a regulation

## Annex I — part II — point 8 — point 8.1 — point a — paragraph 2

Text proposed by the Commission

Amendment

and, where necessary,

deleted

Tuesday 22 October 2013

## Amendment 273

## Proposal for a regulation

## Annex I — part II — point 8 — point 8.7 a (new)

Text proposed by the Commission

Amendment

**8.7a. Medical device manufacturers shall notify their users of the levels of disinfection required to ensure patient safety and of all available methods for achieving those levels of disinfection. Manufacturers shall be required to test their devices using all methods designed to ensure patient safety and to substantiate any decision to reject a solution, either by demonstrating that it is ineffective or by demonstrating that it will cause damage impairing the medical usefulness of their devices to a significantly greater degree than other solutions that they themselves recommend.**

## Amendment 274

## Proposal for a regulation

## Annex I — part II — point 9 — title

Text proposed by the Commission

Amendment

**9. Devices incorporating a substance considered to be a medicinal product *and devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally.***

**9. Devices incorporating a substance considered to be a medicinal product**

## Amendment 275

## Proposal for a regulation

## Annex I — part II — point 9 — point 9.2

Text proposed by the Commission

Amendment

**9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.**

**deleted**

Tuesday 22 October 2013

## Amendment 276

## Proposal for a regulation

## Annex I — part II — point 10 — point 10.2 — point a a (new)

Text proposed by the Commission

Amendment

*(aa) The use of non-animal methods should be promoted. Animal use should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Directive 2010/63/EU, tests on vertebrate animals must be replaced, restricted or refined. Therefore, we call on the Commission to lay down rules to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited.*

## Amendment 277

## Proposal for a regulation

## Annex I — part II — point 10 — point 10.3

Text proposed by the Commission

Amendment

10.3. For devices manufactured utilising other non-viable biological substances the following applies:

10.3. For devices manufactured utilising other non-viable biological substances the following applies:

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons, **including in the waste disposal chain**. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

## Amendment 278

## Proposal for a regulation

## Annex I — part II — point 11 — point 11.2 a (new)

Text proposed by the Commission

Amendment

**11.2a. Devices which can transfer potentially fatal blood-borne infections to healthcare staff, patients or other persons, by unintended cuts and pricks such as needle stick injuries, shall incorporate appropriate safety-engineered protection mechanisms in accordance with Directive 2010/32/EU. However the specificities relating to the dental profession must be respected.**

Tuesday 22 October 2013

## Amendment 279

## Proposal for a regulation

## Annex I — part II — point 11 — point 11.7

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Text proposed by the Commission

11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, patient or other person.

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Amendment

11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and **the substances with which the device has been exposed to** and/or of any waste substances by the user, patient or other person **and, where possible and appropriate, replace with the use of devices and methods with improved safety features and characteristics to reduce as far as possible the exposure of patients, users and other persons to potentially harmful substances, such as chemical or nuclear material.**

## Amendment 280

## Proposal for a regulation

## Annex I — part II — point 13 — point 13.1 — point a

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Text proposed by the Commission

(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

---

Amendment

(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, **and if possible these applications shall be replaced with applications with a higher safety standard,** whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

## Amendment 281

## Proposal for a regulation

## Annex I — part II — point 13 — point 13.3 — paragraph 1

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Text proposed by the Commission

Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate.

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Amendment

Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate: **where possible, methods should be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.**

Tuesday 22 October 2013

## Amendment 282

## Proposal for a regulation

## Annex I — part II — point 13 — point 13.4 — point a

*Text proposed by the Commission*

- (a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

*Amendment*

- (a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use, **and if possible, devices should be used that can at any time during and after treatment monitor the emission of radiation.**

## Amendment 283

## Proposal for a regulation

## Annex I — part II — point 18 — point 18.2 — indent 1 a (new)

*Text proposed by the Commission**Amendment*

- **as laid out in Directive 2010/32/EU, reduce as far as possible the risk of injury and infection to other persons by incorporating safety-engineered protection mechanisms designed to prevent needle stick and other sharp injuries, and**

## Amendment 284

## Proposal for a regulation

## Annex I — part III — point 19 — point 19.1 — point d

*Text proposed by the Commission*

- (d) Labels shall be provided in a human-readable format **but may** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

*Amendment*

- (d) Labels shall be provided in a human-readable format **and shall** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

## Amendment 285

## Proposal for a regulation

## Annex I — part III — point 19 — point 19.2 — point a a (new)

*Text proposed by the Commission**Amendment*

- (aa) **The mention ‘This product is a medical device’.**

Tuesday 22 October 2013

## Amendment 286

## Proposal for a regulation

## Annex I — section 19.2 — point b

Text proposed by the Commission

- (b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.

Amendment

- (b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device and **where applicable that the device is only to be used during a single procedure.**

## Amendment 287

## Proposal for a regulation

## Annex I — part III — point 19 — point 19.2 — point o

Text proposed by the Commission

- (o) ***If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.***

Amendment

***deleted***

## Amendment 288

## Proposal for a regulation

## Annex I — part III — point 19 — point 19.3 — point k

Text proposed by the Commission

- (k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation ***or the maximum number of allowable reuses.***

Amendment

- (k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging, ***the maximum number of allowable reuses*** and, where appropriate, the validated method of re-sterilisation. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation.

Tuesday 22 October 2013

## Amendment 289

## Proposal for a regulation

## Annex I — part III — paragraph 19 — point 19.3 — point 1

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Text proposed by the Commission

- (l) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.

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Amendment

- (l) **With the exception of devices referred to in Article 15b, if the device bears an indication that it is for single use, the evidence justifying that the device cannot be reprocessed safely referred to in Article 15c(1), and which includes all** information on characteristics and technical factors that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.

## Amendment 290

## Proposal for a regulation

## Annex I — part III — point 19 — point 19.3 — paragraph 1 a (new)

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Text proposed by the Commission

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Amendment

**The instructions for use shall be lay-friendly and reviewed by the representatives of relevant stakeholders, including patient and healthcare professionals' organisations.**

## Amendment 291

## Proposal for a regulation

## Annex II — point 5 — paragraph 1 — introductory part

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Text proposed by the Commission

The documentation shall contain **a summary of**

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Amendment

The documentation shall contain **all available information concerning:**

## Amendment 292

## Proposal for a regulation

## Annex II — point 6.1 — point d

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Text proposed by the Commission

- (d) the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate.

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Amendment

- (d) the PMCF plan and PMCF evaluation report, **including a review of the PMCF evaluation report by an independent scientific body for class III medical devices**, in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate.

Tuesday 22 October 2013

## Amendment 293

## Proposal for a regulation

## Annex IV — point 1 — introductory part

## Text proposed by the Commission

1. The CE marking shall consist of the initials ‘CE’ taking the following form:

## Amendment

1. The CE marking shall consist of the initials ‘CE’ **accompanied by the term ‘Medical Device’** taking the following form:

## Amendment 294

## Proposal for a regulation

## Annex VI — points 1 and 2

## Text proposed by the Commission

## 1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.

## 1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

## Amendment

## 1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented. ***This information shall be made publicly available.***

## 1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. ***This does not preclude the notified body to perform conformity assessment activities for different economic operators producing different or similar products.***

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

Tuesday 22 October 2013

Text proposed by the Commission

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;
- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

1.2.4. The impartiality of the notified bodies, of their top level management **and** of the assessment personnel shall be guaranteed. The remuneration of the top level management **and** assessment personnel of a notified body shall not depend on the results of the assessments.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.

### 1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

Amendment

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;
- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

***The notified body shall make publicly available the declarations of interest of its top-level management and the personnel responsible for carrying out the conformity assessment tasks. The national authority shall verify the compliance of the notified body with the provisions under this point and shall report to the Commission twice a year in full transparency.***

1.2.4. The impartiality of the notified bodies, of their top level management, of the assessment personnel **and subcontractors** shall be guaranteed. The remuneration of the top level management, assessment personnel **and subcontractors** of a notified body shall not depend on the results of the assessments.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities. ***The notified body shall provide evidence to the national authority of compliance with this point.***

### 1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to information obtained in carrying out their tasks under this Regulation, ***only in justified cases and*** except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

## 1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

## 1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

## 2. QUALITY MANAGEMENT REQUIREMENTS

2.2. The quality management system of the notified body shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of — the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;

## 1.5. Financial requirements

The notified body, **including its subsidiaries**, shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

## 1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel **including subcontractors**, is informed of **and trained on** the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, **standards**, guidance and best practice documents adopted in the framework of this Regulation. **The notified body shall keep a record of the actions it takes to inform its personnel.**

## 2. QUALITY MANAGEMENT REQUIREMENTS

2.2. The quality management system of the notified body **and its subcontractors** shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of — the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;

Tuesday 22 October 2013

Text proposed by the Commission

— complaints and appeals.

Amendment

— complaints and appeals;

— **continuous training.****Amendment 295****Proposal for a regulation****Annex VI — point 3.1**

Text proposed by the Commission

3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Amendment

3.1.1. A notified body **and its subcontractors** shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility. **In accordance with Article 35, this requirement shall be monitored to ensure that it is of the requisite quality.**

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical, **scientific** and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the **permanent** availability within its organisation of sufficient scientific personnel who possess experience, **a university degree** and **the** knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

**Permanent in-house staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as their declarations of interest and the specific tasks for which they are responsible.**

**Notified bodies shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured.**

**The notified body responsible for carrying out the assessment tasks shall notify the other Member States of the findings of the annual inspections carried out. Those findings shall be set out in a report.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.

***It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.***

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with ***medical, technical and where needed pharmacological*** knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data ***or the evaluation of an assessment made by a subcontractor.***

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel, ***including any subcontractors, subsidiaries and external experts,*** involved in conformity assessment activities and inform the personnel concerned about it.

***3.1.3.a The notified body shall make available the list of its personnel involved in conformity assessment activities and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date.***

#### Amendment 296

#### Proposal for a regulation

#### Annex VI — point 3.2.

Text proposed by the Commission

Amendment

3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation) covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 33, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

3.2.1. The ***MDCG*** shall establish and document ***the principles of high level competence and*** qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation, ***risk management***) covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 33, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Tuesday 22 October 2013

*Text proposed by the Commission*

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. These personnel altogether shall have proven knowledge and experience in the following:

- Union medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of medical device technologies, the medical device industry and the design and manufacture of medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

*Amendment*

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, **safety**, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. These personnel altogether shall have proven knowledge and experience in the following:

- Union medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of medical device technologies, the medical device industry and the design and manufacture of medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.
- **at least three years' appropriate experience in the field of conformity assessments within a notified body,**
- **adequate seniority/experience in conformity assessments under this Regulation or previously applicable directives during a period of at least three years within a notified body. The notified body staff involved in certification decisions shall not have been involved in the conformity assessment on which a certification decision needs to be taken.**

Tuesday 22 October 2013

## Text proposed by the Commission

3.2.4. Notified bodies shall have available personnel with **clinical** expertise. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to discuss **the clinical data contained within the manufacturer's clinical evaluation** with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;
- be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;
- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;
- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

## Amendment

3.2.4. **Clinical experts:** notified bodies shall have available personnel with expertise **in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations. Permanent 'in-house' staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as the specific tasks for which they are responsible.** This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of **the clinical investigation plans and** the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to discuss **the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention** with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;
- be able to scientifically challenge **the clinical investigation plans and** the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;
- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;
- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.
- **ensure independence and objectivity and disclose potential conflicts of interest.**

Tuesday 22 October 2013

## Text proposed by the Commission

3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;
- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;
- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality **management** system shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management

## Amendment

3.2.5. **Product assessors:** the personnel responsible for carrying out product related **reviews** (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the **specialist qualifications, which should include:**

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device (**as defined within a generic device group**) or technology to be assessed or related to the scientific aspects to be assessed;
- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;
- **qualification based on technical or scientific fields (e.g. sterilization, biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging);**
- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;
- **appropriate knowledge and experience of clinical evaluation;**

3.2.6. **Auditor:** The personnel responsible for carrying out audits of the manufacturer's quality **assurance** system shall have **specialist qualifications, which should include:**

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

— *appropriate knowledge of technologies such as those defined by IAF/EAC coding or equivalent.*

#### Amendment 297

#### Proposal for a regulation

#### Annex VI — point 3.4.

Text proposed by the Commission

Amendment

#### 3.4. Subcontractors and external experts

#### 3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities ***in particular where clinical expertise is limited.*** The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented, ***be publicly available and*** be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the notified body shall have adequate own competence in each product area for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the notified body shall have adequate own competence in each product area, ***each treatment or medical speciality*** for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

***3.4.4a. The policy and procedures under points 3.4.2 and 3.4.4 shall be communicated to the national authority before any subcontracting takes place.***

Tuesday 22 October 2013

## Amendment 298

## Proposal for a regulation

## Annex VI — paragraph 3 — point 3.5. — point 3.5.2.

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Text proposed by the Commission

3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.

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Amendment

3.5.2. It shall review the competence of its personnel and identify training needs **and ensure that necessary measures are taken accordingly**, in order to maintain the required level of qualification and knowledge.

## Amendment 299

## Proposal for a regulation

## Annex VI — 3.5 a (new)

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Text proposed by the Commission

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Amendment**3.5.a Additional requirements for special notified bodies****3.5a 1. Clinical experts for special notified bodies**

*Special notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, good clinical practice in the field of clinical investigations and pharmacology. Permanent in-house staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as the specific tasks for which they are responsible. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:*

- *identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;*
- *appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- *be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;*
- *be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;*
- *be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;*
- *be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.*
- *have an understanding of active substances.*
- *ensure independence and objectivity and disclose potential conflicts of interest.*

### 3.5a 2. Product specialists for special notified bodies

*The personnel responsible for carrying out product related reviews (for example design dossier review, technical documentation review or type examination) for devices referred to in Article 43a shall have the following proven product specialist qualification:*

- *Meet the requirement as stipulated above for product assessors;*
- *Have an advanced academic degree in field relevant to medical devices, or alternative have six years of relevant experience in medical devices or related sectors;*
- *Have an ability to identify key risks of products within the specialist's product categories without prior reference to manufacturer's specifications or risk analyses;*
- *Have an ability to assess against the essential requirements in the absence of harmonised or established national standards;*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- The professional experience should be gained in the first product category their qualification is based on, relevant to the product category of designation of the notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;
- Missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;
- For product specialist with qualification in specific technology such as sterilisation, tissues and cells of human and animal origin, combination products, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.

For each designated product category, the Special notify body shall have a minimum of two product specialists of which at least one in house, to review devices referred to in Art. 43 a (new), first paragraph. For those devices, product specialists shall be available in house for the designated technology fields (for example combination products, sterilisation, tissues and cells of human or animal origin) covered by the scope of notification.

### 3.5a 3. Training for product specialists

Product specialists shall receive at minimum 36 hours of training in medical devices, the Medical Device Regulations, and assessment and certification principles, including training in the verification of manufactured product.

The notified body shall ensure that a product specialist to be qualified obtains adequate training in the relevant procedures of the notified body's quality management system and is taken through a training plan consisting of sufficient design dossier reviews witnessed, performed under supervision and peer reviewed before doing a qualifying full independent review.

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*For each product category for which qualification is sought, the notified body must show evidence of appropriate knowledge in the product category. A minimum of five design dossiers (at least two of them initial applications or significant extensions of certification) shall be conducted for the first product category. For subsequent qualification in additional product categories evidence of adequate product knowledge and experience needs to be demonstrated.*

#### 3.5a 4. Maintenance qualification for product specialists

*Qualifications of product specialists shall be reviewed on an annual basis; a minimum of four design dossier reviews, independent of the number of product categories qualified for shall be demonstrated as a four-year rolling average. Reviews of significant changes to the approved design (not full design examinations) count for 50 %, as do reviews supervised.*

*On an ongoing basis, the product Specialist needs to show evidence of state-of-art product knowledge, review experience in each product category for which qualification exists. Annual training with regard to latest status of Regulations, harmonised standards, relevant guidance documents, clinical evaluation, performance evaluation, CTS requirements needs to be demonstrated.*

*If the requirements for renewal of qualification are not met, the qualification shall be suspended. Then the first upcoming design dossier review shall be done under supervision, and re-qualification confirmed based on the outcome of this review.*

### Amendment 300

#### Proposal for a regulation

#### Annex VI — point 4.1

Text proposed by the Commission

Amendment

4.1. The notified body's decision-making process shall be clearly documented, including the **process for the** issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.1. The notified body's decision-making process shall be **transparent and** clearly documented **and its outcome publicly available**, including the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

Tuesday 22 October 2013

**Amendment 301**  
**Proposal for a regulation**  
**Annex VI — point 4.3**

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*Text proposed by the Commission*

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4.3. The notified body shall have in place documented procedures covering at least:

- the application for conformity assessment by a manufacturer or by an authorised representative,
- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification,

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*Amendment*

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4.3. The notified body shall have in place documented procedures **that are publicly available** covering at least:

- the application for conformity assessment by a manufacturer or by an authorised representative,
- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification, **as well as the recommended duration for conducting its conformity assessment,**

**Amendment 302**  
**Proposal for a regulation**  
**Annex VI — point 4 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**4a. Recommended duration for conformity assessments conducted by notified bodies**

**4a.1. Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client**

**4a.2. An audit duration shall be based, inter alia, on the effective number of personnel of the organization, the complexity of the processes within the organization, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration may be adjusted based on any significant factors that uniquely apply to the organization to be audited. The notified body shall ensure that any variation in audit duration does not compromise the effectiveness of audits**

**4a.3. The duration of any scheduled on site audit shall not be less than one auditor/day.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

**4a.4. Certification of multiple sites under one quality assurance system shall not be based on a sampling system.**

#### Amendment 303

##### Proposal for a regulation

##### Annex VII — part III — point 4 — point 4.4 — paragraph 1 — indent 2

Text proposed by the Commission

Amendment

— are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,

— are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III, **with the exception of sutures and staples.**

#### Amendment 304

##### Proposal for a regulation

##### Annex VII — part III — point 6 — point 6.7 — paragraph 1

Text proposed by the Commission

Amendment

All devices incorporating or consisting of nanomaterial **are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot** be released into the **patient's or user's body when the device is used within its intended purpose.**

All devices incorporating or consisting of nanomaterial **deliberately intended to** be released into the **human** body **are in class III.**

#### Amendment 305

##### Proposal for a regulation

##### Annex VII — part III — point 6 — point 6.8

Text proposed by the Commission

Amendment

#### 6.8. Rule 20

**deleted**

**All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.**

Tuesday 22 October 2013

**Amendment 306****Proposal for a regulation****Annex VII — part III — point 6 — point 6.9**

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*Text proposed by the Commission***6.9. Rule 21**

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*Amendment****deleted***

***Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.***

**Amendment 307****Proposal for a regulation****Annex VIII — point 3 — point 3.2 — paragraph 1**

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*Text proposed by the Commission*

3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

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*Amendment*

3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection ***and delivery***. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

**Amendment 308****Proposal for a regulation****Annex VIII — point 3 — point 3.2 — paragraph 2 — point d — indent 2**

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*Text proposed by the Commission*

— the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

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*Amendment*

— the product identification ***and traceability*** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Tuesday 22 October 2013

## Amendment 309

## Proposal for a regulation

## Annex VIII — point 4 — point 4.1

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Text proposed by the Commission

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

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Amendment

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils **all** the obligations imposed by the approved quality management system.

## Amendment 310

## Proposal for a regulation

## Annex VIII — point 4.4 — paragraph 1

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Text proposed by the Commission

The notified body shall randomly perform unannounced **factory** inspections **to the manufacturer** and, if appropriate, at the manufacturer's suppliers and/or subcontractors, **which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.** The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.

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Amendment

The notified body shall randomly perform **at least once every five years and for each manufacturer and generic device group** unannounced inspections **at the relevant manufacturing sites** and, if appropriate, at the manufacturer's suppliers and/or subcontractors. The notified body shall establish a plan for the unannounced inspections which **shall not take a periodicity lower than one inspection per year and** must not be disclosed to the manufacturer. **At the time of such inspections, the notified body shall carry out the tests or ask to carry them in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report.**

## Amendment 311

## Proposal for a regulation

## Annex VIII — point 4 — point 4.4 — paragraph 3

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Text proposed by the Commission

The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.

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Amendment

The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check. **This report shall be made public.**

Tuesday 22 October 2013

## Amendment 312

## Proposal for a regulation

## Annex VIII — point 4 — point 4.5 — paragraph 1

Text proposed by the Commission

*In the case of devices classified as class III, the surveillance assessment shall also include a check of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of finished products.*

Amendment

*deleted*

## Amendment 313

## Proposal for a regulation

## Annex VIII — point 5.3 — paragraph 1

Text proposed by the Commission

The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Amendment

The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. ***The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation. The notified bodies shall comment on the conformity of the following:***

- ***general description of the product,***
- ***design specifications, including a description of the solutions adopted to fulfil the essential requirements,***
- ***systematic procedures used for the design process and techniques used to control, monitor and verify the design of the device.***

The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Tuesday 22 October 2013

## Amendment 314

## Proposal for a regulation

## Annex VIII — point 5 — point 5.3 a (new)

Text proposed by the Commission

Amendment

**5.3 a. For devices in class III the clinical part of the dossier shall be evaluated by an appropriate clinical expert among those contained in the list developed by the MDCG according to Art. 80 g)**

## Amendment 315

## Proposal for a regulation

## Annex VIII — point 8 — introductory part

Text proposed by the Commission

Amendment

8. The manufacturer or his authorised representative shall, for a period **ending** at least **five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market**, keep at the disposal of the competent authorities:

8. The manufacturer or his authorised representative shall, for a period at least **equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer**, keep at the disposal of the competent authorities:

## Amendment 316

## Proposal for a regulation

## Annex IX — point 7 — paragraph 1 — introductory part

Text proposed by the Commission

Amendment

The manufacturer or his authorised representative shall, for a period **ending** at least **five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market**, keep at the disposal of the competent authorities:

The manufacturer or his authorised representative shall, for a period at least **equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer**, keep at the disposal of the competent authorities:

Tuesday 22 October 2013

## Amendment 317

## Proposal for a regulation

## Annex X — part A — point 4 — paragraph 2

Text proposed by the Commission

*In the case of devices classified as class III, the surveillance shall also include a check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products.*

Amendment

*deleted*

## Amendment 318

## Proposal for a regulation

## Annex X — part A — point 6 — paragraph 1 — introductory part

Text proposed by the Commission

The manufacturer or his authorised representative shall, for a period *ending* at least **five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market**, keep at the disposal of the competent authorities:

Amendment

The manufacturer or his authorised representative shall, for a period at least **equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer**, keep at the disposal of the competent authorities:

## Amendment 319

## Proposal for a regulation

## Annex X — part A — point 7 — point 7.5 — introductory part

Text proposed by the Commission

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period **ending** at least **five years after the last device has been placed on the market**, keep at the disposal of the competent authorities:

Amendment

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period at least **equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer**, keep at the disposal of the competent authorities:

Tuesday 22 October 2013

**Amendment 320****Proposal for a regulation****Annex X — Part B — point 4 — paragraph 1***Text proposed by the Commission*

4. The notified body shall carry out the appropriate examinations and tests in order to **verify** the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5.

*Amendment*

4. The notified body shall carry out the appropriate examinations and tests in order to **assess** the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5 **or by examination and testing of the products on a statistical basis as specified in section 6.**

**Amendment 321****Proposal for a regulation****Annex X — Part B — point 5 a (new) — title***Text proposed by the Commission**Amendment***5a. Statistical verification of conformity****Amendment 322****Proposal for a regulation****Annex X — Part B — point 5 a — part 5.1 (new)***Text proposed by the Commission**Amendment*

- 5.1. The manufacturer shall present the manufactured products in the form of homogeneous batches. The proof of homogeneity for the presented products shall be part of the batch documentation.**

**Amendment 323****Proposal for a regulation****Annex X — Part B — point 5 a — part 5.2 (new)***Text proposed by the Commission**Amendment*

- 5.2. A random sample is taken from each batch. The products which make up the sample shall be examined individually and the appropriate physical or laboratory tests defined in the relevant standard(s) referred to in Article 6 or equivalent tests shall be carried out in order to verify the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.**

Tuesday 22 October 2013

## Amendment 324

## Proposal for a regulation

## Annex X — Part B — point 5 a — part 5.3 (new)

Text proposed by the Commission

Amendment

5.3. Statistical control of products shall be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards or equivalent tests referred to in Article 6, taking account of the specific nature of the product categories in question.

## Amendment 325

## Proposal for a regulation

## Annex X — Part B — point 5 a — part 5.4 (new)

Text proposed by the Commission

Amendment

5.4. The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests carried out.

All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market.

In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

## Amendment 326

## Proposal for a regulation

## Annex X — Part B — point 7 — paragraph 1 — introductory part

Text proposed by the Commission

Amendment

The manufacturer or his authorised representative shall, for a period **ending** at least **five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market**, keep at the disposal of the competent authorities:

The manufacturer or his authorised representative shall, for a period at least **equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer**, keep at the disposal of the competent authorities:

Tuesday 22 October 2013

## Amendment 327

## Proposal for a regulation

## Annex X — Part B — point 8 — point 8.4 — introductory part

*Text proposed by the Commission*

8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period **ending** at least **five years after the last** device **has been placed on the market**, keep at the disposal of the competent authorities:

*Amendment*

8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period at least **equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer**, keep at the disposal of the competent authorities:

## Amendment 328

## Proposal for a regulation

## Annex XIII — part A — point 2

*Text proposed by the Commission*

2. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.

*Amendment*

2. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.

***Data from independent scientific institutions or medical societies based on their own collections of clinical data shall also be taken into account.***

## Amendment 329

## Proposal for a regulation

## Annex XIII — Part A — point 5

*Text proposed by the Commission*

5. In the case of **implantable devices and** devices falling within **class III**, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

*Amendment*

5. In the case of devices falling within **Article 43a(1), with the exception of those used for a short term**, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

Tuesday 22 October 2013

**Amendment 330****Proposal for a regulation****Annex XIII — point 5 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**5a. All clinical data collected by the manufacturer as part of a PMCF should be made accessible to health professionals.**

**Amendment 331****Proposal for a regulation****Annex XIII — part B — point 1**

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*Text proposed by the Commission*

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*Amendment*

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect, **register in the electronic system on vigilance referred to in Article 62** and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

**Amendment 332****Proposal for a regulation****Annex XIII — part B — point 3**

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*Text proposed by the Commission*

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*Amendment*

3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation.

3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation **and be sent periodically to the concerned Member States.**

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

*For class III medical devices, the manufacturer's PMCF evaluation report shall be reviewed by a third party or external expert under the principles of highest scientific competence and impartiality. In order to conduct its review, the manufacturer shall provide the relevant data to the third party or external expert. Both the manufacturer's PMCF evaluation report and its review by an independent body shall be part of the technical documentation for class III medical devices.*

**Amendment 333****Proposal for a regulation****Annex XIII — part B — point 4**

Text proposed by the Commission

Amendment

4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them.

4. The conclusions of the PMCF evaluation report, ***and where applicable its review by a third party or external experts as referred to in paragraph 3***, shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them ***and inform the concerned Member States***.

Tuesday 22 October 2013

## Amendment 334

## Proposal for a regulation

## Annex XIV — part I — point 1 — paragraph 1

*Text proposed by the Commission*

Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.

*Amendment*

Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008. ***Conformity with the above principles shall be granted after an examination by the concerned Ethics Committee. Regulation of the detailed requirements relating to the participation of subjects in clinical trials shall be the responsibility of the Member States.***

## Amendment 335

## Proposal for a regulation

## Annex XIV — Part I — paragraph 2 — point 2.1.

*Text proposed by the Commission*

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

*Amendment*

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute ***the technical performance of the device, the clinical safety and efficacy of the device when used for the intended purpose in the target population and in accordance with the instructions of use,*** and the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

Tuesday 22 October 2013

**Amendment 336****Proposal for a regulation****Annex XIV — Part I — paragraph 2 — point 2.3.***Text proposed by the Commission*

2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device.

*Amendment*

2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device **for the intended purpose in the target population.**

**Amendment 337****Proposal for a regulation****Annex XIV — part I — point 2 — point 2.7***Text proposed by the Commission*

2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain **a critical evaluation of all the** data collected during the clinical investigation, including negative findings.

*Amendment*

2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain **all clinical** data collected during the clinical investigation **and a critical evaluation of such data**, including negative findings.

**Amendment 338****Proposal for a regulation****Annex XIV — Part I a (new) — point 1***Text proposed by the Commission**Amendment***1. Incapacitated subjects**

***In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, clinical investigations may be conducted only where, in addition to the general conditions, all of the following conditions are met:***

- ***the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;***
- ***the incapacitated subject has received adequate information in relation to his or her capacity for understanding regarding the clinical investigation and its risks and benefits from the investigator or his/her representative, in accordance with the national law of the Member State concerned;***

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from the clinical investigation at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal representative as a result shall be followed by the investigator;
- no incentives or financial inducements are given except compensation for participation in the clinical investigation;
- such research is essential to validate data obtained in a clinical investigation on persons able to give informed consent or by other research methods;
- such research relates directly to medical condition from which the person concerned suffers;
- the clinical investigation has been designed to minimise pain, discomfort, fear, and any other foreseeable risk in relation to the disease and developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;
- the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subject;
- there are grounds for expecting that participation in the clinical investigation will produce a benefit to the incapacitated subject outweighing the risks or will produce only a minimal risk;
- an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;

The test subject shall as far as possible take part in the consent procedure.

Tuesday 22 October 2013

**Amendment 339**  
**Proposal for a regulation**  
**Annex XIV — Part I a (new) — point 2**

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*Text proposed by the Commission*

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*Amendment*

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**2. Minors**

*A clinical investigation may be conducted only where, in addition to the general conditions, all of the following conditions are met:*

- the written informed consent of the legal representative or representatives has been obtained, whereby consent shall represent the minor's presumed will;*
- the informed and express consent of the minor has been obtained, where they are able to give consent according to national law,*
- the minor has received all relevant information in a way adapted to his or her age and maturity, from a medical doctor (either the investigator or member of the study team) trained or experienced in working with children, regarding the study, the risks and the benefits;*
- without prejudice to second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from the clinical investigation at any time, is duly taken into consideration by the investigator;*
- no incentives or financial inducements are given except compensation for participation in the clinical investigation;*
- such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;*
- the clinical investigation has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;*
- there are grounds to expect that some direct benefit for the category of patients concerned by the study may be obtained from the clinical investigation;*
- the corresponding scientific guidelines of the EMA have been followed;*
- the interest of the patient shall always prevail over those of science and society;*

Tuesday 22 October 2013

Text proposed by the Commission

Amendment

- *the clinical investigation does not replicate other studies based on the same hypothesis and age-appropriate technology are used;*
- *an ethics committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol.*

*The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.*

*If during a clinical investigation the minor reaches the age of majority as defined in the national law of the Member State concerned, his/her express informed consent shall be obtained before the clinical investigation may continue.*

#### Amendment 340

#### Proposal for a regulation

#### Annex XIV — Part II — point 1 — point 1.11

Text proposed by the Commission

Amendment

1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation).

1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation). ***As randomised controlled investigations usually generate a higher level of evidence for clinical efficacy and safety, the use of any other design or study has to be justified. Also the choice of the control intervention shall be justified. Both justifications shall be provided by independent experts with the necessary qualifications and expertise.***

#### Amendment 343

#### Proposal for a regulation

#### Annex XIV — part II — point 3 — point 3.1 — point 3.1.3

Text proposed by the Commission

Amendment

3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s).

3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s), ***as well as information about the contract between the sponsor and the investigating establishment, together with details of the funding.***

Tuesday 22 October 2013

**Amendment 344****Proposal for a regulation****Annex XIV — part II — point 3 — point 3.1 — point 3.1.4**

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*Text proposed by the Commission*

3.1.4. Overall synopsis of the clinical investigation.

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*Amendment*3.1.4. Overall synopsis of the clinical investigation ***in the national language of the country concerned.*****Amendment 347****Proposal for a regulation****Annex XIV — part II — point 3 — point 3.15 a (new)**

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*Text proposed by the Commission*

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*Amendment****3.15a. A plan for the further treatment of subjects after the clinical investigation.***  

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Tuesday 22 October 2013

P7\_TA(2013)0429

## Ship recycling \*\*\*I

**European Parliament legislative resolution of 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on ship recycling (COM(2012)0118 — C7-0082/2012 — 2012/0055(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/21)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0118),
  - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0082/2012),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 12 July 2012 <sup>(1)</sup>,
  - after consulting the Committee of the Regions,
  - having regard to the undertaking given by the Council representative by letter of 27 June 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0132/2013),
1. Adopts its position at first reading hereinafter set out <sup>(2)</sup>;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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## P7\_TC1-COD(2012)0055

**Position of the European Parliament adopted at first reading on 22 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1257/2013.)*

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<sup>(1)</sup> OJ C 299, 4.10.2012, p. 158.

<sup>(2)</sup> This position replaces the amendments adopted on 18 April 2013 (Texts adopted P7\_TA(2013)0182).

Tuesday 22 October 2013

P7\_TA(2013)0430

**European statistics on demography \*\*\*I**

**European Parliament legislative resolution of 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on European statistics on demography (COM(2011)0903 — C7-0518/2011 — 2011/0440(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/22)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0903),
  - having regard to Article 294(2) and Article 338(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0518/2011),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the undertaking given by the Council representative by letter of 11 September 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on Employment and Social Affairs and the opinions of the Committee on Regional Development and the Committee on Constitutional Affairs (A7-0050/2013),
1. Adopts its position at first reading hereinafter set out <sup>(1)</sup>;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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**P7\_TC1-COD(2011)0440**

**Position of the European Parliament adopted at first reading on 22 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council on European demographic statistics**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1260/2013.)*

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<sup>(1)</sup> This position replaces the amendments adopted on 18 April 2013 (Texts adopted P7\_TA(2013)0181).

Wednesday 23 October 2013

P7\_TA(2013)0437

## **Draft general budget of the European Union for the financial year 2014 — all sections**

**European Parliament resolution of 23 October 2013 on the Council position on the draft general budget of the European Union for the financial year 2014 (13176/2013 — C7-0260/2013 — 2013/2145(BUD))**

(2016/C 208/23)

*The European Parliament,*

- having regard to Article 314 of the Treaty on the Functioning of the European Union and Article 106a of the Treaty establishing the European Atomic Energy Community,
- having regard to Council Decision 2007/436/EC, Euratom of 7 June 2007 on the system of the European Communities' own resources <sup>(1)</sup>,
- having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 <sup>(2)</sup>,
- having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management <sup>(3)</sup> (IIA),
- having regard to its resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework 2014 — 2020 <sup>(4)</sup>,
- having regard to its resolution of 13 March 2013 on the general guidelines for the preparation of the 2014 budget — section III <sup>(5)</sup>,
- having regard to its resolution of 17 April 2013 on Parliament's estimates of revenue and expenditure for the financial year 2014 <sup>(6)</sup>,
- having regard to the draft general budget of the European Union for the financial year 2014, which the Commission adopted on 28 June 2013 (COM(2013)0450),
- having regard to the recommendations on the mandate for the trilogue on the 2014 budget, given by BUDG Coordinators,
- having regard to the position on the draft general budget of the European Union for the financial year 2014, which the Council adopted on 2 September 2013 and forwarded to Parliament on 11 September 2013 (13176/2013 — C7-0260/2013),
- having regard to Letter of amendment No 1/2014 to the draft general budget of the European Union for the financial year 2014 presented by the Commission on 18 September 2013 (COM(2013)0644),
- having regard to Rule 75b of its Rules of Procedure,
- having regard to the report of the Committee on Budgets and the opinions of the other committees concerned (A7-0328/2013),

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<sup>(1)</sup> OJ L 163, 23.6.2007, p. 17.

<sup>(2)</sup> OJ L 298, 26.10.2012, p. 1.

<sup>(3)</sup> OJ C 139, 14.6.2006, p. 1.

<sup>(4)</sup> Texts adopted, P7\_TA(2013)0304.

<sup>(5)</sup> Texts adopted, P7\_TA(2013)0081.

<sup>(6)</sup> Text adopted, P7\_TA(2013)0173.

Wednesday 23 October 2013

**Section III***General overview*

1. Recalls that its priorities for the 2014 budget are economic and sustainable growth, competitiveness, the creation of employment and the fight against youth unemployment as well as the EU's role in the world; reiterates, therefore, its support for policies contributing to the fight against youth unemployment, research, development and innovation, the digital agenda, competitiveness, small and medium-sized enterprises (SMEs), entrepreneurship and self-employment, education, professional training, mobility and external aid;
2. Insists that the Commission and the Member States should make every effort to ensure that the EU budget is spent in an efficient way and that anything financed with it should have a clear European added value. Member States should in particular share tasks wherever possible and increase mutual cooperation;
3. Recalls its determination to ensure a sufficient and realistic level of commitment and payment appropriations to allow the programmes to kick-off with sufficient funds in the multiannual financial framework (MFF) for the period 2014 — 2020 and to avoid delays in their implementation, as well as to ensure the successful conclusion of the programmes started under the 2007 — 2013 MFF;
4. Deplores therefore the Council's decision to proceed again this year with the usual approach of horizontal cuts to the draft budget, aimed at artificially reducing the level of the Union's resources for 2014 by an overall total of EUR 240 million (- 0,2 %) in commitment appropriations and EUR 1 061 million (- 0,8 %) in payment appropriations as compared to the draft budget, thus leading to a significant decrease compared to the 2013 budget (including amending budgets Nos 1 to 5) both in commitments (-6 %) and in payments (- 6,6 %);
5. Is surprised that in its position the Council has not only not taken into account the agreement on the MFF, regarding the frontloading of the Erasmus+, COSME and Horizon 2020 programmes but has further decreased the appropriations for some of those programmes;
6. Deeply regrets that the Council has introduced cuts in both commitment and payment appropriations in all headings; recalls that the most affected ones are Heading 1a (- 0,36 % in commitment appropriations and - 3,6 % in payment appropriations as compared to the draft budget), Heading 4 (- 0,21 % in commitment appropriations and - 2,5 % in payment appropriations as compared to the draft budget) and Heading 5 (- 1,78 % in commitment and payment appropriations as compared to the draft budget); notes that Headings 1a and 4 contain programmes and initiatives that are instrumental for the delivery of the objectives of the Europe 2020 strategy as well as the EU external policy agenda, and that these across-the-board cuts will affect initiatives that are priority areas for Parliament in these two fields;
7. Emphasises the fact that those cuts are in direct contradiction with the political agreement on the MFF on frontloading and also disregard Parliament's priorities, as outlined in its resolution on the general guidelines for the preparation of the 2014 budget and the recommendations on the mandate for the trilogue on the 2014 budget;
8. Rejects the Council's argument that the proposed cuts correspond to under-implemented or low-performing programmes, since Council's cuts in commitments affect mostly the implementation capacity of a new generation of multiannual programmes which have not yet started; furthermore, Council's cuts in payments affect mostly the completion of programmes that have shown not only good implementation rates but even over-implementation (e.g. the Common Strategic Framework for Research and Innovation, Galileo, Customs and Fiscalis under Heading 1a, ESF, ERDF and the Cohesion Fund under Heading 1b); emphasises in particular that such cuts in payment appropriations completely disregard the multiannual character of the Union's policies, and of cohesion policy in particular; underlines the fact that 52 % of the payment appropriations requested in the 2014 draft budget are devoted to the completion of programmes under the 2007 — 2013 MFF;
9. Deplores the arbitrary cuts proposed by the Council on the administrative and support lines financing the implementation of key EU programmes; considers these cuts to be detrimental to the successful start of the new programmes as a lack of administrative capacity entails a serious risk of hampering implementation of EU policies; regrets Member States' tendency to care more about trivial, preposterous short-term savings rather than long-term results; restores therefore, the draft budget on all lines of administrative and support expenditure cut by the Council;

**Wednesday 23 October 2013**

10. Takes note of the draft Council statement on payments adopted by the Council in its position on the 2014 draft budget; is convinced, however, that, unless substantially improved, it cannot serve as a satisfactory political guarantee to ensure a sufficient and adequate level of payments in 2014; is determined to provide assurance and reverse the trend of the last years, where the outstanding payments at the end of the year have grown exponentially; calls therefore on the Council to agree to a joint political commitment to use all means available under the MFF Regulation for the period 2014-2020 including recourse to the contingency margin and/or revision of the payment ceiling in order not to jeopardise the new programmes and at the same time to decrease the amount of the outstanding year-end payments;

11. Welcomes the statement by some Member States that a better balance between commitments and payments should be sought in order to avoid the situation where the Union cannot meet its legal obligations; is comforted that several Council delegations have started vocally raising the same concerns that Parliament has repeatedly raised over the past budgetary procedures;

12. Cannot accept Council's decision to reduce commitment and payment appropriations; recalls that commitments reflect Union political priorities and should be set with a long-term perspective, taking into account a time when the economic downturn might have ended; takes the view, therefore, that in general principle, commitments should be restored at draft budget level; intends, however, to increase commitment appropriations slightly above the draft budget on a selected number of budget lines relating to the programmes of direct benefit for European citizens, and contributing to the delivery of the Europe 2020 priorities — which are crucial for the growth and competitiveness of the Union — as well as those projecting European values and solidarity abroad;

13. Sets, therefore, the overall level of appropriations for 2014 at EUR 142 625 million and EUR 136 077 million in commitment and payment appropriations respectively;

14. Calls, therefore, for the mobilisation of the Flexibility Instrument for an amount of EUR 274,2 million in commitment appropriations; considers that — in Heading 1b — the Flexibility Instrument will reinforce the Fund for European Aid to the Most Deprived, pending the final agreement of the legislative authority on the legal basis that needs to reflect the political agreement on the MFF of 27 June 2013 on the overall allocation to this Fund, and will grant additional assistance to Cyprus from the Structural Funds as agreed by the Heads of States and Governments at their meeting of 27—28 June 2013; considers that in Heading 4 the Flexibility Instrument will provide further support for humanitarian aid in the Middle East;

15. Intends to launch a substantial debate on the revenue side in the annual budget procedure, as it is an integral part of the Union budget and should not be dissociated from the expenditure side; questions, in this respect, the justification for Member States to retain 25 % of traditional own resources as administrative costs and calls for a more careful scrutiny of the use of this amount; calls for a more realistic budgeting of the expected revenue from fines imposed by the Commission on companies in breach of Union competition law and for further discussion on the budgeting of the surplus in the budget in order to avoid a complex procedure, incomprehensible to the outside world, which currently consists of returning it to Member States via a reduction of their respective GNI-contribution;

#### *Payment appropriations*

16. Deplores the cuts in payments brought by the Council, which result in a decrease of EUR 9,5 billion (9 500 million) (- 6,6 %) as compared to the adopted budget for 2013 (including amending budgets Nos 1 to 5); reiterates that despite the adoption of a lower MFF for the period 2014-2020 and the absolute need to keep honouring past commitments, the Council kept blindly following its past strategy to artificially cut the level of payments, without taking into consideration the real needs and relatively sparing expenditure under shared management to ensure Member States' apparent 'return on investment';

17. Notes that this happened despite the serious situation in relation to payments already in 2013, when implementation was, in early September, EUR 9 billion and EUR 18 billion above the corresponding figures in 2012 and 2011 respectively at the same point in time; stresses that such good and increasing absorption capacity demonstrates that Union programmes are actually delivering well on the ground; is determined to ensure that the implementation of previously agreed commitments is not to be impaired by artificial constraint on budgeted payments;

18. Considers that — particularly this year — the Council's position to leave an artificial margin of EUR 1 billion under the 2014 payments ceiling serves no purpose, and cannot be justified in any way, especially given the magnitude of the expected carry-over of outstanding payments at the end of 2013;

Wednesday 23 October 2013

19. Stresses the fact that the Council position does not take account of the dramatic shortage of payments, notably in the field of cohesion policy, points that the latest forecasts (September 2013), provided by the Member States themselves on their payment claims to be submitted before the end of 2013, as screened and adjusted by the Commission, show that a carry-over of some EUR 20 billion is expected at the end of 2013, even with the second tranche of amending budget No 2/2013 (draft amending budget No 8/2013) adopted in full; recalls that valid payment claims carried over from 2013 will have to be deducted from — and will consequently reduce — the level of payment appropriations available for 2014; stresses that this will put the 2014 budget under heavy pressure, not least given the unprecedented level of unpaid claims and, more generally, of the outstanding commitments (RALs);

20. Is astonished that some of the cuts in payments proposed by the Council affect the Horizon 2020, COSME and the ESF programmes, in plain opposition with the spirit and the letter of the recent political agreement on the MFF to frontload some appropriations in 2014 and 2015 to these programmes and with the institutions' commitment at the highest level to tackle youth unemployment; recalls, moreover, that part of the Council's cuts concern lines which were reinforced in the framework of the agreement on the first tranche of amending budget No 2/2013;

21. Strongly rejects, therefore, the Council's approach to payments and amends its position on payments to ensure that the decrease between 2013 and 2014 ceilings is not detrimental to the proper implementation and completion of programmes under the 2007-2013 MFF, bearing in mind that, in the Commission's proposal, 52 % of payment appropriations address outstanding commitments, nor detrimental to the start of new programmes;

22. Decides to restore the draft budget in payments for most lines cut by the Council; notes that, despite reinforcements contained in payment appropriations on a limited number of budget items and several decreases on other budget items, the payment ceiling does not allow for an adequate financing of priorities selected by Parliament; proposes accordingly, after having examined all possibilities for re-allocating payment appropriations, to mobilise the Flexibility Instrument in payments for an amount of EUR 211 million to finance humanitarian aid;

23. Hopes that the interinstitutional meeting on payments held on 26 September 2013 will help both Parliament and the Council to agree on this joint political commitment and find a common position during the budgetary conciliation, without any unnecessary dispute over the size and quality of figures provided by the Commission paving the way to addressing any shortfall in payments during the execution of budget 2014;

24. Welcomes the adoption by the Commission of draft amending budget No 8/2013 (second tranche of amending budget No 2/2013), which provides for an additional EUR 3,9 billion for outstanding payments from 2013 and which is one of the conditions to put the MFF Regulation to the vote; calls for its swift and full adoption by Council; reiterates its position, as set out in its resolution of 3 July 2013 on the political agreement on the MFF, that Parliament will not give its consent to the MFF Regulation or adopt the 2014 budget until draft amending budget No 8/2013, covering the second tranche of amending budget No 2/2013, has been adopted by the Council;

#### *Heading 1a*

25. Reiterates the fact that excluding large-scale infrastructure projects, the appropriations for Heading 1a included in the draft budget already resulted in a decrease of EUR 1,1 billion as compared to the 2013 budget; deplores the fact that in addition, and regardless of all the recent political engagements in favour of the objectives of this heading undertaken by the Heads of State and Government, the Council decided to cut further the commitments of Heading 1a by EUR 60 million as compared to the draft budget;

26. Stresses that part of the Council's cuts particularly affect programmes identified as those strategic for growth and economic recovery by the European Council, namely Horizon 2020 (EUR - 43,7 million) and COSME (EUR - 0,5 million); deplores the fact that this openly contradicts the spirit and the letter of the political agreement on the MFF that includes arrangements for specific flexibility to tackle youth unemployment and strengthen research;

**Wednesday 23 October 2013**

27. Reaffirms its support in favour of EU programmes in the field of research, competitiveness, entrepreneurship, innovation and social inclusion, which are at the heart of the Europe 2020 strategy; takes the approach, therefore, to restore all lines cut by the Council in order not to further weaken this heading; takes the decision, furthermore, to frontload appropriations for a selected number of lines in certain priority areas, such as Horizon 2020, COSME and Erasmus+, which does not represent an increase as the overall amount for those programmes in the MFF for the period 2014-2020 is not modified, and to increase the digital agenda, transport policy, social dialogue, EURES, Progress Microfinance and Social entrepreneurship, special annual events and the quality of European statistics;

28. Takes on board in its reading the political agreement on the MFF as regards the frontloading for 2014 of Horizon 2020 by EUR 212,2 million (EUR 106,1 million for European Research Council and EUR 106,1 million for Marie Skłodowska-Curie actions), COSME by EUR 31,7 million and Erasmus+ by EUR 137,5 million, for an overall amount of EUR 381,4 million;

29. Endorses also the corresponding back-loading of EUR 381,4 million, in line with the political agreement on the MFF and the Commission's Letter of amendment No 1/2014, whereby ITER is reduced by EUR 212,2 million and CEF-Energy by EUR 169,2 million, the latter cut being already included in the draft budget, albeit originally intended for a different purpose;

30. Considers that some areas should be subject to targeted cuts and/or to the putting in reserve of commitments, namely the communication on Economic and Monetary Union on the one hand (EUR - 2 million), and the financial reporting and auditing on the other hand (reserve pending an agreement on the relevant Union programme);

31. Integrates in its reading the results of the legislative negotiations known at this stage; decides in particular to create a number of new lines with token entries under the Horizon 2020 programme and endorses, albeit also with token entries, the new lines proposed by the Commission in its Letter of amendment No 1/2014; expects the Commission to make a comprehensive proposal for bringing the draft budget into line with the new legal bases for all the affected programmes in the framework of the conciliation on the 2014 budget, taking over and complementing the lines adopted by Parliament;

32. Supports the creation of a specific sub-line under Erasmus+ aimed at ensuring adequate transparency with respect to the youth actions under that programme and makes a budgetary transfer of 11,5 % of the original Erasmus+ allocation in favour of that dedicated line to youth; deletes the sub-line created by the Council ensuring operating grants for national agencies;

33. Decides to revert to the nomenclature of the previous programming period as regards social dialogue; splits, therefore, this line and its appropriations into three separate sub-lines as in the past;

34. Notes that as a result of its reading, a margin of [EUR 65 446 000] remains under Heading 1a;

*Heading 1b*

35. Notes that while the commitments have been left practically untouched (only EUR - 3,3 million), the Council has further decreased the level of payments (EUR - 202,2 million or - 0,4 % as compared to the draft budget), affecting both the Investing for growth and jobs goal (EUR-114,151 million or - 0,23 %) and the European Territorial cooperation objective (EUR - 84,805 million or - 6,19 %) respectively and has only artificially increased the margin by EUR 3,3 million;

36. Stresses that the ERDF and the Cohesion Fund have been the most affected by cuts (ERDF: EUR - 125,155 million, Cohesion Fund: EUR - 44,312 million, while the ESF was decreased by EUR 32,788 million); strongly deplores that 69,33 % of global cuts in payments concern the appropriations for completion of programmes from previous periods (i.e. EUR 98,7 million);

37. Regrets that the Commission has taken as a basis for pre-financing the level that was agreed by the European Council in February 2013, an issue which is subject to the on-going inter-institutional sectoral negotiations, where Parliament has the right of co-decision, thus running the risk of pre-empting the outcome of those negotiations; recalls that pre-financing is essential as Member States and regions require sufficient funding at the beginning of the period to invest in projects that will contribute to the efforts of overcoming the current economic and financial crisis; in this respect, reiterates the Parliament's Committee on Regional Development's position of opting for the same pre-financing rates as in the current period, as the crisis is ongoing;

Wednesday 23 October 2013

38. Recalls that Heading 1b bears the biggest part of the current outstanding commitments; is deeply concerned that the amount of outstanding bills at the end of 2013 will amount to approximately EUR 20 billion within cohesion policy, creating a large deficit that will have to be deducted from, and consequently reduce the level of payment appropriations available for, the completion of current as well as the start of the new programmes in 2014; underlines that the recurrent shortages of payment appropriations have been the main cause of the unprecedentedly high level of RALs especially in the last years of the 2007-2013 MFF period;

39. Rejects, therefore, the cuts introduced by the Council on Heading 1b; considers that it would lead to a much more serious shortage in payments than already expected and would impede the reimbursement for already spent resources by the beneficiary Member States and regions, with serious consequences, especially for those Member States which are already encountering economic, social and financial constraints;

40. Decides to restore the draft budget in commitments and payments for all budget lines cut by the Council under this heading, and to exceed the draft budget in commitment appropriations for a number of lines, mostly in line with the Commission's Letter of amendment No 1/2014, providing allocation from the Structural Funds to Cyprus for a total amount of EUR 100 million in current prices for 2014;

41. Recalls the poverty reduction target of reducing by at least 20 million the number of people at risk of poverty and social exclusion set through the Europe 2020 strategy; recalls furthermore the political agreement on the MFF, through which it was agreed that provision should be made for an additional increase of up to EUR 1 billion (on top of the EUR 2,5 billion already agreed) for the whole period 2014-2020 for the Fund for European Aid to the Most Deprived; decides therefore to reinforce this fund, by allocating a total commitment appropriation of EUR 500 million to the actions promoting social cohesion and alleviating the worst forms of poverty in the Union;

42. Creates two dedicated budget lines for technical assistance to the Union strategies for the Baltic Sea macro-region, acknowledging its successful implementation in the current programming period, as well as for the first time for the Danube macro-regions (with EUR 2,5 million in commitment and payment appropriations each);

43. Welcomes the agreement on the Youth Employment Initiative (YEI) reached in the framework of the 2014-2020 MFF negotiations; considers that an adequate level of funding is necessary to ensure its immediate launching to meet the unprecedentedly high levels of youth unemployment; approves, therefore, the frontloading and the backloading of appropriations for the YEI, as well as the corresponding backloading from the European Territorial Cooperation as proposed by the Commission; reiterates that additional appropriations will be needed as of 2016 to ensure its effectiveness and sustainability;

44. Approves the creation of new dedicated budget lines for technical assistance for all five Structural Funds with a token entry (p.m.) and corresponding budget remarks, alongside with the existing budget lines, in order to comply with Member States' requests, as indicated in the Commission's Letter of amendment No 1/2014; expects that this will improve the implementation of the new programmes at Member State level;

45. Regrets that there is not any room for manoeuvre for Parliament under this heading, reiterates its conviction that the political agreement on the MFF is binding for all the institutions and that the flexibility instruments provided by this agreement shall be mobilised in order to ensure the timely launching of, and the necessary level of funding for, its priorities;

## Heading 2

46. Notes that although Heading 2 was least affected by the Council's cuts, some programmes witnessed a decrease in their appropriations, notably the LIFE+ programme, which is a priority for Parliament (- 4,07 % in payment appropriations);

47. Restores the draft budget on all lines cut by the Council and increases commitment appropriations for the School Fruit Scheme by EUR 28 million to align its appropriations to the political agreement reached in June 2013 on the new Common Agricultural Policy for the period 2014 — 2020;

48. Approves the creation of new dedicated budget lines with token entries for technical assistance for the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund, as indicated in the Commission's Letter of amendment No 1/2014;

**Wednesday 23 October 2013***Heading 3*

49. Recalls that Heading 3, though the smallest heading of the MFF in terms of financial allocation, covers issues of key concern to Union citizens;

50. Notes the cuts to this heading already proposed by the Commission in the draft budget; regrets the fact that the Council has further cut commitment appropriations by EUR 5,2 million (-0,24 % compared to the draft budget) and payments appropriations by EUR 10 million (-0,60 % compared to the draft budget);

51. Takes the general approach of restoring the draft budget on all lines to ensure the proper implementation of programmes and actions under this heading;

52. Reiterates the strong support consistently given by Parliament to adequate funding for rights, citizens, culture and media programmes which enjoy high implementation rates and produce noticeable leverage and spill-over effects and generate clear and proven European added value by encouraging trans-border cooperation and active citizenship; is particularly concerned about the proposed cuts in the programmes and actions within these areas; proposes increases in the level of appropriations above the draft budget for a few budget lines within the culture and media sub-programmes, Europe for Citizens, Rights and Citizenship programmes and multimedia actions (a total of EUR 11,3 million of increase in commitment appropriations);

53. Recalls that the EU budget is exposed to multiple risks like VAT fraud, smuggling, counterfeiting and corruption stemming mainly from organised crime; calls for a clear priority to be set to the fight against EU fraud and organised cross-border crime and hence to strengthen the respective EU bodies and agencies involved in prohibiting and fighting these threats and their underlying criminal structures effectively;

54. Stresses that solidarity between Member States in the field of asylum and migration should be reinforced and that the EU budget should demonstrate a clear commitment in that direction, including an adequate contribution from Member States;

55. Notes the tight margin leaving little room for manoeuvre to cope with unanticipated situations under this heading;

*Heading 4*

56. Deplores the Council's cuts to Heading 4 (-0,21 % in commitment appropriations and -2,5 % in payment appropriations), which was already one of the most heavily affected by the decrease in the draft budget (-12,5 % in commitment appropriations and -8,2 % in payment appropriations) as compared to the 2013 levels; reiterates the fact that although it takes up less than 6 % of the total Union budget, Heading 4 is the projection of EU engagement abroad;

57. In this regard, considers it to be of utmost importance to enhance cooperation, step up coordination and develop synergies with programmes and projects of Member States in third countries in order to improve the effectiveness of EU external action and cope with current budgetary restraints;

58. Considers the cuts by Council to Parliament's priority lines unacceptable and proposes to restore the draft budget on the lines decreased by the Council and to even exceed the draft budget in commitment appropriations for some lines of strategic importance for the EU's external relations to a total of EUR 233 million (Humanitarian Aid, European Neighbourhood Instrument, Development Cooperation Instrument, Instrument for Pre-Accession Assistance, Instrument for Stability and the European Instrument for Democracy and Human Rights); calls in this context for an increase in the appropriations for geographic and thematic areas covered by the Development Cooperation Instrument, in view of getting closer to the attainment of the Millennium Development Goals;

59. Believes that to effectively implement the European Neighborhood Policy, greater support must be ensured for partner countries committed to building democratic societies and undertaking reforms; takes into account the ongoing difficult political situation in some of the partner countries; believes that greater support must also be ensured to promote confidence building and other measures contributing to security and the prevention and settlement of conflicts;

60. Recalls the importance of transparency as an underlying budgetary principle; calls, therefore, for a split of the European Union Special Representatives (EUSRs) line to allow for a better overview of the allocations for the individual EUSRs; proposes to fully transfer the budget lines for EUSRs to the European External Action Service (EEAS) budget;

Wednesday 23 October 2013

61. Disagrees with the Commission's proposal to split geographic and thematic lines into one for poverty reduction and sustainable development and one for governance issues as this new nomenclature does not distinguish objectives from means in development policy; proposes, therefore, an updated nomenclature, reflecting better the needs of development policy;

62. Proposes the mobilisation of the Flexibility Instrument for EUR 50 million in order to finance the real needs for the Union's contribution to the Middle East peace process; reiterates, therefore, its support for long-term programming and sufficient funding for assistance to United Nations Relief and Works Agency (UNRWA), Palestine and the peace process; highlights the importance of endowing UNRWA with the necessary means to enable them to provide the essential services for which UNRWA has been mandated by the UN General Assembly, and to safeguard the safety and livelihood of refugees in the light of the instability in the region;

63. Is of the opinion that, for the sake of transparency and efficiency of aid, the policy of direct budget support should be evaluated critically and that the level of auditing should be improved; stresses that in cases of fraud and misuse, the EU should cancel financial aid;

64. Calls for an increase of the payment appropriations for the Emergency Aid Reserve (EUR + 147 million) in order to avoid a repeat of the situation where the Commission is not in a position to react in a timely manner to emerging humanitarian crises;

#### Heading 5

65. Is surprised by the Council's cuts to Heading 5, amounting to a total of EUR - 153,283 million in commitments and payments (- 1,8 % compared to the draft budget levels), where the highest cuts are in pensions and European schools (EUR - 5,2 million , - 3,2 %) and on expenditure related to officials and temporary staff in policy areas (EUR - 69,7 million or - 3,5 %);

66. Points out that in its draft budget the Commission already largely included the savings brought about by the new Staff Regulations and the 1 % reduction of posts, as agreed by the institutions;

67. Views the additional cuts on administrative expenditure made by the Council as unjustified and as disregarding statutory and contractual obligations and the Union's new competences and tasks; notes that 'excluding the amounts relating to the salary adjustment for 2011 and 2012' could further imbalance the Union budget;

68. Notes in particular that if the Court of Justice of the European Union ('Court of Justice') rules in 2014 in favour of the Commission on the challenged pensions and salary adjustment from 1 July 2012, that would not leave an adequate margin under the ceiling of Heading 5 in order to be able to cope with that unforeseen situation; notes, therefore, that the Council has not achieved the objective it set itself when adopting its position;

69. Restores, therefore, the draft budget on all lines of administrative and support expenditure and on all lines in Heading 5 cut by the Council, except for the line 'Remuneration and allowances' in Section III, which is decreased by EUR - 1,2 million to cover European Chemical Agency's contribution to the financing of Type II European Schools;

70. Decides to hold some appropriations in reserve pending appropriate information to be received from the Commission in relation to decentralised agencies and External Assistance Management Reports;

71. Splits the line for the European Anti-Fraud Office (OLAF) expenditure related to officials and temporary staff, to reflect the widened mandate and strengthened independence of the secretariat of the OLAF Supervisory Committee provided for in the new OLAF Regulation <sup>(1)</sup>;

#### Agencies

72. Endorses, as a general rule, the Commission's estimates of agencies' budgetary needs; notes that the Commission had already considerably reduced most agencies' initial requests;

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<sup>(1)</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

**Wednesday 23 October 2013**

73. Considers, therefore, that any further cuts as proposed by the Council would endanger the proper functioning of the agencies and would not allow them to fulfil the tasks they have been assigned by the legislative authority; rejects Council's horizontal approach in cutting appropriations for agencies, whose needs have to be assessed on a case-by-case basis;

74. Cannot accept, however, the Commission's approach to staff, according to which the agencies' establishment plans are not only to be reduced by 1 % on the basis of the political agreement on the MFF, which applies to all institutions and bodies, but are also to contribute another 1 % to a 'redeployment pool';

75. Emphasises the fact that the staff reduction agreed upon shall be based on the existing staff and tasks as on the reference date of 31 December 2012 and that any new tasks of existing agencies or the set-up of new agencies have to be accompanied by additional resources;

76. Modifies therefore the establishment plans of most agencies in such a way as to implement the agreed 1 % reduction; does not do so, however, for agencies which in their initial request already applied the 1+1 % reduction; reiterates, however, that this additional contribution of 1 % needs to be taken into account for the 2015 budget, so as to treat all agencies equally;

77. Stresses the additional tasks already delegated to the European Supervisory Authorities (ESAs), as well as future tasks envisaged in the legislative proposals yet to be agreed, which will require commensurate budgetary increases in order for them to fulfil their supervisory role in a satisfactory manner; recalls its position that the ESAs need independent budget lines and should become financially independent from their national member authorities;

78. Decides to increase the 2014 budget appropriations for the three financial supervisory agencies; believes that those appropriations should reflect the needs to fulfil the required tasks, as more regulations, decisions and directives have been and are being adopted to overcome the current financial and economic crisis which is strongly linked to the stability of the financial sector;

79. Decides to also increase the appropriations for European Maritime Safety Agency and a number of agencies in Heading 3 due to the additional tasks that have been entrusted to them (Frontex, Europol, the European Monitoring Centre for Drugs and Drug Addiction the European Agency for the operational management of large-scale IT systems and the European Asylum Support Office); increases the appropriations for the European Medicines Agency since the Commission in its draft budget had taken the assigned revenues into account, which should not be the case for primarily fee-financed agencies; anticipates the possible entry into force of the 4th Railway Package by putting additional appropriations for European Railway Agency into reserve;

80. Calls on the Commission to intensify its efforts to identify, together with the Member States which seem to be most reluctant, agencies that could either be merged or at least relocated in order to share buildings or certain administrative functions;

81. Expects, furthermore, the Commission to present a new financial statement when a legislative procedure has been finalised by Parliament and the Council extending the mandate of an agency; is aware that such an extension might require additional resources which need to be agreed upon by both institutions;

*Pilot projects and preparatory actions (PP-PAs)*

82. Having carried out a careful analysis of the pilot projects and preparatory actions submitted — as regards the rate of success of the on-going ones and excluding initiatives already covered by existing legal bases, and taking fully into account the Commission's assessment of the projects' implementability, decides to adopt a compromise package made up of a limited number of PP-PAs, also in view of the limited margins available;

**Other sections**

83. Believes that the budget of each Union institution, due to its specific mission and situation, should be treated individually, without 'one-size-fits-all' solutions, taking into account the particular development stage, operational tasks, management goals, staffing needs and building policies of each institution;

Wednesday 23 October 2013

84. Maintains that Parliament and the Council, while supporting all possible savings and gains of efficiency stemming from constant re-evaluation of on-going and new tasks, should set a sufficient level of appropriations to ensure the smooth functioning of the institutions, respect for internal and external legal obligations and provision of a highly professional public service to Union citizens;

85. Is concerned by the Council's cuts, in the 2014 draft budget, of staff salary adjustments of 1,7 % for 2011 and 2012 in those institutions which had included an annual impact of those adjustments in their budgetary estimates, especially in light of the pending ruling of the Court of Justice; reinstates that expenditure in the 2014 budget as a measure of sound and prudent financial management; is also concerned about the mounting backlog of principal and interest payments which the institutions would become liable for, and notes that Council has not anticipated any appropriations as a precautionary measure;

86. Is deeply concerned, therefore, that there is almost a non-existent payment margin and an insufficient commitment margin in Heading 5 and the sub-ceiling for administrative expenditure; recalls that according to Article 203 of Regulation (EU, Euratom) No 966/2012, 'administrative expenditure shall be non-differentiated appropriations' and therefore, the lower of the two ceilings is key; reiterates the fact that additional payment appropriations might be needed to cover the outstanding salary adjustments and warns that there might be also a margin problem with commitments;

87. Requests an amending budget to cover the backlog and the respective salary adjustments, should the Court of Justice rule in favour of the salary adaptation prescribed by the Staff Regulations; notes that there are minor additional savings as a result of the adoption of the Staff Regulations which were not yet integrated in the draft budget; notes the exact details of the Commission's Letter of amendment No 2/2014 (COM(2013)0719); calls on the Council to reflect the Letter's content in the 2014 budgetary procedure;

88. Welcomes the efforts made by the institutions to find savings, where possible, without jeopardising the quality of their service; welcomes increased inter-institutional cooperation such as the ongoing negotiations between Parliament, the European Economic and Social Committee and the Committee of the Regions to strengthen their political linkages, achieve efficiency gains and encourage staff mobility to support the core functions of the respective institutions;

## **Section I — European Parliament**

### *General framework*

89. Recalls that it insisted, when adopting its estimates for 2014, on the need to exercise a high degree of budgetary responsibility, control and self-restraint and to make further efforts to implement changes, savings and structural reforms with the intention of keeping the budget increase closer to the rate of inflation;

90. Stresses that the European Parliament and the Council, in order to create long term savings in the EU budget, must address the need for a roadmap to a single seat, as stated in its previous resolutions, notably its resolutions of 23 October 2012 on the Council position on the draft general budget of the European Union for the financial year 2013- all sections <sup>(1)</sup> and of 6 February 2013 on the guidelines for the 2014 budget procedure — sections other than the Commission <sup>(2)</sup> and its decision of 10 May 2012 on discharge in respect of the implementation of the general budget of the European Union for the financial year 2010, Section I — European Parliament <sup>(3)</sup>;

91. Welcomes the agreement reached during the conciliation meeting of 24 September 2013 between the Bureau and the Committee on Budgets; points out that the overall level of its 2014 budget is EUR 1 783 976 098, which represents a net reduction of EUR 29 168 108 compared to the preliminary draft estimates of 26 February 2013;

<sup>(1)</sup> Texts adopted, P7\_TA(2012)0359.

<sup>(2)</sup> Texts adopted, P7\_TA(2013)0048.

<sup>(3)</sup> OJ L 286, 17.10.2012, p. 1.

**Wednesday 23 October 2013**

92. Points out that the level of its 2014 budget is 1,9 % above the 2013 budget; notes that the costs for Croatian accession of 0,17 % and the one-off costs for the change of parliamentary term represent 2,1 % of the increase; emphasises that despite the unavoidable costs related to the change of parliamentary term following the European elections of 2014, there is a net decrease of 0,37 % in the operating budget with a further decrease by the expected rate of inflation;

93. Emphasises that appropriations have been included in its budget to partly cover the impending salary adjustments for 2011 and 2012 in light of the pending ruling of the Court of Justice; is deeply concerned about the Council's approach to neither anticipate any appropriations in its own budget nor to maintain the appropriations anticipated in the budget of the other institutions as a precautionary measure to partly cover the budgetary implications that could stem from the Court of Justice's expected ruling; notes that the net decrease of 0,37 % in Parliament's operating budget in 2014 would have been further decreased by 1,3 %, had it not anticipated appropriations to cover the impending salary adjustments for 2011 and 2012 in the event of such a Court of Justice ruling;

94. Approves the following adjustments to the estimates:

- incorporation of the impact of the adoption of the new Staff Regulations and the related changes to the establishment plan;
- the taking into account the savings stemming from the replacement in Luxembourg of the PRES building by the GEOS building;
- reduction in the appropriations for the House of European History due to the contribution of the Commission towards the operating costs and internal savings;
- incorporation of the savings stemming from the implementation of 'paperless Parliament' working methods;
- transfer of the management of Members' pensions under the Statute for Members, like officials' pensions, to the specific budget line under Section III;
- endowing the new DG for Parliamentary Research Services with human and financial resources following the successful conclusions of cooperation agreement with the European Economic and Social Committee and the Committee of the Regions;

*Joint Working Group*

95. Welcomes the continuation of the work of the Joint Bureau — Committee on Budgets working group on Parliament's budget, which has proven useful in the process of reform as a platform for discussion and identification of possible efficiency reserves in order to counter-balance necessary investments to increase Parliament's effectiveness;

96. Recalls the past success of the working group in identifying strategies to achieve savings in Members' travel costs;

97. Maintains that the reforms initiated in the deliberations of the working group, such as the interinstitutional cooperation with the Committee of the Regions and the European Economic and Social Committee, measures to implement a 'paperless Parliament' and e-meetings, a more efficient structure of Parliament's working arrangements and outsourcing of payments and introduction of a new human resources management software, should continue in order to bring real efficiency gains and free up resources to improve independent scientific advice to Members, and to improve Parliament's capacity of scrutiny;

*Staff Regulations reform*

98. Notes that the changes to the Staff Regulations, agreed by Parliament and the Council by means of the ordinary legislative procedure, include a new method of indexation of staff salaries and provide for a freeze of salary adjustment for all institutions, including Parliament, in 2013 and 2014, which creates savings of EUR 14,5 million in Parliament's 2014 budget;

99. Takes into account, furthermore, that other reforms to the Staff Regulations, such as the changes to the rules governing officials' annual travel expenses, will amount to savings of EUR 2,8 million, in addition to the savings of EUR 0,8 million as a result of adjustments to staff career development and the speed of promotions and the creation of a new SC staff function group;

Wednesday 23 October 2013

100. Notes that the Commission's proposal to reduce total staffing level by 1 % per annum in the case of Parliament will result in the deletion of 67 posts in the 2014 establishment plan; takes note of the Secretary General's Note to the Bureau of 2 September 2013 in which the Secretary General does not touch upon the balance between political and administrative support to Members; notes that political groups have frozen their staff resources since 2012 and that their needs were only partially covered in the two preceding budgetary years; insists that the total level of staff in political groups in 2014 and the following years should not be lower than the current level;

101. Reiterates its request expressed in its resolution of 17 April 2013 to present a roadmap for the implementation of the revised Staff Regulations to the Committee on Budgets now that the negotiations between Parliament and the Council have been concluded with an agreement on the Staff Regulations reform;

#### *Cooperation with Advisory Committees*

102. Welcomes the ongoing negotiations and encourages Parliament and the European Economic and Social Committee and the Committee of Regions to develop an interinstitutional cooperation agreement with a view to deeper cooperation;

103. Underlines that the estimated changes to the establishment plans of Parliament, the European Economic and Social Committee and the Committee of the Regions, related to the interinstitutional cooperation agreement being under negotiation, are directly linked to and, consequently, are subject to bringing the political agreement to a final conclusion; is of the opinion that the result of this cooperation can be a gradual transfer of qualified personnel from the Committees' translation services to Parliament's new DG for Parliamentary Research Services (including the respective increase of its establishment plan) of up to 80 posts on a voluntary basis and the respective deletion of a proportionate number of posts in the Committees' establishment plans in the year following the staff transfer;

#### *Contingency reserve*

104. Decides, since neither the start nor the pace of this staff transfer can be established with the adequate degree of precision at the time of the 2014 budget procedure, to add EUR 0,7 million to Parliament's salary line, while placing a proportionate amount of appropriations of the Committees' salary lines in reserve, pending the progress of staff transfer; understands that up to EUR 3,3 million in appropriations could be ultimately transferred from the contingency reserve to the salary line, if needed, subject to the decision of Parliament's competent committee; expects the two advisory committees to reduce an adequate proportion of appropriations in their own budgets, pending the progress of transfer and the underlying political agreement with Parliament;

#### *Transfer of Members' pensions*

105. Is convinced that the management of the pensions of former Members is not part of Parliament's day-to-day operational tasks and the potential growth of pension expenses reduces the transparency of the budget; supports, therefore, the transfer of the management of three types of pensions — retirement, invalidity and survivors' pensions — falling under the Statute for Members to Section III of the Union budget, while continuing to consult and advise Members on pension-related issues; points out that the concentration of the management of pensions in one institution creates administrative efficiencies;

106. Notes that a coherent approach is needed for the provision of information about the European elections of 2014; supports, therefore, the promotion of voter turnout at the 2014 elections, the provision of information about the election date, and awareness-raising among citizens of the Union by informing them about their electoral rights and the impact of the Union on their daily lives in all languages of the Union; believes that an ex post evaluation of the communication strategy for the 2009 and 2014 elections should be undertaken;

#### *Additional savings*

107. Believes that in these times of economic restraint, every effort must be made to scrutinise institutional budgets for potential savings by introducing more practices which do not reduce the Members' quality of work; recalls that visible expressions of self-restraint include the fact that staff mission allowances have not been indexed since 2007 and the freeze on all Members' allowances at the 2011 level until the end of the current parliamentary term; welcomes, moreover, the freeze of all Members' allowances until the end of 2014;

**Wednesday 23 October 2013**

108. Decides, in this spirit, to decrease Parliament's expenditure by EUR 9 658 000 in comparison to the 2014 draft budget;

109. Reduces, in the spirit of self-restraint, the appropriations for delegations and, therefore, the overall number of delegations for Members even further than the cuts decided and implemented in the last two years;

#### ***Sections IV to X***

110. Commends all other institutions on the savings and efficiency gains which they have already incorporated into their draft budgets; restores the salary adjustment for 2011 and 2012, considering the imminent Court of Justice ruling on the matter in line with the principle of prudent and sound financial management;

#### ***Section IV — Court of Justice***

111. Readjusts the standard abatement rate to 3 %, reinstating the appropriations of EUR 1,43 million, in order to allow the full use of the Court of Justice's establishment plan and to ensure that the Court of Justice can deal adequately with the ever-increasing workload;

112. Increases the salary lines of the Court of Justice above the draft budget to account for the 2011 and 2012 staff salary adjustments, which were not initially included in the Court of Justice's budget estimates;

#### ***Section V — Court of Auditors***

113. Restores the draft budget in respect of the amount of the 2011 and 2012 staff salary adjustments having an impact on the 2014 budget, which were removed by the Council in its reading, especially in the light of the Court of Justice's imminent ruling on the matter;

114. Expresses its particular satisfaction that the Court of Auditors has been austere and has found internal efficiency reserves in its draft budget;

#### ***Section VI — European Economic and Social Committee***

115. Restores the draft budget in respect of the amount of the 2011 and 2012 staff salary adjustments having an impact on the 2014 budget, which were removed by the Council in its reading, especially in light of the Court of Justice's imminent ruling on the matter;

116. Welcomes the on-going negotiations between Parliament and the European Economic and Social Committee on a cooperation agreement and encourages its successful completion; places into reserve a part of salary appropriations, pending the signature of cooperation agreement with Parliament and a possible gradual transfer of up to 48 staff members, by inserting an asterisk in the establishment plan indicating that those posts would be deleted in the year following the completion of staff transfer, subject to bringing the final agreement to conclusion;

#### ***Section VII — Committee of the Regions***

117. Restores the draft budget in the amount of 2011 and 2012 staff salary adjustments having an impact on the 2014 budget, which were removed by the Council in its reading, especially in light of the Court of Justice's imminent ruling on the matter;

118. Welcomes the on-going negotiations between Parliament and the Committee of Regions on a cooperation agreement and encourages its successful completion; places into reserve a part of salary appropriations, pending the signature of such cooperation agreement and a possible gradual transfer of up to 32 staff members, by inserting an asterisk in the establishment plan indicating that those posts would be deleted in the year following the completion of staff transfer, subject to bringing the final agreement to conclusion;

119. Restore the level of the draft budget for the travel lines for Members to ensure that the level of political activities is not reduced;

Wednesday 23 October 2013

120. Notes that the European Conservatives and Reformists (ECR) group has set up a new political group in the Committee of the Regions; reminds that every political group should receive administrative support according to its size to facilitate their participation in the political activities of the Committee;

#### **Section VIII — European Ombudsman**

121. Restores the draft budget in the amount of 2011 and 2012 staff salary adjustments having an impact on the 2014 budget, which were removed by the Council in its reading, especially in light of the Court of Justice's imminent ruling on the matter;

122. Recognises the justified approach of the European Ombudsman to carry out the 5 % staff cut over five years according to its own schedule, given the relatively small size of the institution;

#### **Section IX — European Data Protection Supervisor**

123. Restores the draft budget in the amount of 2011 and 2012 staff salary adjustments having an impact on the 2014 budget, which were removed by the Council in its reading, especially in light of the Court of Justice's imminent ruling on the matter;

124. Recognizes the justified approach of the European Data Protection Supervisor to carry out the 5 % staff cut over five years according to its own schedule, given the relatively small size of the body;

#### **Section X — European External Action Service**

125. Restores the draft budget in the amount of 2011 and 2012 staff salary adjustments having an impact on the 2014 budget, which were removed by the Council in its reading, especially in light of the Court of Justice's imminent ruling on the matter;

126. Readjusts the standard abatement rate to 5,3 % (by reinstating the appropriations of circa EUR 0,4 million) in the headquarters and at 2,7 % in the delegations (EUR 0,5 million), in order to reflect progress in recruitments to meet operational needs;

127. Reinforces the appropriations for security in the amount of EUR 5,4 million for secure IT systems and networks and EUR 0,6 million for contract agents;

128. Recognises the aspiration of the EEAS to follow the request of Parliament's Committee on Foreign Affairs to integrate EUSRs and their staff into the budget and institutional structure of the EEAS; notes that in order to enable the transfer of human and financial resources from the Commission to the EEAS budget, a compromise solution with the Commission and the Council must be found and, further, an appropriate legal basis must be adopted; proposes the reinforcement of the EEAS budget and establishment plan;

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129. Instructs its President to forward this resolution to the Council, the Commission, the other institutions and bodies concerned and the national parliaments.

#### ANNEX I

#### JOINT STATEMENT

#### **Dates for the 2014 budgetary procedure and modalities for the functioning of the Conciliation Committee**

A. The European Parliament, the Council and the Commission agree on the following key dates for 2014 budgetary procedure:

1. The Council will endeavour to adopt its position and transmit it to the European Parliament by 11 September 2013, in order to facilitate a timely agreement with the European Parliament;

**Wednesday 23 October 2013**

2. The European Parliament's Committee on Budgets will vote on amendments to the Council's position by the end of week 41 (early October) at the latest;
  3. A trilogue will be called on 16 October 2013 in the afternoon before the reading of the European Parliament;
  4. The European Parliament's Plenary will vote on its reading in week 43;
  5. The Conciliation period will start on 24 October 2013. In agreement with the provisions of Article 314(4)(c) TFEU, the time available for conciliation will expire on 13 November 2013;
  6. The Conciliation Committee will meet on 4 November 2013 in the afternoon hosted by the European Parliament and on 11 November 2013 hosted by the Council; the sessions of the Conciliation Committee will be prepared by trilogues. A trilogue is scheduled on 7 November 2013 in the morning. Additional trilogues may be called during the 21-day conciliation period.
- B. The European Parliament, the Council and the Commission also agree on the modalities for the functioning of the Conciliation Committee set out in the annex, which shall be applicable until the new IIA enters into force.

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## ANNEX II

### **Modalities for the functioning of the Conciliation Committee in the 2014 budgetary procedure**

1. If the EP votes amendments to the Council's position, the President of the Council will, during the same plenary meeting, take note of the differences in the position of the two institutions and give his/her agreement for the President of the EP to convene the Conciliation Committee immediately. The letter convening the Conciliation Committee will be sent on the same day as the plenary vote was delivered and the conciliation period will start on the following day. The 21-day time period is calculated pursuant to Regulation (EEC, Euratom) No 1182/71 determining the rules applicable to periods, dates and time limits.
2. If the Council cannot agree on all the amendments voted by the European Parliament, it will confirm its position by letter sent before the date scheduled for the first Conciliation Committee meeting foreseen in point A.6 of the joint statement. In such case, the Conciliation Committee will proceed in the conditions laid down in the following paragraphs.
3. A common set of documents (input documents) comparing the various steps of the budgetary procedure will be made available to the Conciliation Committee <sup>(1)</sup>. It will include 'line by line' figures <sup>(2)</sup>, totals by financial framework headings and a comparative document both for figures and budgetary remarks with amendments by budget line for all budget lines deemed technically 'open'. These documents will be classified by budgetary nomenclature.

Other documents will also be attached to the input documents for the Conciliation Committee <sup>(3)</sup>.

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<sup>(1)</sup> The various steps will include: 2013 budget (including adopted amending budgets); the initial draft budget; the Council's position on the draft budget; the European Parliament's amendments on the Council's position and the letters of amendment presented by the Commission. For comparison purposes, the initial draft budget will include only those letters of amendment taken into consideration by both the Council's and the European Parliament's readings.

<sup>(2)</sup> Budget lines deemed technically closed will be highlighted in the input material. A budget line deemed technically closed is a line for which there is no disagreement between the European Parliament and the Council, and for which no letter of amendment has been presented, without prejudice to the final decision of the Conciliation Committee.

<sup>(3)</sup> Including a 'letter of executability' of the Commission on the Council's position and the European Parliament's amendments; a letter of amendment for agriculture (and other areas, if need be); possibly, the autumn Budget Forecast Alert Note prepared by the Commission; and possible letters from other Institutions on the Council's position and the European Parliament's amendments.

Wednesday 23 October 2013

4. With a view to reaching agreement by the end of the conciliation period, trilogue(s) will:

- define the scope of the negotiations of the budgetary issues to be addressed;
- discuss outstanding issues identified under the previous indent in view of reaching agreement to be endorsed by the Conciliation Committee;
- address thematic issues, including by headings of the multiannual financial framework, possibly on the basis of working document(s) or non-paper(s).

As far as possible, tentative conclusions will be drawn jointly during or immediately after each trilogue, simultaneously with the agenda of the following meeting. Such conclusions will be registered by the institution hosting the trilogue.

5. Any provisional conclusions of trilogue(s) and a document with the budget lines for which an agreement has been tentatively reached during the trilogue(s) shall be available at the meetings of the Conciliation Committee for possible endorsement.

6. The Commission shall take all the necessary initiatives with a view to reconciling the positions of the European Parliament and the Council. In this perspective, full equality of treatment and information is provided to both the Council and the European Parliament.

7. The joint text provided for in Article 314(5) TFEU shall be established by the secretariats of the European Parliament and of the Council with the assistance of the Commission. It will consist of a letter of transmission addressed to the Presidents of the European Parliament and the Council, containing the date of the agreement at the Conciliation Committee, and annexes, which will include:

- line by line figures for all budget items <sup>(1)</sup> and summary figures by financial framework headings;
- a consolidated document, indicating figures and final text of agreed amendments to the draft budget <sup>(2)</sup> or to Council's position.

The Conciliation Committee may also approve possible joint statements in relation to the 2014 budget.

8. The joint text will be translated in all languages (by the services of the European Parliament) and will be submitted to the approval of the European Parliament and of the Council within 14 days from the date following the date of agreement on the joint text pursuant to point 6.

The budget will be subject to legal-linguistic finalisation after the adoption of the joint text by integrating the annexes of the joint text with the budget lines not modified during the conciliation process.

9. The institution hosting the trilogue or Conciliation Committee meeting will provide interpretation facilities with a full linguistic regime applicable to the Conciliation Committee meetings and an ad hoc linguistic regime for the trilogues.

The institution hosting the meeting will ensure reproduction and distribution of room documents.

The services of the three institutions will cooperate for the encoding of the results of the negotiations in order to finalise the joint text.

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<sup>(1)</sup> Lines not modified with regard to the draft budget or to the Council's position will be highlighted.

<sup>(2)</sup> Including letters of amendment taken into consideration by both the Council's and the European Parliament's readings

**Wednesday 23 October 2013**

10. With a view to completing the work of the Conciliation Committee, the institutions will act in a spirit of loyal cooperation, timely exchanging relevant information and documents at formal and informal level, and regularly maintaining contacts at all levels throughout the entire budgetary procedure through a proactive role of their respective negotiators.

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Wednesday 23 October 2013

P7\_TA(2013)0439

**Application and enforcement of international trade rules \*\*\*I**

**Amendments adopted by the European Parliament on 23 October 2013 on the proposal for a regulation of the European Parliament and of the Council concerning the exercise of the Union's rights for the application and enforcement of international trade rules (COM(2012)0773 — C7-0415/2012 — 2012/0359(COD)) <sup>(1)</sup>**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/24)

**Amendment 1****Proposal for a regulation****Title**

*Text proposed by the Commission*

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the exercise of the Union's rights for the application and enforcement of international trade rules

*Amendment*

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the exercise of the Union's rights for the application and enforcement of international trade rules **and amending Council Regulation (EC) No 3286/94**

**Amendment 2****Proposal for a regulation****Recital 2**

*Text proposed by the Commission*

(2) It is essential that the Union possesses appropriate instruments to ensure the effective exercise of the Union's rights under international trade agreements, in order to safeguard its economic interests. This is particularly the case in situations where third countries enact trade restrictive measures that diminish the benefits accruing to the Union's economic operators under international trade agreements. The Union should be in a position to react swiftly and in a flexible manner in the context of the procedures and deadlines set out by the international trade agreements which it has concluded. The Union should therefore adopt legislation defining the framework for exercising the Union's rights in certain specific situations.

*Amendment*

(2) It is essential that the Union possesses appropriate instruments to ensure the effective exercise of the Union's rights under international trade agreements, in order to safeguard its economic interests. This is particularly the case in situations where third countries enact trade restrictive measures that diminish the benefits accruing to the Union's economic operators under international trade agreements. The Union should be in a position to react swiftly and in a flexible manner in the context of the procedures and deadlines set out by the international trade agreements which it has concluded. The Union should therefore adopt legislation defining the framework for exercising the Union's rights in certain specific situations, **and provide adequate resources to ensure that the resources available are efficiently used for those instruments.**

<sup>(1)</sup> The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0308/2013).

Wednesday 23 October 2013

**Amendment 3**  
**Proposal for a regulation**  
**Recital 2 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (2a) *The measures aimed at ensuring the effective exercise of the Union's rights should be so selected as to take into account their capacity to encourage the third countries concerned to respect not only the rules of international trade but also their capacity to bring relief to those economic operators and Member States that have been most affected by the trade restrictive measures taken by third countries. The measures taken pursuant to this Regulation should not restrict the Union's access to raw materials vital to European industries.*

**Amendment 4**  
**Proposal for a regulation**  
**Recital 3**

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*Text proposed by the Commission*

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*Amendment*

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- (3) The WTO and other, including regional or bilateral, dispute settlement mechanisms aim at finding a positive solution to any disputes arising between the Union and the other party or parties to those agreements. The Union should, nevertheless, suspend concessions or other obligations, in accordance with those dispute settlement rules, when other avenues to find a positive solution to a dispute have proven unsuccessful. Action by the Union in such cases serves the purpose of inducing compliance of the third country concerned with the relevant international trade rules, in order to restore a situation of reciprocal benefits.

- (3) The WTO and other, including regional or bilateral, dispute settlement mechanisms aim at finding a positive solution to any disputes arising between the Union and the other party or parties to those agreements. The Union should, nevertheless, suspend concessions or other obligations, in accordance with those dispute settlement rules, when other avenues to find a positive solution to a dispute have proven unsuccessful. Action by the Union in such cases serves the purpose of inducing compliance of the third country concerned with the relevant international trade rules, in order to restore a situation of reciprocal benefits. ***The Union should always use the most efficient dispute settlement mechanism available.***

Wednesday 23 October 2013

**Amendment 5**  
**Proposal for a regulation**  
**Recital 4**

*Text proposed by the Commission*

- (4) Under the WTO Agreement on Safeguards, a WTO member proposing to apply a safeguard measure or seeking the extension of a safeguard measure should endeavour to maintain a substantially equivalent level of concessions and other obligations between it and the exporting members, which would be adversely affected by such a safeguard measure. Similar rules apply in the context of other, including regional or bilateral international trade agreements concluded by the Union. The Union should take rebalancing measures by suspending concessions or other obligations in cases where the third country concerned implements no **satisfactory** adjustments. Action by the Union in such cases serves the purpose of inducing the introduction of trade-enhancing measures by third countries in order to restore a situation of reciprocal benefits.

*Amendment*

- (4) Under the WTO Agreement on Safeguards, a WTO member proposing to apply a safeguard measure or seeking the extension of a safeguard measure should endeavour to maintain a substantially equivalent level of concessions and other obligations between it and the exporting members, which would be adversely affected by such a safeguard measure. Similar rules apply in the context of other, including regional or bilateral international trade agreements concluded by the Union. The Union should take rebalancing measures by suspending concessions or other obligations in cases where the third country concerned implements no **adequate and proportionate** adjustments. Action by the Union in such cases serves the purpose of inducing the introduction of trade-enhancing measures by third countries in order to restore a situation of reciprocal benefits.

**Amendment 6**  
**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

- (5) Article XXVIII of the GATT 1994 and the related Understanding govern the modification or withdrawal of concessions established in the tariff schedules of WTO Members. WTO members affected by any such modification are entitled, under certain conditions, to withdraw substantially equivalent concessions. The Union should adopt rebalancing measures in such cases, unless compensatory adjustments are agreed. Action by the Union would be aimed at inducing third countries to implement **trade-enhancing** measures.

*Amendment*

- (5) Article XXVIII of the GATT 1994 and the related Understanding **and Article XXI of the General Agreement on Trade in Services (GATS) and related procedures for its implementation** govern the modification or withdrawal of concessions **and commitments** established in the tariff schedules **and the schedule of specific commitments** of WTO Members. WTO members affected by any such modification are entitled, under certain conditions, to withdraw substantially equivalent concessions **or commitments**. The Union should adopt rebalancing measures in such cases, unless compensatory adjustments are agreed. Action by the Union would be aimed at inducing third countries to implement measures **restoring reciprocal advantages and enhancing trade**.

Wednesday 23 October 2013

**Amendment 7**  
**Proposal for a regulation**  
**Recital 6**

Text proposed by the Commission

- (6) **The Union *should have* the possibility to enforce its rights in the area of government procurement *in view of the fact that* the WTO Agreement on Government Procurement *states that any dispute arising thereunder shall not result in the suspension of concessions or other obligations under any other covered agreement of the WTO.***

Amendment

- (6) ***It is essential for the Union to have* the possibility to **swiftly** enforce its rights in the area of government procurement **when a party fails to respect its commitments under** the WTO Agreement on Government Procurement **or under any bilateral or regional binding agreements.** *The Union's action should be aimed at ensuring the maintenance of a substantially equivalent level of concessions in the field of government procurement.***

**Amendment 8**  
**Proposal for a regulation**  
**Recital 7**

Text proposed by the Commission

- (7) This Regulation should **focus on those measures where** the Union **has experience in their design and application;** the possibility to extend the scope of this Regulation to the sectors of services and intellectual property rights should be **assessed in due time with regard to the specificities of each area.**

Amendment

- (7) This Regulation should **make it possible for the Union to establish a complete and effective framework to enable measures to be taken without delay.** However, the possibility to extend its scope with new measures covering new trade areas, such as intellectual property rights, should be **considered as part of a study carried out at the same time as the evaluation report on the functioning of this Regulation referred to in Article 10, and should be presented to the European Parliament .**

**Amendment 9**  
**Proposal for a regulation**  
**Recital 9**

Text proposed by the Commission

- (9) The Commission should evaluate the functioning of this Regulation no later than **three** years after the first instance of **its implementation** with a view to assessing and, if necessary, improving its efficiency.

Amendment

- (9) The Commission should evaluate the functioning of this Regulation no later than **five** years after the first instance of **adoption of an implementing act under this Regulation** with a view to assessing its implementation and, if necessary, improving its efficiency. **The Commission should include in its reports on the Europe 2020 Strategy an analysis of the relevance of this Regulation, particularly as regards its ability to remove barriers to trade.**

Wednesday 23 October 2013

**Amendment 10**  
**Proposal for a regulation**  
**Recital 9 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (9a) *The Commission should regularly inform the European Parliament when it intends to implement commercial policy measures pursuant to this Regulation. That information should entail a detailed description of the specific case and of the envisaged measures, of the damage incurred by Union industry, the justification for and the possible impact of the envisaged measures. After the measures have been taken, the Commission should inform the European Parliament of the actual impact of the measures.*

**Amendment 11**  
**Proposal for a regulation**  
**Recital 9 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (9b) *When assessing the Union's general interest in respect of the adoption of enforcement measures, while pursuing a balanced approach, the Commission should take particular account of the situation of the Union's producers. The Commission should inform the European Parliament of how it has determined the Union's general interest on a case-by-case basis.*

**Amendment 12**  
**Proposal for a regulation**  
**Recital 10 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (10a) *The Commission should keep the European Parliament regularly informed, particularly when the Union has referred a matter to a dispute settlement body. After each decision by a dispute settlement body authorising the Union to take measures, the Commission should appear before the European Parliament's committee responsible for international trade to give an account of its intention to take or withhold from taking such measures. If the Union decides to take measures, the Commission should appear before the European Parliament to give an account of the measures selected.*

Wednesday 23 October 2013

**Amendment 13**  
**Proposal for a regulation**  
**Recital 13 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(13a) ***At the request of the European Parliament, the Commission should regularly participate in the Dispute Settlement and Enforcement Dialogue provided for in this Regulation.***

**Amendment 14**  
**Proposal for a regulation**  
**Article 1 — introductory part**

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*Text proposed by the Commission*

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*Amendment*

This Regulation lays down rules and procedures in order to ensure an effective exercise of the Union's rights to suspend or withdraw concessions or other obligations under international trade agreements, with the aim of:

This Regulation lays down rules and procedures in order to ensure an effective ***and timely*** exercise of the Union's rights to suspend or withdraw concessions or other obligations under international trade agreements, with the aim of:

**Amendment 15**  
**Proposal for a regulation**  
**Article 1 — point a**

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*Text proposed by the Commission*

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*Amendment*

(a) responding to breaches by third countries of international trade rules which affect the interests of the Union, with a view to seeking a satisfactory solution.

(a) responding to breaches by third countries of international trade rules which affect the interests of the Union, with a view to seeking a satisfactory solution ***that provides relief to the affected economic operators of the Union.***

**Amendment 16**  
**Proposal for a regulation**  
**Article 1 — point b**

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*Text proposed by the Commission*

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*Amendment*

(b) rebalancing concessions or other obligations in the trade relations with third countries, when the ***import*** treatment accorded to goods from the Union is altered.

(b) rebalancing concessions or other obligations in the trade relations with third countries, when the treatment accorded to goods ***or services*** from the Union is altered.

Wednesday 23 October 2013

**Amendment 17**  
**Proposal for a regulation**  
**Article 2 — point b**

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*Text proposed by the Commission*

- (b) 'concessions or other obligations' means tariff concessions or any other benefits that the Union committed to apply in its trade with third countries by virtue of international trade agreements to which it is a party,

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*Amendment*

- (b) 'concessions or other obligations' means tariff concessions, **specific commitments in the field of services** or any other benefits that the Union committed to apply in its trade with third countries by virtue of international trade agreements to which it is a party,

**Amendment 18**  
**Proposal for a regulation**  
**Article 3 — paragraph 1 — point d**

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*Text proposed by the Commission*

- (d) in cases of modification of concessions by a WTO member under Article XXVIII of the General Agreement on Tariffs and Trade 1994, where no compensatory adjustments have been agreed.

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*Amendment*

- (d) in cases of modification of concessions **or commitments** by a WTO member under Article XXVIII of the General Agreement on Tariffs and Trade 1994 **or Article XXI of the GATS**, where no compensatory adjustments have been agreed.

**Amendment 19**  
**Proposal for a regulation**  
**Article 4 — paragraph 1**

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*Text proposed by the Commission*

1. Where action is necessary to safeguard the interests of the Union in the cases referred to in Article 3(1), the Commission shall adopt an implementing act determining the appropriate commercial policy measures. Such implementing act shall be adopted in accordance with the examination procedure referred to in Article 8(2).

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*Amendment*

1. Where action is necessary to safeguard the interests of the Union in the cases referred to in Article 3(1), the Commission shall adopt an implementing act determining the appropriate commercial policy measures. Such implementing act shall be adopted in accordance with the examination procedure referred to in Article 8(2). **The Commission shall duly justify to the European Parliament the choice of commercial policy measures provided for in Article 5.**

Wednesday 23 October 2013

## Amendment 20

## Proposal for a regulation

## Article 4 — paragraph 2 — point d

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*Text proposed by the Commission*

- (d) Concessions withdrawn in the trade with a third country in connection with Article XXVIII of the GATT 1994 and the related Understanding shall be substantially equivalent to the concessions modified or withdrawn by that third country, in accordance with the terms established in Article XXVIII of the GATT 1994 and the related Understanding.

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*Amendment*

- (d) Concessions **or commitments modified or** withdrawn in the trade with a third country in connection with Article XXVIII of the GATT 1994 and the related Understanding **or Article XXI of the GATS and related implementing procedures** shall be substantially equivalent to the concessions **or commitments** modified or withdrawn by that third country, in accordance with the terms established in Article XXVIII of the GATT 1994 and the related Understanding **or Article XXI of the GATS and related implementing procedures**.

## Amendment 21

## Proposal for a regulation

## Article 4 — paragraph 3 — point b

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*Text proposed by the Commission*

- (b) potential of the measures to provide relief to economic operators within the Union affected by third country measures;

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*Amendment*

- (b) potential of the measures to provide relief to **Member States and** economic operators within the Union affected by third country measures;

## Amendment 22

## Proposal for a regulation

## Article 4 — paragraph 3 — point c

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*Text proposed by the Commission*

- (c) availability of alternative sources of supply for the products concerned, in order to avoid or minimise any negative impact on downstream industries or final consumers within the Union;

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*Amendment*

- (c) availability of alternative sources of supply for the products **or services** concerned, in order to avoid or minimise any negative impact on downstream industries or final consumers within the Union;

## Amendment 23

## Proposal for a regulation

## Article 4 — paragraph 3 a (new)

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*Text proposed by the Commission*

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*Amendment*

- 3a. The Commission shall outline in its proposal for an implementing act how it has determined the Union's general interest in the specific case in question.**

Wednesday 23 October 2013

## Amendment 24

## Proposal for a regulation

## Article 5 — point b a (new)

Text proposed by the Commission

Amendment

(ba) *the suspension of the application of obligations and specific commitments in the area of trade in services, with respect to the GATS or any bilateral and regional agreements;*

## Amendment 25

## Proposal for a regulation

## Article 5 — point c — point i

Text proposed by the Commission

Amendment

(i) the exclusion from public procurement of tenders the total value of which is made up for more than 50 % of goods or services originating in the third country concerned; and/or

(i) the exclusion from public procurement of tenders the total value of which is made up for more than 50 % of goods or services originating in the third country concerned; **implementing acts may set thresholds, according to the characteristics of the goods or services concerned, above which the exclusion is to apply, taking into account the provisions of Article 4(3), including considerations regarding administrative capacity, and the level of nullification or impairment;** and/or

## Amendment 26

## Proposal for a regulation

## Article 5 — paragraph 1 a (new)

Text proposed by the Commission

Amendment

**The Commission shall duly justify to the European Parliament the choice of the specific commercial policy measures adopted pursuant to this Article.**

## Amendment 27

## Proposal for a regulation

## Article 7 — paragraph 1

Text proposed by the Commission

Amendment

1. Where, subsequently to the adoption of an implementing act pursuant to Article 4(1), the third country concerned accords **satisfactory** compensation to the Union in the cases referred to in Article 3(1)(a) and (b), the Commission may suspend the application of that implementing act for the duration of the compensation period. The suspension shall be decided in accordance with the examination procedure referred to in Article 8(2).

1. Where, subsequently to the adoption of an implementing act pursuant to Article 4(1), the third country concerned accords **adequate and proportionate** compensation to the Union in the cases referred to in Article 3(1) (a) and (b), the Commission may suspend the application of that implementing act for the duration of the compensation period. The suspension shall be decided in accordance with the examination procedure referred to in Article 8(2).

Wednesday 23 October 2013

## Amendment 28

## Proposal for a regulation

## Article 7 — paragraph 2 — point b

Text proposed by the Commission

- (b) in cases of rebalancing of concessions or other obligations following the adoption by a third country of a safeguard measure, when the safeguard measure is withdrawn or expires, or when the third country concerned accords **satisfactory** compensation to the Union subsequently to the adoption of an implementing act under Article 4(1);

Amendment

- (b) in cases of rebalancing of concessions or other obligations following the adoption by a third country of a safeguard measure, when the safeguard measure is withdrawn or expires, or when the third country concerned accords **adequate and proportionate** compensation to the Union subsequently to the adoption of an implementing act under Article 4(1);

## Amendment 29

## Proposal for a regulation

## Article 7 — paragraph 2 — point c

Text proposed by the Commission

- (c) in cases of modification of concessions by a WTO member under Article XXVIII of the *General Agreement on Tariffs and Trade* 1994, when the third country concerned accords satisfactory compensation to the Union subsequently to the adoption of an implementing act under Article 4(1).

Amendment

- (c) in cases of **withdrawal or** modification of concessions **or commitments** by a WTO member under Article XXVIII of the GATT 1994 **or Article XXI of the GATS**, when the third country concerned accords **adequate and proportionate** compensation to the Union subsequently to the adoption of an implementing act under Article 4(1).

## Amendment 30

## Proposal for a regulation

## Article 7 — paragraph 4 a (new)

Text proposed by the Commission

Amendment

- 4a. The Commission shall duly justify to the European Parliament when it envisages suspending, modifying or terminating a measure provided for in Article 5.**

## Amendment 31

## Proposal for a regulation

## Article 9 — paragraph 1

Text proposed by the Commission

1. The Commission shall seek information and views regarding the Union's economic interests in specific products or sectors, in the application of this Regulation, through a notice in the Official Journal of the European Union or other suitable public communication means.

Amendment

1. The Commission shall seek information and views regarding the Union's economic interests in specific products, **services** or sectors, in the application of this Regulation, through a notice in the Official Journal of the European Union or other suitable public communication means **and shall take those views into account.**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

*The notice shall indicate the period within which the information is to be submitted. That period shall not exceed two months.*

## Amendment 32

## Proposal for a regulation

## Article 9 — paragraph 2

Text proposed by the Commission

Amendment

2. Information received pursuant to this Regulation shall be used only for the purpose for which it was requested.

2. Information received pursuant to this Regulation shall be used only for the purpose for which it was requested. **The Commission shall duly inform the European Parliament of the outcome of such information gathering and how it intends to take account of the information when determining the Union's general interest.**

## Amendment 33

## Proposal for a regulation

## Article 9 — paragraph 4

Text proposed by the Commission

Amendment

4. The supplier of information may request that information supplied be treated as confidential. In such cases, it shall be accompanied by a non-confidential summary or a statement of the reasons why the information cannot be summarised.

4. The supplier of information may request that information supplied be treated as confidential. In such cases, it shall be accompanied by a non-confidential summary **which presents the information in a generalised form** or a statement of the reasons why the information cannot be summarised.

## Amendment 34

## Proposal for a regulation

## Article 9 a (new)

Text proposed by the Commission

Amendment

## Article 9a

**Dispute settlement and enforcement dialogue**

**The Commission shall regularly participate in an exchange of views with the European Parliament's Committee responsible for international trade on the management of trade disputes, including ongoing cases, effects on Union industries, envisaged measures, justification and impact of the envisaged measures, and on the implementation of commercial policy measures pursuant to this Regulation.**

Wednesday 23 October 2013

**Amendment 35**  
**Proposal for a regulation**  
**Article 10**

*Text proposed by the Commission*

No later than **three** years after the first instance of adoption of an implementing act under this Regulation, the Commission shall review its implementation and report to the European Parliament and the Council.

*Amendment*

No later than **five** years after the first instance of adoption of an implementing act under this Regulation, the Commission shall review its implementation and report to the European Parliament and the Council.

Wednesday 23 October 2013

P7\_TA(2013)0440

**Trade between the Community and third countries in drug precursors \*\*\*I**

**European Parliament legislative resolution of 23 October 2013 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (COM(2012)0521 — C7-0316/2012 — 2012/0250(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/25)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0521),
  - having regard to Article 294(2) and Article 207 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0316/2012),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the undertaking given by the Council representative by letter of 16 July 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on International Trade (A7-0167/2013),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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**P7\_TC1-COD(2012)0250**

**Position of the European Parliament adopted at first reading on 23 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1259/2013.)*

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Wednesday 23 October 2013

P7\_TA(2013)0441

## European Maritime and Fisheries Fund \*\*\*I

**Amendments adopted by the European Parliament on 23 October 2013 on the amended proposal for a regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund repealing Council Regulation (EC) No 1198/2006 and Council Regulation (EC) No 861/2006 and Council Regulation No XXX/2011 on integrated maritime policy (COM(2013)0245 — C7-0108/2013 — 2011/0380(COD))** <sup>(1)</sup>

(Ordinary legislative procedure: first reading)

(2016/C 208/26)

### Amendment 1

#### Draft legislative resolution

#### Paragraph 1 a (new)

Text proposed by the Commission

Amendment

**1a. Recalls that, in its resolution of 8 June 2011,<sup>(1)</sup> Parliament stressed that fisheries resources constitute a public good vital for global food security; it pointed to the fact that the fisheries and aquaculture sector and related activities are often the main source of livelihood and sustainable employment in coastal, island and remote regions; it furthermore considered that, in order to achieve its medium and long-term goals (stable, sustainable and viable fisheries sector), to recover its fish stocks and to tackle the social aspects linked to the reduction of fishing effort, the reformed Common Fisheries Policy (CFP) will need adequate financial resources after 2013;**

<sup>(1)</sup> Texts adopted, P7\_TA(2011)0266.

### Amendment 2

#### Proposal for a regulation

#### Citation 1

Text proposed by the Commission

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 42, Article 43(2), Article 91(1), Article 100(2), Article 173(3), Article 175, Article 188, Article 192(1), Article 194(2) **and** Article 195(2) thereof,

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 42, Article 43(2), Article 91(1), Article 100(2), Article 173(3), Article 175, Article 188, Article 192(1), Article 194(2), Article 195(2) **and Article 349** thereof,

<sup>(1)</sup> The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0282/2013).

Wednesday 23 October 2013

**Amendment 3**  
**Proposal for a regulation**  
**Recital 1 a (new)**

Text proposed by the Commission

Amendment

- (1a) *The fisheries sector is of strategic importance for the socio-economic situation, for the public supply of fish and for the food balance of the different Member States and of the Union, as well as its considerable contribution to the socio-economic well-being of coastal communities, to local development, to employment, to the maintenance/creation of economic activities and of jobs both upstream and downstream, to the supply of fresh fish and to the maintenance of local cultural traditions;*

**Amendment 4**  
**Proposal for a regulation**  
**Recital 2**

Text proposed by the Commission

Amendment

- (2) The scope of the EMFF should cover the support of the CFP which extends to conservation, management and exploitation of marine biological resources, fresh water biological resources and– aquaculture, as well as to the processing and marketing of fishery and aquaculture products, where such activities take place on the territory of Member States, or in Union waters, **including by fishing vessels flying the flag of, and registered in, third countries**, or by Union fishing vessels, or by nationals of Member States, without prejudice to the primary responsibility of the flag State, bearing in mind the provisions of Article 117 of the United Nations Convention on the Law of the Sea.

- (2) The scope of the EMFF should cover the support of the CFP which extends to conservation, management and **sustainable** exploitation of marine biological resources, fresh water biological resources and aquaculture, as well as to the processing and marketing of fishery and aquaculture products, where such activities take place on the territory of Member States, or in Union waters, or by Union fishing vessels, or by nationals of Member States, without prejudice to the primary responsibility of the flag State, bearing in mind the provisions of Article 117 of the United Nations Convention on the Law of the Sea.

**Amendment 5**  
**Proposal for a regulation**  
**Recital 2 a (new)**

Text proposed by the Commission

Amendment

- (2a) *It should be stressed that the CFP is a food-related policy, justifying public intervention through the EMFF in order to maintain the food security of citizens of the Union.*

Wednesday 23 October 2013

**Amendment 6**  
**Proposal for a regulation**  
**Recital 2 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (2b) *The EMFF should take full account of the specific situation of the outermost regions pursuant to Article 349 TFEU. The situation of the outermost regions and the specific nature of the fisheries sector in them means that the CFP and the associated funds, in particular the EMFF, should be adapted to the specific features, constraints, additional costs and realities of those regions, which profoundly differ from the rest of the Union. To that end, specific measures should be authorised for these regions.*

**Amendment 7**  
**Proposal for a regulation**  
**Recital 2 c (new)**

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*Text proposed by the Commission*

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*Amendment*

- (2c) *The future EMFF should make full allowance for the problems and specific needs of small scale fisheries, bearing in mind that, in the Union, the small scale fleet is the one which employs the greatest number of people per fish caught.*

**Amendment 8**  
**Proposal for a regulation**  
**Recital 3**

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*Text proposed by the Commission*

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*Amendment*

- (3) The success of the Common Fisheries Policy depends on an effective system of control, inspection and enforcement as well as on reliable complete data, both for scientific advice and for implementation and control purposes; therefore the EMFF should support these policies.

- (3) The success of the Common Fisheries Policy depends on an effective system of control, inspection, **including workplace inspections** and enforcement as well as on reliable complete data, both for scientific advice and for implementation and control purposes; therefore the EMFF should support these policies.

Wednesday 23 October 2013

**Amendment 9**  
**Proposal for a regulation**  
**Recital 3 a (new)**

Text proposed by the Commission

Amendment

- (3a) *In order to foster in fishermen a sense of ownership of the CFP, thereby contributing to the correct implementation and the overall success of the CFP, the EMFF should support partnership, cooperation and dialogue between scientists and fishermen.*

**Amendment 10**  
**Proposal for a regulation**  
**Recital 4**

Text proposed by the Commission

Amendment

- (4) The scope of the EMFF should cover the support to the IMP which extends to the development and implementation of coordinated operations and decision-making in relation to the oceans, seas, coastal regions and maritime sectors complementing the different EU policies that touch upon them, notably the Common Fisheries Policies, transport, industry, territorial cohesion, environment, energy and tourism. Coherence and integration should be ensured in the management of different sectoral policies within the Baltic Sea, North Sea, Celtic Seas, Bay of Biscay and the Iberian Coast, Mediterranean and Black Sea sea basins.

- (4) The scope of the EMFF should cover the support to the IMP which extends to the development and implementation of coordinated operations and decision-making in relation to the oceans, seas, coastal regions and maritime sectors complementing the different EU policies that touch upon them, notably the Common Fisheries Policies, transport, industry, territorial cohesion, environment, energy and tourism, **areas for which it is necessary to promote scientific research, professional competence and training.** Coherence and integration should be ensured in the management of different sectoral policies within the Baltic Sea, North Sea, Celtic Seas, Bay of Biscay and the Iberian Coast, Mediterranean and Black Sea sea basins.

**Amendment 11**  
**Proposal for a regulation**  
**Recital 4 a (new)**

Text proposed by the Commission

Amendment

- (4a) *When defining and implementing the policies and actions relating to the reform of the CFP, IMP and EMFF, the Union should take into account requirements linked to the promotion of a high level of employment, a guarantee of adequate social protection, the fight against social exclusion and a high level of education, training and protection of human health, in accordance with Article 9 TFEU.*

Wednesday 23 October 2013

**Amendment 12**  
**Proposal for a regulation**  
**Recital 5**

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*Text proposed by the Commission*

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- (5) In line with the conclusions of the European Council of 17 June 2010, whereby the Europe 2020 Strategy was adopted, the Union and Member States should implement the delivery of smart, sustainable and inclusive growth, while promoting harmonious development of the Union. In particular, resources should be concentrated to meet the Europe 2020 objectives and targets and effectiveness should be improved by an increased focus on results. The inclusion of the IMP in the new EMFF also contribute to the major policy objectives set out in the Communication from the Commission of 3 March 2010 'Europe 2020 — A strategy for smart, sustainable and inclusive growth ('Europe 2020 Strategy') and is in line with the general objectives to increase economic, social and territorial cohesion set out in the Treaty.

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*Amendment*

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- (5) In line with the conclusions of the European Council of 17 June 2010, whereby the Europe 2020 Strategy was adopted, the Union and Member States should implement the delivery of smart, sustainable and inclusive growth, while promoting harmonious development of the Union. In particular, resources should be concentrated to meet the Europe 2020 objectives and targets, **and in particular those linked to employment and the fight against poverty, social exclusion and climate change. Furthermore,** effectiveness should be improved by an increased focus on results. The inclusion of the IMP in the new EMFF also contribute to the major policy objectives set out in the Communication from the Commission of 3 March 2010 'Europe 2020 — A strategy for smart, sustainable and inclusive growth ('Europe 2020 Strategy') and is in line with the general objectives to increase economic, social and territorial cohesion set out in the Treaty.

**Amendment 13**  
**Proposal for a regulation**  
**Recital 6**

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*Text proposed by the Commission*

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- (6) To ensure that the EMFF contributes to the achievement of the objectives of the CFP, the IMP and the Europe 2020 Strategy, it is necessary to **focus on a limited number** of core priorities relating to fostering innovation and knowledge based fisheries and aquaculture, promoting sustainable and resource-efficient fishing and aquaculture, and increasing employment and territorial cohesion by unlocking the growth and job potential of coastal and inland fisheries communities and promoting diversification of fisheries activities into other sectors of the marine economy.

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*Amendment*

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- (6) To ensure that the EMFF contributes to the achievement of the objectives of the CFP, the IMP and the Europe 2020 Strategy, it is necessary to **identify a range** of core priorities relating to fostering innovation and knowledge based fisheries and aquaculture, promoting sustainable and resource-efficient fishing and aquaculture, and increasing employment and territorial cohesion by unlocking the growth and job potential of coastal and inland fisheries communities and promoting diversification of fisheries activities into other sectors of the marine economy.

Wednesday 23 October 2013

**Amendment 14**  
**Proposal for a regulation**  
**Recital 7 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (7a) *The EMFF should contribute to improving the standards of living of those who depend on fishing, guaranteeing better working standards for fishermen, in particular through ensuring compliance with legislation on health and safety in the workplace and with the provisions of collective labour agreements.*

**Amendment 15**  
**Proposal for a regulation**  
**Recital 7 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (7b) *In order to avoid confusion about the application and impact of specific financial measures of the EMFF on the various stakeholders who participate in the fishing sector, it is useful to introduce a clear distinction between ship owners and wage-earning fishermen, as has already been set forth in ILO Convention No 188.*

**Amendment 16**  
**Proposal for a regulation**  
**Recital 8**

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*Text proposed by the Commission*

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*Amendment*

- (8) The overall objective of the Common Fisheries Policy is to ensure that fishing and aquaculture activities contribute to long-term sustainable **environmental conditions which are necessary for economic and social** development. It should contribute moreover to increased productivity, a fair standard of living for the fisheries sector, stable markets, ensure the availability of resources and that supplies reach consumers at reasonable prices.

- (8) The overall objective of the Common Fisheries Policy is to ensure that fishing and aquaculture activities contribute to long-term **economically, socially and environmentally** sustainable development. It should contribute moreover to increased productivity, a fair standard of living for the fisheries sector, stable markets, ensure the availability of resources and that supplies reach consumers at reasonable prices.

Wednesday 23 October 2013

**Amendment 17**  
**Proposal for a regulation**  
**Recital 9**

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*Text proposed by the Commission*

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- (9) It is paramount to better integrate environmental concerns into the CFP which should deliver on the objectives and targets of the Union's environmental policy and the Europe 2020 Strategy. The CFP is aimed at an exploitation of living marine biological resources that restores and maintains fish stocks at levels which can produce the maximum sustainable yield, **not later than 2015**. The CFP **should** implement the **precautionary and eco-system approaches to fisheries management**. Consequently the EMFF should contribute to the protection of the marine environment as set out in the Directive 2008/56/EC of the European Parliament and the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)

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*Amendment*

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- (9) It is paramount to better integrate environmental concerns into the CFP which should deliver on the objectives and targets of the Union's environmental policy and the Europe 2020 Strategy. The CFP is aimed at an exploitation of living marine biological resources that restores and maintains fish stocks at levels which can produce the maximum sustainable yield **by 2015, where possible, and in any event by 2020**. The CFP **should** implement **a balanced approach to sustainable development, which it should achieve through fisheries planning, exploitation and management which takes into account aspirations and current social needs, without undermining the advantages that future generations should be able to derive from all the goods and services arising from marine eco-systems**. Consequently the EMFF should contribute to the protection of the marine environment as set out in the Directive 2008/56/EC of the European Parliament and the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)

**Amendment 18**  
**Proposal for a regulation**  
**Recital 9 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (9a) **The measures financed through the EMFF should comply with Articles 39 and 41 TFEU, which refer to a balanced approach in the use of labour law and effective coordination as regards vocational training.**

Wednesday 23 October 2013

**Amendment 19**  
**Proposal for a regulation**  
**Recital 10**

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*Text proposed by the Commission*

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- (10) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States given the scale and effects of the operations to be financed under the operational programmes and the structural problems encountered in the development of the fisheries and maritime sectors as well as the limited financial resources of the Member States, these objectives can therefore be better achieved at Union level by providing multi-annual financial assistance focused on the relevant priorities, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on the European Union. In accordance with the principle of proportionality as set out in Article 5(4) of that Treaty, this Regulation does not go beyond what is necessary in order to achieve that objective.

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*Amendment*

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- (10) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States given the scale and effects of the operations to be financed under the operational programmes and the structural problems encountered in the development of the fisheries, **aqua-culture** and maritime sectors as well as the limited financial resources of the Member States, these objectives can therefore be better achieved at Union level by providing multi-annual financial assistance focused on the relevant priorities, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on the European Union. In accordance with the principle of proportionality as set out in Article 5(4) of that Treaty, this Regulation does not go beyond what is necessary in order to achieve that objective.

**Amendment 20**  
**Proposal for a regulation**  
**Recital 11**

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*Text proposed by the Commission*

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- (11) The financing of the Common Fisheries Policy and Maritime Integrated Policy expenditure through a single fund, the EMFF, should address the need for simplification as well as strengthening the integration of both policies. The extension of shared management to Common Markets Organisations including the compensation for the outermost regions, control and data collection activities should further contribute to simplification and reduce the administrative burden both for the Commission and the Member States as well as achieve greater coherence and efficiency of the support granted.

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*Amendment*

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- (11) The financing of the Common Fisheries Policy and Maritime Integrated Policy expenditure through a single fund, the EMFF, should address the need for simplification as well as strengthening the integration of both policies. The extension of shared management to Common Markets Organisations including the compensation for the outermost regions, control and data collection **and management** activities should further contribute to simplification and reduce the administrative burden both for the Commission and the Member States as well as achieve greater coherence and efficiency of the support granted.

Wednesday 23 October 2013

**Amendment 21**  
**Proposal for a regulation**  
**Recital 11 a (new)**

*Text proposed by the Commission*

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*Amendment*

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- (11a) *The financing should be as defined in point 17 of the Interinstitutional Agreement of XX/201z between the European Parliament, the Council and the Commission on cooperation in budgetary matters and sound financial management.*

**Amendment 22**  
**Proposal for a regulation**  
**Recital 11 b (new)**

*Text proposed by the Commission*

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*Amendment*

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- (11b) *Any financing should be without prejudice to the provisions of the Regulation laying down the multi-annual financial framework for the years 2014–2020 and the Interinstitutional Agreement of xxx/201z between the European Parliament, the Council and the Commission on cooperation in budgetary matters and sound financial management.*

Wednesday 23 October 2013

**Amendment 23**  
**Proposal for a regulation**  
**Recital 12**

*Text proposed by the Commission*

- (12) The Union budget should finance the Common Fisheries Policy and the Integrated Maritime Policy expenditure through a single fund, the EMFF, either directly or in the context of shared management with the Member States. Shared management with the Member States should apply not only to measures to support fisheries, aquaculture and community-led local development but also to **Common Markets Organisations** and the compensation for the outermost regions, control and data collection activities. Direct management should apply to scientific advice, voluntary contributions to Regional Fisheries Management Organisations, advisory councils and operations for the implementation of an Integrated Maritime Policy. The types of measures that can be financed using the EMFF should be specified.

*Amendment*

- (12) The Union budget should finance the Common Fisheries Policy and the Integrated Maritime Policy expenditure through a single fund, the EMFF, either directly or in the context of shared management with the Member States. Shared management with the Member States should apply not only to measures to support fisheries, aquaculture and community-led local development but also to **marketing and processing measures and to the compensation for the outermost regions, control and data collection activities**. Direct management should apply to **the preparation of production and marketing plans, storage aid**, scientific advice, voluntary contributions to Regional Fisheries Management Organisations, advisory councils and operations for the implementation of an Integrated Maritime Policy. The types of measures that can be financed using the EMFF should be specified.

**Amendment 24**  
**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

- (14) According to Articles 50 and 51 of the [Regulation on the Common Fisheries Policy] (hereinafter CFP Regulation) Union financial assistance under EMFF should be made conditional upon compliance by Member States as well as by operators with the rules of the CFP. This conditionality is intended to reflect the responsibility of the Union to ensure, in public interest, conservation of marine biological resources under the CFP, as enshrined in **Article 3** of the TFEU.

*Amendment*

- (14) According to Articles 50 and 51 of the [Regulation on the Common Fisheries Policy] (hereinafter CFP Regulation) Union financial assistance under EMFF should be made conditional upon compliance by Member States as well as by operators with the rules of the CFP. This conditionality is intended to reflect the responsibility of the Union to ensure, in **the public interest, the conservation of marine biological resources under the CFP, as well as to ensure respect for requirements linked to the promotion of a high level of employment and to guarantee of adequate social protection**, as enshrined in **Articles 3 and 9 respectively** of the TFEU.

Wednesday 23 October 2013

**Amendment 25**  
**Proposal for a regulation**  
**Recital 15**

Text proposed by the Commission

- (15) The achievement of the objectives of the CFP would be undermined if Union financial assistance under EMFF is disbursed to operators who, ex-ante, do not comply with requirements related to the public interest of conservation of marine biological resources. Therefore **only** operators should be admissible **who**, within a particular period of time before lodging an application for aid, were not involved in the operation, management or ownership of fishing vessels included in the Union IUU vessel list as set out in Article 40(3) of Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulation (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999, **and who** have not committed a serious infringement under 42 of the Regulation (EC) No 1005/2008 or Article 90(1) of the Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006. or other cases of non-compliance with CFP rules which particularly jeopardise the sustainability of the stocks concerned and constitute a serious threats to the sustainable exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the Maximum Sustainable Yield (hereinafter MSY).

Amendment

- (15) The achievement of the objectives of the CFP would be undermined if Union financial assistance under EMFF is disbursed to operators who, ex-ante, do not comply with requirements related to the public interest of conservation of marine biological resources. Therefore operators should **only** be admissible **on condition that**, within a particular period of time before lodging an application for aid, **they** were not involved in the operation, management or ownership of fishing vessels included in the Union IUU vessel list as set out in Article 40(3) of Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulation (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999, **and they were not involved in the operation, management or ownership of fishing vessels flagged to countries identified as non-cooperating third countries as referred to in Article 33 of Regulation (EC) No 1005/2008. Equally, operators should only be admissible on condition that they** have not committed a serious infringement under **Article 42** of the Regulation (EC) No 1005/2008 or Article 90(1) of the Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006. or other cases of non-compliance with CFP rules which particularly jeopardise the sustainability of the stocks concerned and constitute a serious threats to the sustainable exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the Maximum Sustainable Yield (hereinafter MSY).

Wednesday 23 October 2013

**Amendment 26**  
**Proposal for a regulation**  
**Recital 17**

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*Text proposed by the Commission*

- (17) The consequences laid down for the failure to fulfil the eligibility conditions should apply in case of infringements of the CFP rules by the beneficiaries. In order to determine the amount of ineligible expenditure, the gravity of the non compliance by the beneficiary with CFP rules, the economic advantage derived from the non-compliance with CFP rules or the importance of the EMFF contribution to the economic activity of the beneficiary should be taken into account.

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*Amendment*

- (17) The consequences laid down for the failure to fulfil the eligibility conditions should apply in case of infringements of the CFP rules by the beneficiaries. In order to determine the amount of ineligible expenditure, the gravity **(including the extent, duration and any re-occurrence)** of the non compliance by the beneficiary with CFP rules, the economic advantage derived from the non-compliance with CFP rules or the importance of the EMFF contribution to the economic activity of the beneficiary should be taken into account.

**Amendment 27**  
**Proposal for a regulation**  
**Recital 18**

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*Text proposed by the Commission*

- (18) The achievement of the objectives of the CFP would also be undermined if Union financial assistance under EMFF is paid to Member States who do not comply with their obligations under the CFP rules related to the public interest of conservation of marine biological resources, such as collecting data and implementing the control obligations. Moreover, without complying with those obligations there is a risk that inadmissible beneficiaries or ineligible operations are not detected by the Member States.

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*Amendment*

- (18) The achievement of the objectives of the CFP would also be undermined if Union financial assistance under EMFF is paid to Member States who do not comply with their obligations **to strike a balance between the fishing fleet and the fishing opportunities in accordance with Article 34(1) of the CFP Basic Regulation or their obligations** under the CFP rules related to the public interest of conservation of marine biological resources, such as collecting data and implementing the control obligations. Moreover, without complying with those obligations there is a risk that inadmissible beneficiaries or ineligible operations are not detected by the Member States.

Wednesday 23 October 2013

**Amendment 28**  
**Proposal for a regulation**  
**Recital 19**

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*Text proposed by the Commission*

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- (19) As precautionary measures, in order to prevent that non compliant payments take place as well as incentivise the Member State to comply with CFP rules or require compliance by the beneficiary, interruption of the payment deadline and suspension of payments, which are timely limited in their scope of application, should both be used. In order to respect the principle of proportionality, the financial corrections which have definite and irrevocable consequences should only apply to expenditure directly linked to operations during which the cases of non-compliance with CFP rules have been committed.

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*Amendment*

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*(Does not affect English version.)*

**Amendment 29**  
**Proposal for a regulation**  
**Recital 20**

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*Text proposed by the Commission*

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- (20) In order to improve coordination and harmonise implementation of the Funds providing support under the cohesion policy, namely the European Regional Development Fund (ERDF), the European Social Fund (ESF) and the Cohesion Fund (CF), with the Funds for rural development, namely the European Agricultural Fund for Rural Development (EAFRD), and for the maritime and fisheries sector, namely the European Maritime and Fisheries Fund (EMFF), common provisions have been established for all these Funds (the 'CSF Funds') in the [Regulation (EU) No [...] laying down Common Provisions]. In addition to this Regulation, the EMFF contains specific provisions due to the particularities of the CFP and the IMP.

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*Amendment*

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- (20) In order to improve coordination and harmonise implementation of the Funds providing support under the cohesion policy, namely the European Regional Development Fund (ERDF), the European Social Fund (ESF) and the Cohesion Fund (CF), with the Funds for rural development, namely the European Agricultural Fund for Rural Development (EAFRD), and for the maritime and fisheries sector, namely the European Maritime and Fisheries Fund (EMFF), common provisions have been established for all these Funds (the 'CSF Funds') in the [Regulation (EU) No [...] laying down Common Provisions]. ***It should also be stressed that the Funds may be used in a complementary manner so that the priorities of the Union's cohesion policy and the Europe 2020 strategy can be achieved more efficiently; attention should be drawn in this connection to the need for synergy between the EMFF and the ESF in order to achieve the key objectives relating to employment and the fight against poverty and social exclusion.*** In addition to this Regulation, the EMFF contains specific provisions due to the particularities of the CFP and the IMP.

Wednesday 23 October 2013

**Amendment 30**  
**Proposal for a regulation**  
**Recital 22**

Text proposed by the Commission

- (22) **Action by the Union should be complementary to action carried out by Member States or seek to contribute to that action.** In order to ensure significant added value the partnership between the Commission **and** Member States should be strengthened through arrangements for the participation of **various types of partners** with full regard to the institutional competences of the Member States. **Particular attention should be paid to ensuring adequate representation for women and minority groups.** This partnership concerns regional, local and other public authorities, as well as other appropriate bodies, including those responsible for the environment and for the promotion of equality between men and women, the economic and social partners and other competent bodies. The partners concerned should be involved in the preparation of Partnership Contracts, as well as in the preparation, implementation, monitoring and evaluation of programming.

Amendment

- (22) In order to ensure significant added value the partnership between the Commission, **the Member State authorities and the various types of partners** should be strengthened through arrangements for the participation of **these players including the social partners concerned**, with full regard to the institutional competences of the Member States. This partnership concerns regional, local and other public authorities, as well as other appropriate bodies, including those responsible for the environment and for the promotion of equality between men and women, the economic and social partners, **the fishing industry** and other competent bodies. **Given the specific nature of the fishing sector, provision should be made to guarantee the participation of economic and social partners representing the various subsectors and territorial levels, scientific research organisations and national and regional networks of fisheries local action groups (FLAGS).** **Particular attention should be paid to ensuring adequate representation for women and minority groups.** The partners concerned should be involved in the preparation of Partnership Contracts, as well as in the preparation, implementation, monitoring and evaluation of programming.

**Amendment 31**  
**Proposal for a regulation**  
**Recital 24**

Text proposed by the Commission

- (24) The Commission should establish an annual breakdown by Member States of available commitment appropriations using objective and transparent criteria; these criteria should include the **historical** allocations under Council Regulation (EC) No 1198/2006 and the historical consumption under Council Regulation (EC) No 861/2006.

Amendment

- (24) The Commission should establish an annual breakdown by Member States of available commitment appropriations using objective and transparent criteria; these criteria should include the **history of** allocations under Council Regulation (EC) No 1198/2006 and the historical consumption under Council Regulation (EC) No 861/2006.

Wednesday 23 October 2013

**Amendment 32**  
**Proposal for a regulation**  
**Recital 25**

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*Text proposed by the Commission*

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- (25) The fulfilment of certain ex-ante conditionalities is of outmost importance in the context of the CFP, especially as regards the submission of a Multiannual National Strategy Plan on Aquaculture and proven administrative capacity to comply with the data requirements for fisheries management and to enforce with the implementation of a Union control, inspection and enforcement system.

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*Amendment*

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- (25) The fulfilment of certain ex-ante conditionalities is of outmost importance in the context of the CFP, especially as regards the submission of a Multiannual National Strategy Plan on Aquaculture and proven administrative capacity to comply with the data requirements for fisheries management and to enforce with the implementation of a Union control, inspection and enforcement system; **and to ensure the implementation of Union law on working conditions, particularly that related to safety, health, education and training.**

**Amendment 33**  
**Proposal for a regulation**  
**Recital 26**

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*Text proposed by the Commission*

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- (26) In line with the goal of simplification, all activities of the EMFF which fall under shared management, including control and data collection, should take the form of one single operational programme per Member State, in accordance with its national structure. The programming exercise shall cover the period from 1 January 2014 to 31 December 2020. Each Member State should prepare a single operational programme. Each programme should identify a strategy for meeting targets in relation to the Union priorities for the EMFF and a selection of measures. Programming should comply with Union priorities, while being adapted to national contexts and complement **the other Union policies, in particular rural development policy and cohesion policy.**

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*Amendment*

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- (26) In line with the goal of simplification, all activities of the EMFF which fall under shared management, including control and data collection, should take the form of one single operational programme per Member State, in accordance with its national structure. The programming exercise shall cover the period from 1 January 2014 to 31 December 2020. Each Member State should prepare a single operational programme. Each programme should identify a strategy for meeting targets in relation to the Union priorities for the EMFF and a selection of measures. Programming should comply with Union priorities, while being adapted to national **and regional** contexts, **in particular the specific characteristics of the outermost regions**, and complement other Union policies, **while maintaining the current management and control system, so as not to generate additional costs or cause delays to the implementation of programmes.**

Wednesday 23 October 2013

**Amendment 34**  
**Proposal for a regulation**  
**Recital 30**

*Text proposed by the Commission*

- (30) Member States should draw up the section on data collection of the Operational Programme in line with a Multiannual Union programme; In order to adapt to the specific needs of data collection activities, Member States should elaborate annual work plan which should adapted annually under the guidance of the Commission and which should subject to its approval.

*Amendment*

- (30) Member States should draw up the section on data collection of the Operational Programme in line with a Multiannual Union programme; In order to adapt to the specific needs of data collection **and management** activities, Member States should elaborate annual work plan which should adapted annually under the guidance of the Commission and which should subject to its approval.

**Amendment 35**  
**Proposal for a regulation**  
**Recital 31**

*Text proposed by the Commission*

- (31) In order to increase the competitiveness and economic performance of fishing activities it is vital to stimulate innovation and entrepreneurship. Therefore the EMFF should support innovative operations and **business** development.

*Amendment*

- (31) In order to increase the competitiveness and economic performance of fishing activities it is vital to stimulate innovation and entrepreneurship. Therefore the EMFF should support innovative operations and **the ecologically sustainable development of businesses, in accordance with the precautionary principle and an ecosystem-based approach.**

**Amendment 36**  
**Proposal for a regulation**  
**Recital 31 a (new)**

*Text proposed by the Commission**Amendment*

- (31a) **As a consequence of the economic turbulence of recent years due to the financial crisis, many young people are experiencing difficulties in gaining the finance needed to enter the fisheries sector. EMFF support should therefore focus inter alia on helping young people gain access to the fishing sector by, for example, by contributing to first-time business start-ups.**

Wednesday 23 October 2013

**Amendment 37**  
**Proposal for a regulation**  
**Recital 32**

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*Text proposed by the Commission*

- (32) Investment in human capital is also vital to increase the competitiveness and economic performance of fishing and maritime activities. Therefore, the EMFF should support lifelong learning, co-operation between scientists and fishermen stimulating the dissemination of knowledge as well as for advisory services helping to improve the overall performance and competitiveness of operators.

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*Amendment*

- (32) Investment in human capital is also vital to increase the competitiveness and economic performance of fishing and maritime activities. Therefore, the EMFF should support **vocational training (which in addition to covering technical issues should also target knowledge of sustainable fisheries management and the proper handling of fish with a view to achieving greater profitability), improved health and safety and hygiene standards at work**, lifelong learning, co-operation between scientists and fishermen stimulating the dissemination of knowledge as well as for advisory services helping to improve the overall performance and competitiveness of operators. **In addition, it is important for the EMFF to promote generational renewal and rejuvenate the profession by creating specific mechanisms to encourage young people to enter the sector, namely by raising the status of the fishing profession through ensuring better health and safety and welfare standards on board, training and vocational training, and increased income.**

**Amendment 38**  
**Proposal for a regulation**  
**Recital 32 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (32a) **The EMFF should support small scale fisheries in order to address issues that are specific to that segment, and to support local, sustainable management of the fisheries involved and the development of coastal communities.**

**Amendment 39**  
**Proposal for a regulation**  
**Recital 32 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (32b) **Whereas small enterprises have difficulty accessing Community aid, the EMFF should encourage the deployment of collective projects and support technical assistance for those responsible for such projects.**

Wednesday 23 October 2013

**Amendment 40**  
**Proposal for a regulation**  
**Recital 32 c (new)**

Text proposed by the Commission

Amendment

- (32c) *The EMFF should support sustainable locally based fisheries management and the development of coastal communities.*

**Amendment 41**  
**Proposal for a regulation**  
**Recital 32 d (new)**

Text proposed by the Commission

Amendment

- (32d) *The EMFF should foster the involvement of small fishing operators in the small scale coastal and inland sectors in devising joint projects and should provide technical assistance to the project leaders.*

**Amendment 42**  
**Proposal for a regulation**  
**Recital 33**

Text proposed by the Commission

Amendment

- (33) Recognising the importance of the role that spouses of self-employed fishermen play in small scale coastal fishing, the EMFF should support training and networking contributing to their professional development and giving them the means to better fulfil the ancillary tasks they traditionally perform.

- (33) Recognising the importance of the role that spouses of self-employed fishermen play in small scale coastal fishing, the EMFF should support **lifelong** training and networking contributing to their professional development and giving them the means to better fulfil the ancillary tasks they traditionally perform **or other tasks arising from the diversification of fishing activities.**

**Amendment 43**  
**Proposal for a regulation**  
**Recital 33 a (new)**

Text proposed by the Commission

Amendment

- (33a) *The EMFF should provide support for social dialogue at European, national, regional and local level, involving the social partners and enhancing their organisational capabilities.*

Wednesday 23 October 2013

**Amendment 44**  
**Proposal for a regulation**  
**Recital 33 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (33b) *Ancillary fishing and aquaculture activities, designated as such by the Member States — such as those that could be carried out by the net makers, bait suppliers, packers and others dealing directly with fishermen — should be eligible for support from the EMFF for developing their specific activities in order to contribute to improving the functioning of the sector.*

**Amendment 45**  
**Proposal for a regulation**  
**Recital 34**

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*Text proposed by the Commission*

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*Amendment*

- (34) Conscious of the ***weak presence of small scale*** coastal fishermen ***in the social dialogue***, the EMFF should support organisations ***promoting this*** dialogue in the appropriate fora

- (34) Conscious of the ***social and territorial importance of*** coastal fishermen, the EMFF should support organisations ***that promote the social dialogue of the coastal fishing sector*** in the appropriate fora

**Amendment 46**  
**Proposal for a regulation**  
**Recital 34 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (34a) *Support should be given for the development and implementation of multiannual plans (Articles 9–11 of the Regulation on the CFP)*

Wednesday 23 October 2013

**Amendment 47**  
**Proposal for a regulation**  
**Recital 35**

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*Text proposed by the Commission*

- (35) **Conscious of the potential that diversification offers for small scale coastal fishermen and their crucial role in coastal communities**, the EMFF should help **diversification** by covering business start-ups and **investments for the retrofitting of their vessels**, in addition to the relevant training to acquire professional skills **in the relevant field outside fishing activities**.

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*Amendment*

- (35) The EMFF should help **create jobs** by covering business start-ups **in the fisheries sector** and **the development of complementary activities linked to fishing activity**, in addition to the relevant training to acquire **adequate** professional skills.

**Amendment 48**  
**Proposal for a regulation**  
**Recital 35 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (35a) **In order to ensure generational renewal in the fisheries sector it is important for the EMFF to encourage young people to enter fishing, in particular through incentives for young fishermen who are acquiring a vessel for the first time.**

**Amendment 49**  
**Proposal for a regulation**  
**Recital 35 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (35b) **It should be borne in mind that the International Labour Organisation (ILO) considers fishing to be a hazardous occupation by comparison with other occupations, and that various conventions and recommendations have been signed or adopted by that organisation with the aim of promoting decent working conditions for fishermen. The principles contained in such conventions and recommendations should serve as guiding principles for better use of EMFF resources.**

Wednesday 23 October 2013

**Amendment 50**  
**Proposal for a regulation**  
**Recital 36**

*Text proposed by the Commission*

- (36) In order to address health and safety needs on board, the EMFF should support investments covering safety and hygiene on board.

*Amendment*

- (36) In order to address health and safety needs on board, the EMFF should support investments covering safety and hygiene on board **and improvements in the habitability of vessels.**

**Amendment 51**  
**Proposal for a regulation**  
**Recital 37**

*Text proposed by the Commission*

- (37) *As a result of the establishment of systems of transferable fishing concessions envisaged in Article 27 of the [CFP Regulation] and in order to support Member States in the implementation of these new systems, the EMFF should grant support in terms of capacity building and exchange of best practices.*

*Amendment*

**deleted**

**Amendment 52**  
**Proposal for a regulation**  
**Recital 37 a (new)**

*Text proposed by the Commission*

*Amendment*

- (37a) **Recognising the importance of maritime heritage, the EMFF should support investments for the protection and preservation of maritime heritage and related traditional crafts;**

Wednesday 23 October 2013

**Amendment 53**  
**Proposal for a regulation**  
**Recital 38**

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*Text proposed by the Commission*

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*Amendment*

- (38) *The introduction of the transferable fishing concessions systems should make the sector more competitive. Consequently, there may be a need for new professional opportunities outside the fishing activities. Therefore, the EMFF should support the diversification and job creation in fishing communities in particular by supporting business start-ups and the reassignment of vessels for maritime activities outside fishing activities of small scale coastal fishing vessels. This last operation seems to be appropriate as the small scale coastal fishing vessels are not covered by the transferable fishing concessions systems.*

*deleted*

**Amendment 54**  
**Proposal for a regulation**  
**Recital 38 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (38a) *In line with the objective of creating jobs included in the Europe 2020 strategy, the EMFF should also provide resources for facilitating the adoption of measures for creating and improving employment levels throughout the whole fishing industry, from catching and aquaculture to processing and marketing.*

**Amendment 55**  
**Proposal for a regulation**  
**Recital 38 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (38b) *In order to create a sustainable future for the fishing sector, it is important for the EMFF to promote job creation in fishing communities, in particular by supporting new business start-ups and by helping young people to enter professions in the fisheries sector.*

Wednesday 23 October 2013

**Amendment 56**  
**Proposal for a regulation**  
**Recital 39**

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*Text proposed by the Commission*

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*Amendment*

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- (39) *The objective of the Common Fisheries Policy is to ensure a sustainable exploitation of fish stocks. Overcapacity has been identified as a major driver for overfishing. It is therefore paramount to adapt the Union fishing fleet to the resources available. The removal of overcapacity through public aid such as temporary or permanent cessation and scrapping schemes has proven ineffective. The EMFF will therefore support the establishment and management of systems of transferable fishing concessions aiming at the reduction of overcapacity and increased economic performance and profitability of the operators concerned.*

*deleted*

**Amendment 57**  
**Proposal for a regulation**  
**Recital 40**

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*Text proposed by the Commission*

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*Amendment*

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- (40) *With overcapacity being one of the key drivers of overfishing, measures need to be taken to adapt the Union fishing fleet to the resources available; in this context, the EMFF should support the establishment, modification and management of the systems of transferable fishing concessions introduced by the CFP as management tools for reducing overcapacity.*

*deleted*

**Amendment 59**  
**Proposal for a regulation**  
**Recital 40 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (40a) *Member States which do not fulfil their data collection and transmission obligations or fail to report their actual fishing fleet capacity should have their funds from the EMFF frozen or decreased.*

Wednesday 23 October 2013

**Amendment 60**  
**Proposal for a regulation**  
**Recital 40 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (40b) *In order to guarantee that Member States respect the fishing capacity ceilings established in Annex II [to Regulation (EU) No .../.... on the CFP], the Commission should be authorised to suspend all or part of the payments and commitments for the operational programmes of Member States that fail to respect their capacity ceilings, following a review conducted 3 years after the entry into force of this Regulation.*

**Amendment 61**  
**Proposal for a regulation**  
**Recital 40 c (new)**

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*Text proposed by the Commission*

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*Amendment*

- (40c) *Member States which do not fulfil their data collection and transmission obligations or fail to report their actual fishing fleet and capacity should have their funds from the EMFF frozen or decreased.*

**Amendment 62**  
**Proposal for a regulation**  
**Recital 40 d (new)**

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*Text proposed by the Commission*

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*Amendment*

- (40d) *In order to safeguard fishermens' incomes, contributions should be made from the EMFF to mutual funds that cover losses resulting from natural disasters, bad weather, environmental or health-related accidents or sharp rises in fuel prices.*

Wednesday 23 October 2013

**Amendment 63**  
**Proposal for a regulation**  
**Recital 41**

Text proposed by the Commission

- (41) It is paramount to integrate environmental concerns into the EMFF and support the implementation of conservation measures under the CFP taking however into account the diverse conditions throughout the Union waters. For this purpose it is essential to develop a regionalised approach to conservation measures.

Amendment

- (41) It is paramount to integrate environmental concerns into the EMFF and support the implementation of conservation measures under the CFP taking however into account the diverse conditions throughout the Union waters. For this purpose it is essential to develop a regionalised approach to conservation measures, **through a multi-annual approach to fisheries management, establishing as a priority multi-annual plans reflecting the biological specificities of different species and the special characteristics of each fishery.**

**Amendment 64**  
**Proposal for a regulation**  
**Recital 41 a (new)**

Text proposed by the Commission

Amendment

- (41a) **It is critically important to mitigate the negative impact of climate change in coastal and marine ecosystems. The EMFF should support investments to reduce the contribution of the fishing sector to emissions of greenhouse gases as well as projects that aim to protect and restore seagrass beds and coastal wetlands which are major carbon sinks.**

**Amendment 65**  
**Proposal for a regulation**  
**Recital 42**

Text proposed by the Commission

Amendment

- (42) In the same vein, the EMFF should support the reduction of the impact of fishing on the marine environment **in particular through the promotion of eco innovation**, more selective gears and equipment as well as measures aiming at protecting and restoring marine biodiversity and ecosystems and the services they provide, in line with the EU Biodiversity Strategy to 2020.

- (42) In the same vein, the EMFF should support the reduction of the **negative** impact of fishing on the marine environment, **support the reduction of greenhouse gas emissions, promote** more selective gears and equipment **and support the development of more fuel-efficient vessels. The EMFF should, in particular, promote eco-innovation in connection with hulls, engines and gear**, as well as measures aiming at protecting and restoring marine biodiversity and ecosystems and the services they provide, in line with the EU Biodiversity Strategy to 2020 **and the headline targets of the Europe 2020 Strategy on climate change.**

Wednesday 23 October 2013

**Amendment 66**  
**Proposal for a regulation**  
**Recital 42 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (42a) *In order to contribute to the positive development of water sources and to the maintenance of fishing outside the closed season, the EMFF should be able to support biological seasons, whenever those seasons, when they occur during certain critical phases of the species' life cycle, are necessary for the sustainable exploitation of fisheries resources.*

**Amendment 67**  
**Proposal for a regulation**  
**Recital 42 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (42b) *In order to minimise the impact of fishing on marine ecosystems, the EMFF should support the establishment, management, monitoring and control of a coherent network of fish stock recovery areas.*

**Amendment 69**  
**Proposal for a regulation**  
**Recital 43 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (43a) *Recognising the risks involved in investing in fishing activities, the EMFF should contribute to business security by covering access to insurance against variables of production, thereby safeguarding the income of producers in the event of abnormal production losses due, in particular, to natural disasters, adverse climatic events, sudden water quality changes, diseases or pest infestations and destruction of production tools.*

Wednesday 23 October 2013

**Amendment 70**  
**Proposal for a regulation**  
**Recital 44**

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*Text proposed by the Commission*

- (44) Conscious of the importance of fishing ports, landing sites and shelters, the EMFF should support relevant investments in particular to increase energy efficiency, environmental protection, the quality of the product landed, as well as safety and working conditions.

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*Amendment*

- (44) Conscious of the importance of fishing ports, **auctions**, landing sites and shelters, the EMFF should support relevant investments in particular to increase energy efficiency, environmental protection, the quality of the product landed, as well as safety and working conditions.

**Amendment 71**  
**Proposal for a regulation**  
**Recital 44 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (44a) **With a view to promoting small scale coastal fishing, Member States should attach to their operational programmes action plans for developing such fishing and for ensuring that it is competitive and sustainable.**

**Amendment 72**  
**Proposal for a regulation**  
**Recital 44 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (44b) **The EMFF should support the establishment of a coherent network of fish stock recovery areas, in which all fishing activities are prohibited, and which include areas important for fish productivity, in particular nursery grounds, spawning grounds and feeding grounds for fish stocks.**

Wednesday 23 October 2013

**Amendment 73**  
**Proposal for a regulation**  
**Recital 44 c (new)**

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*Text proposed by the Commission*

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*Amendment*

- (44c) *Some EMFF provisions need to be adjusted in order to meet the needs of outermost regions while continuing to pursue the core objective of ensuring that fishing and aquaculture are sustainable and responsible. The EMFF should, in particular, take account of the fact that some of those regions are lagging behind in terms of resource assessment, infrastructure, organisation of the industry and monitoring of activity and production. The EMFF should therefore be used to modernise the sector, especially its infrastructure, and to renew and modernise its production resources, having due regard for the specific circumstances in outermost region sea basins and resource availability.*

**Amendment 74**  
**Proposal for a regulation**  
**Recital 45**

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*Text proposed by the Commission*

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*Amendment*

- (45) It is vital for the Union that a sustainable balance be achieved between fresh water resources and their exploitation; **therefore** having due regard to environmental impact while ensuring that these sectors retain economic viability, appropriate provisions should support inland fishing.

- (45) It is vital for the Union that a sustainable balance be achieved between fresh water resources and their exploitation, **in view of the fact that river basins, estuaries and coastal lagoons are privileged breeding habitats and act as hatcheries for many species of juvenile fish**, having due regard to environmental impact while ensuring that these sectors retain economic viability, appropriate provisions should support inland fishing.

Wednesday 23 October 2013

## Amendment 75

## Proposal for a regulation

## Recital 46

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*Text proposed by the Commission*

- (46) In line with the Commission's Strategy for the Sustainable Development of European Aquaculture, the CFP objectives and Europe 2020 Strategy, the EMFF should support the environmentally, economically and socially sustainable development of the aquaculture industry.

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*Amendment*

- (46) In line with the Commission's Strategy for the Sustainable Development of European Aquaculture, the CFP objectives and Europe 2020 Strategy, the EMFF should support the environmentally, economically and socially sustainable development of the aquaculture industry, ***focussing, in particular, on promoting eco innovation, reducing dependence on fish meal and oil, improving the welfare of farmed organisms and promoting organic and closed system aquaculture.***

## Amendment 76

## Proposal for a regulation

## Recital 46 a (new)

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*Text proposed by the Commission*

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*Amendment*

- (46a) ***Due to the potential impact on wild marine populations of escapes of farmed animals from aquaculture sites, the EMFF should not provide incentives for the farming of exotic species or genetically modified organisms.***

Wednesday 23 October 2013

**Amendment 77**  
**Proposal for a regulation**  
**Recital 47**

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*Text proposed by the Commission*

- (47) Aquaculture contributes to growth and jobs in coastal and rural regions. Therefore, it is crucial that the EMFF is accessible to aquaculture enterprises, **in particular SMEs** and contributes to bringing new aquaculture farmers into the business. In order to increase the competitiveness and economic performance of aquaculture activities it is vital to stimulate innovation and entrepreneurship. Therefore the EMFF should support innovative operations and business development, **in particular** non-food and off-shore aquaculture.

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*Amendment*

- (47) Aquaculture contributes to growth and jobs in coastal and rural regions. Therefore, it is crucial that the EMFF is accessible to aquaculture enterprises, **regardless of their size**, and contributes to bringing new aquaculture farmers into the business. In order to increase the competitiveness and economic performance of aquaculture activities it is vital to stimulate innovation and entrepreneurship. Therefore the EMFF should support innovative operations and **the** business development **of aquaculture enterprises in general, including** non-food and off-shore aquaculture.

**Amendment 78**  
**Proposal for a regulation**  
**Recital 48**

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*Text proposed by the Commission*

- (48) New forms of income combined with aquaculture activities have already shown their added value for business development. Therefore the EMFF should support these complementary activities outside aquaculture such as angling-tourism, educational or environmental activities.

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*Amendment*

- (48) New forms of income combined with aquaculture activities have already shown their added value for business development. Therefore the EMFF should support these complementary activities outside aquaculture, such as angling-tourism, **aquaculture tourism that promotes the aquaculture sector and its products**, educational or environmental activities.

Wednesday 23 October 2013

**Amendment 79**  
**Proposal for a regulation**  
**Recital 49**

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*Text proposed by the Commission*

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- (49) Another important form of increasing the income of aquaculture enterprises is adding value to their products by processing and marketing their own production, as well as introducing new species with good market prospects and thus diversifying their production.

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*Amendment*

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- (49) Another important form of increasing the income of aquaculture enterprises is adding value to their products by processing and marketing their own production, as well as introducing new species **which are biologically compatible** with **existing species with** good market prospects and thus diversifying their production.

**Amendment 80**  
**Proposal for a regulation**  
**Recital 50**

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*Text proposed by the Commission*

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- (50) Conscious of the need to identify the most suitable areas for developing aquaculture taking into account access to waters and space, the EMFF should support national authorities in making their strategic choices at national level.

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*Amendment*

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- (50) Conscious of the need to identify the most suitable **geographical** areas for developing aquaculture taking into account access to waters and space **and the importance of developing a precautionary approach to guarantee stock sustainability**, the EMFF should support national authorities in making their strategic choices at national level **and should support regional authorities in developing their regional variations**.

**Amendment 81**  
**Proposal for a regulation**  
**Recital 51**

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*Text proposed by the Commission*

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- (51) Investment in human capital is also vital to increase the competitiveness and economic performance of aquaculture activities. Therefore, the EMFF should support lifelong learning and networking stimulating the dissemination of knowledge **as well as** advisory services **helping** to improve the overall performance and competitiveness of operators.

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*Amendment*

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- (51) Investment in human capital is also vital to increase the competitiveness and economic performance of aquaculture activities. Therefore, the EMFF should support lifelong learning and networking stimulating the dissemination **and exchange** of knowledge **and good practices, through all the competent** advisory services **(in terms of materials available), including professional associations, so that they can help** to improve the overall performance and competitiveness of operators.

Wednesday 23 October 2013

**Amendment 82**  
**Proposal for a regulation**  
**Recital 51 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (51a) *Given the need to identify geographical areas with a greater potential for the development of aquaculture in terms of access to both water and land, the EMFF should support the national and regional authorities in their strategic choices, particularly regarding the definition and mapping of the zones which may be considered most suitable to the development of aquaculture, taking into account, if relevant, the maritime spatial planning process.*

**Amendment 83**  
**Proposal for a regulation**  
**Recital 52**

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*Text proposed by the Commission*

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*Amendment*

- (52) In order to promote environmentally sustainable aquaculture, the EMFF should support aquaculture activities which are highly respectful of the environment, the conversion of aquaculture enterprises to **eco-management**, the use of audit schemes as well as the conversion to organic aquaculture. In the same vein, the EMFF should also support aquaculture providing for special environmental services.

- (52) In order to promote environmentally, **socially and economically** sustainable aquaculture, the EMFF should support aquaculture activities which are highly respectful of the environment, the conversion of aquaculture enterprises to **sustainable management**, the use of audit schemes as well as the conversion to organic aquaculture. In the same vein, the EMFF should also support aquaculture, providing for special environmental services **and services of public interest**.

**Amendment 84**  
**Proposal for a regulation**  
**Recital 53**

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*Text proposed by the Commission*

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*Amendment*

- (53) Conscious of the importance of consumer protection, the EMFF should ensure adequate support to farmers in order to prevent and mitigate the risk for public and animal health that aquaculture rearing may generate.

- (53) Conscious of the importance of consumer protection, the EMFF should ensure adequate support to farmers in order to prevent and mitigate the risk for public and animal health that aquaculture rearing may generate, **particularly through programmes designed to reduce the dependency of aquaculture activities on veterinary products**.

Wednesday 23 October 2013

**Amendment 85**  
**Proposal for a regulation**  
**Recital 53 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (53a) *The EMFF should support the establishment of a coherent network of fish stock recovery areas, which include areas important for fish productivity, in particular nursery grounds, spawning grounds and feeding grounds for fish stocks and in which all fishing activities are prohibited.*

**Amendment 86**  
**Proposal for a regulation**  
**Recital 54**

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*Text proposed by the Commission*

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*Amendment*

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| <p>(54) Recognizing the risk of investments in aquaculture activities, the EMFF should contribute to business security by covering access to stock insurance and therefore safeguarding the income of producers in case of abnormal production losses due in particular to natural disasters, adverse climatic events, sudden water quality changes, diseases or pest infestations and destruction of production facilities.</p> | <p>(54) Recognizing the risk of investments in aquaculture activities, the EMFF should contribute to business security by covering access to stock insurance <b>or by supporting the development of mutual funds,</b> and therefore safeguarding the income of producers in case of abnormal production losses due in particular to natural disasters, adverse climatic events, sudden water quality changes, diseases or pest infestations and destruction of production facilities.</p> |
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**Amendment 87**  
**Proposal for a regulation**  
**Recital 55**

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*Text proposed by the Commission*

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*Amendment*

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| <p>(55) Considering that the community-led approach for local development has, over a number of years, proven its utility in promoting the development of <b>fisheries</b> and rural <b>areas</b> by fully taking into account the multi-sectoral needs for endogenous development, support should be continued and reinforced in the future.</p> | <p>(55) Considering that the community-led approach for local development has, over a number of years, proven its utility in promoting the development of <b>fishing</b> and rural <b>communities</b> by fully taking into account the multi-sectoral needs for endogenous development, support should be continued and reinforced in the future.</p> |
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Wednesday 23 October 2013

**Amendment 88**  
**Proposal for a regulation**  
**Recital 56**

*Text proposed by the Commission*

- (56) In fisheries areas, community-led local development should encourage innovative approaches to create growth and jobs, in particular by adding value to fisheries products and diversifying the local economy towards new economic activities, including those offered by 'blue growth' and the broader maritime sectors.

*Amendment*

- (56) In fisheries areas, community-led local development should encourage innovative approaches to create growth and jobs, in particular by adding value to fisheries products and diversifying the local economy **also** towards new economic activities, including those offered by 'blue growth' and the broader maritime sectors.

**Amendment 89**  
**Proposal for a regulation**  
**Recital 57**

*Text proposed by the Commission*

- (57) The sustainable development of fisheries areas should contribute to the EU 2020 objectives of promoting social inclusion and poverty reduction and to fostering innovation at local level as well as to the objective of territorial cohesion, a main priority in the Lisbon Treaty.

*Amendment*

- (57) The sustainable development of fisheries areas should contribute to the EU 2020 objectives of promoting social inclusion and poverty reduction, **to raising employment rates** and to fostering innovation, **including social innovation**, at local level as well as to the objective of territorial cohesion, a main priority in the Lisbon Treaty.

**Amendment 90**  
**Proposal for a regulation**  
**Recital 58**

*Text proposed by the Commission*

- (58) Community-led local development should be implemented through a bottom-up approach by local partnerships that are composed of representatives of the public, private and civil society sectors and mirror correctly the local society; these local actors are best placed to draw up and implement integrated multi-sectoral local development strategies to meet the needs of their local fisheries areas; **it** is important in order to ensure the representativeness of local action groups that **no single interest groups has more than 49 % of the voting right** in the decision-making bodies.

*Amendment*

- (58) Community-led local development should be implemented through a bottom-up approach by local partnerships that are composed of representatives of the public, private and civil society sectors and mirror correctly the local society; these local actors are best placed to draw up and implement integrated multi-sectoral local development strategies to meet the needs of their local fisheries areas. **It** is important, in order to ensure **that** local action groups **are representative and that the actions of those groups address the challenges** in the **fisheries and aquaculture sectors, that fishermen and/or fish farmers make up the majority of the economic actors represented in the** decision-making bodies.

Wednesday 23 October 2013

**Amendment 91**  
**Proposal for a regulation**  
**Recital 60**

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*Text proposed by the Commission*

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- (60) The support to fisheries areas through the EMFF should be coordinated with the local development support offered by other Union Funds and should cover all aspects of the preparation and implementation of local development strategies and operations of local action groups as well as the costs of animating the local area and running the local partnership.

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*Amendment*

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- (60) The support to fisheries areas through the EMFF should be coordinated with the local development support offered by other Union Funds and should cover all aspects of the preparation and implementation of local development strategies and operations of local action groups as well as the costs of animating the local area and running the local partnership. ***That support should include the possibility of receiving technical, especially financial engineering assistance in setting up local development projects, especially for small scale coastal fishing and fishing in inland waters.***

**Amendment 92**  
**Proposal for a regulation**  
**Recital 61**

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*Text proposed by the Commission*

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- (61) In order to ensure the viability of fisheries and aquaculture in a highly competitive market, it is necessary to lay down provisions granting support for the implementation of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products]<sup>1</sup> as well as for marketing and processing activities carried by operators to maximise the value of fisheries and aquaculture products. Particular attention should be paid to the promotion of operations which integrate producing, processing and marketing activities of the supply chain. ***In order to adapt to the new discard ban policy, the EMFF should also support the processing of unwanted catches.***

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*Amendment*

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- (61) In order to ensure the viability of fisheries and aquaculture in a highly competitive market, it is necessary to lay down provisions granting support for the implementation of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products]<sup>1</sup> as well as for marketing and processing activities carried by operators to maximise the value of fisheries and aquaculture products. Particular attention should be paid to the promotion of operations which integrate producing, processing and marketing activities of the supply chain.

Wednesday 23 October 2013

**Amendment 93**  
**Proposal for a regulation**  
**Recital 62**

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*Text proposed by the Commission*

- (62) Priority should be given to producer organisations and associations of producer organisations by granting them support. ***The compensation for storage aid and aid for production and marketing plans should gradually be phased out as the importance of this particular kind of support has lost its interest in the light of the evolving structure of the Union market for this kind of products and the growing importance of strong producer's organisations.***

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*Amendment*

- (62) Priority should be given to producer organisations and associations of producer organisations by granting them support.

**Amendment 94**  
**Proposal for a regulation**  
**Recital 63**

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*Text proposed by the Commission*

- (63) Recognising the growing competition small scale coastal fishermen are confronted ***to***, the EMFF should support entrepreneurial initiatives of small scale coastal fishermen adding value to the fish they catch, in particular by carrying out the processing or direct marketing of the fish they catch.

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*Amendment*

- (63) Recognising the growing competition ***with which*** small scale coastal fishermen are confronted ***and the dependency of certain coastal communities on fishing***, the EMFF should support entrepreneurial initiatives of small scale coastal fishermen adding value to the fish they catch, in particular by carrying out the processing or direct marketing of the fish they catch.

Wednesday 23 October 2013

**Amendment 95**  
**Proposal for a regulation**  
**Recital 63 a (new)**

*Text proposed by the Commission*

*Amendment*

- (63a) *The EMFF should support entrepreneurial initiatives and joint initiatives aiming to achieve the objectives of the Union in the areas of environmental protection and the preservation of fish stocks through the establishment of joint aqua–environmental measures, in particular for fishing in inland waters.*

**Amendment 96**  
**Proposal for a regulation**  
**Recital 64**

*Text proposed by the Commission*

*Amendment*

- (64) **Fishing** activities in the outermost regions of the European Union are facing difficulties, in particular because of **the additional costs incurred in the marketing of certain fishery products, due to** the particular handicaps recognised by Article 349 of the Treaty on the Functioning of the European Union.

- (64) **Given that fishing** activities in the outermost regions of the European Union are facing difficulties, in particular because of **their remoteness and special climatic conditions, the EMFF should take into account** the particular handicaps recognised by Article 349 of the Treaty on the Functioning of the European Union.

Wednesday 23 October 2013

**Amendment 97**  
**Proposal for a regulation**  
**Recital 65**

*Text proposed by the Commission*

- (65) In order to maintain the competitiveness of certain fishery products from the outermost regions of the European Union compared with that of similar products from other European Union's regions, the European Union introduced measures in 1992 to compensate for the related additional costs in the fisheries sector. The measures applying for the period 2007–2013 are laid down in Council Regulation (EC) No 791/2007<sup>1</sup>. It is necessary to **continue providing** support to offset the additional costs for the marketing of certain fishery products as of 1 January 2014.

*Amendment*

- (65) In order to maintain the competitiveness of certain fishery products from the outermost regions of the European Union compared with that of similar products from other European Union's regions, the European Union introduced measures in 1992 to compensate for the related additional costs in the fisheries sector. The measures applying for the period 2007–2013 are laid down in Council Regulation (EC) No 791/2007<sup>1</sup>. **Given the difficulties encountered by fishing activities in the outermost regions,** it is necessary to **increase** support to offset the additional costs for the marketing of certain fishery products as of 1 January 2014.

**Amendment 98**  
**Proposal for a regulation**  
**Recital 66**

*Text proposed by the Commission*

- (66) In view of the different marketing conditions in the outermost regions concerned, the fluctuations in captures and stocks and of market demands, it should be left to the Member States concerned to determine the fishery products eligible for compensation, their respective maximum quantities and the compensation amounts within the overall allocation per Member State.

*Amendment*

- (66) In view of the different **production, processing and** marketing conditions **for fishery and aquaculture products** in the outermost regions concerned, **and** the fluctuations in captures and stocks and of market demands, it should be left to the Member States concerned to determine the fishery **and aquaculture** products **or product categories that are to be** eligible for compensation, their respective maximum quantities and the compensation amounts within the overall allocation per Member State.

Wednesday 23 October 2013

## Separate vote

## Proposal for a regulation

## Recital 68

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Text proposed by the Commission

- (68) Member States should set the compensation amount at a level which allows appropriate off-setting of additional costs, arising from the specific handicaps of the outermost regions and in particular from the costs of transporting the products to mainland Europe. **To avoid overcompensation, the amount should be proportional to the additional costs the aid off-sets and in no case exceed 100 % of the transport and other related costs to mainland Europe. To this end, it should also take into account other types of public intervention having an impact on the level of additional costs.**

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Amendment

- (68) Member States should set the compensation amount at a level which allows appropriate off-setting of additional costs, arising from the specific handicaps of the outermost regions and in particular from the costs of transporting the products to mainland Europe..

## Amendment 100

## Proposal for a regulation

## Recital 69

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Text proposed by the Commission

- (69) It is paramount that Member States and operators are equipped in such a way that controls can be carried out to a high standard and therefore ensure compliance with the rules of the Common Fisheries Policy while providing for the sustainable exploitation of living aquatic resources; the EMFF should therefore support Member States and operators in conformity with Council Regulation (EC) No 1224/2009. By creating a culture of compliance, this support should contribute to sustainable growth.

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Amendment

- (69) It is paramount that Member States and operators are equipped in such a way that controls can be carried out to a high standard and therefore ensure compliance with the rules of the Common Fisheries Policy while providing for the sustainable exploitation of living aquatic resources; the EMFF should therefore support Member States and operators in conformity with Council Regulation (EC) No 1224/2009. By creating a culture of compliance, this support should contribute to sustainable growth. **In order to standardise and step up the level of monitoring, the Member States should also be able to put in place common control systems.**

Wednesday 23 October 2013

**Amendment 101**  
**Proposal for a regulation**  
**Recital 70**

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*Text proposed by the Commission*

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- (70) The support granted to Member States on the basis of the Regulation (EC) No 861/2006 for the expenditure incurred relating to the implementation of the Union control system should be **continued** under the EMFF pursuing the logic of a single fund.

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*Amendment*

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- (70) The support granted to Member States on the basis of the Regulation (EC) No 861/2006 for the expenditure incurred relating to the implementation of the Union control system should be **increased** under the EMFF pursuing the logic of a single fund.

**Amendment 102**  
**Proposal for a regulation**  
**Recital 72 a (new)**

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*Text proposed by the Commission*

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- Amendment*
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- (72a) ***The EMFF should support funds for extra control activities and inspections in areas where IUU fishing is reported to take place.***

**Amendment 103**  
**Proposal for a regulation**  
**Recital 73**

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*Text proposed by the Commission*

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- (73) Provisions should be laid down for support to collect, manage and use of fisheries data as specified in the multiannual Union programme, in particular to support national programmes and the management and use of data for scientific analysis and CFP implementation. The support granted to Member States on the basis of the Regulation (EC) No 861/2006 for the expenditure incurred relating to the collection, management and use of fisheries data should be continued under the EMFF pursuing the logic of a single fund.

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*Amendment*

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- (73) ***Rrelevant stakeholders should be informed through the Advisory Councils of procedures*** . Provisions should be laid down for support to collect, manage and use of fisheries data as specified in the multiannual Union programme, in particular to support national programmes and the management and use of data for scientific analysis and CFP implementation. The support granted to Member States on the basis of the Regulation (EC) No 861/2006 for the expenditure incurred relating to the collection, management and use of fisheries data should be continued under the EMFF pursuing the logic of a single fund.

Wednesday 23 October 2013

**Amendment 104****Proposal for a regulation****Recital 73 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (73a) *The paramount importance of funding data collection, the cornerstone of the CFP, should be emphasised. It is the essential prerequisite for the definition of precise objectives to be achieved, particularly as regards the achievement of the MSY and better fisheries management. In this sense it is appropriate to ensure that data collection is allocated a part of the EMFF budget that is commensurate with its importance. It is also appropriate to provide for a co-financing rate that encourages a comprehensive review of the state of European fish stocks.*

**Amendment 105****Proposal for a regulation****Recital 74**

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*Text proposed by the Commission*

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*Amendment*

- (74) It is also necessary to support the cooperation among Member States, as well as with third countries where relevant, with respect to the collection of data within the same sea basin, as well as with the relevant international scientific bodies.
- (74) It is also necessary to support the cooperation among Member States, as well as with third countries where relevant, with respect to the collection of data within the same sea basin, as well as with the relevant international scientific bodies **and the Regional Advisory Councils.**

Wednesday 23 October 2013

**Amendment 106**  
**Proposal for a regulation**  
**Recital 76**

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*Text proposed by the Commission*

- (76) Sustained funding is needed for the implementation and further development of the Integrated Maritime Policy for the European Union as reflected in the statements of the Council, the European Parliament and the Committee of the Regions.

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*Amendment*

- (76) Sustained funding is needed for the implementation and further development of the Integrated Maritime Policy for the European Union as reflected in **Regulation (EU) No 1255/2011 of the European Parliament and of the Council of 30 November 2011 establishing a Programme to support the further development of an Integrated Maritime Policy<sup>(1)</sup>** and the statements of the Council, the European Parliament and the Committee of the Regions. **The development of maritime affairs through financial support for IMP measures is expected to have a significant impact in terms of economic, social and territorial cohesion.**

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<sup>(1)</sup> OJ L 321, 5.12.2011, p. 1

**Amendment 107**  
**Proposal for a regulation**  
**Recital 76 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (76a) **In this respect, the EMFF should be designed to support exploratory work on actions which aim to promote the strategic objectives of the IMP, due attention being paid to their cumulative impacts, on the basis of the ecosystem approach, to sustainable economic growth, employment, innovation and competitiveness in coastal, insular and outermost regions, and to the promotion of the international dimension of the IMP.**

Wednesday 23 October 2013

**Amendment 108**  
**Proposal for a regulation**  
**Recital 77**

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*Text proposed by the Commission*

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- (77) The EMFF should support the promotion of integrated maritime governance at all levels especially through exchanges of best practices and the further development and implementation of sea basin strategies. These strategies aim at setting up an integrated framework to address common challenges in European sea basins and strengthened co-operation between stakeholders to maximise the use of Union financial instruments and funds and contribute to the economic, social and territorial cohesion of the Union.

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*Amendment*

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- (77) The EMFF should support the promotion of integrated maritime governance at all levels especially through exchanges of best practices and the further development and implementation of sea basin strategies. ***In this context, it is very important to improve maritime governance, including through the enhancement of cooperation and coordination, at the appropriate level, among the competent authorities performing coast guard functions in the Union, ensuring healthier, safer and more secure seas and oceans in particular by implementing the existing maritime legislation.*** These strategies aim at setting up an integrated framework to address common challenges in European sea basins and strengthened co-operation between stakeholders to maximise the use of Union financial instruments and funds and contribute to the economic, social and territorial cohesion of the Union ***and to environmental sustainability. It is therefore very important to improve and enhance external cooperation and coordination in relation to achieving the objectives of the IMP, on the basis of the United Nations Convention on the Law of the Sea (UNCLOS).***

**Amendment 109**  
**Proposal for a regulation**  
**Recital 77 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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- (77a) ***In order to enhance the approximation of the fisheries and aquaculture funds and the funds for the Integrated Maritime Policy, the EMFF should provide for a specific framework to promote the contribution that fisheries and aquaculture make to the Integrated Maritime Policy. It is essential to encourage full consideration of these activities through support for participation in integrated governance and collective projects that contribute to the implementation of the IMP.***

Wednesday 23 October 2013

**Amendment 110**  
**Proposal for a regulation**  
**Recital 79**

Text proposed by the Commission

- (79) Interconnection of the certain information systems run by those sectors may require mobilisation of their own funding mechanisms in a coherent way and in line with Treaty provisions. Maritime spatial planning and integrated coastal zone management are essential for the sustainable development of marine areas and coastal regions and both contributing to the aims of ecosystem-based management and the development of land-sea links. These tools are also important to manage diverse uses of our coasts, seas and oceans to enable their sustainable economic development and to stimulate cross-border investment, whereas the implementation of the Marine Strategy Framework Directive will further define the boundaries of sustainability of human activities that have an impact on the marine environment. Furthermore, it is necessary to improve knowledge of the marine world, and stimulate innovation by facilitating collection, free sharing, re-use and dissemination of data concerning the status of oceans and seas.

Amendment

- (79) Interconnection of the certain information systems run by those sectors may require mobilisation of their own funding mechanisms in a coherent way and in line with Treaty provisions. Maritime spatial planning and integrated coastal zone management are essential for the sustainable development of marine areas and coastal regions and both contributing to the aims of ecosystem-based management and the development of land-sea links. These tools are also important to manage diverse uses of our coasts, seas and oceans to enable their sustainable economic development and to stimulate cross-border investment, whereas the implementation of the Marine Strategy Framework Directive will further define the boundaries of sustainability of **industrial, construction and** human activities that have an impact on the marine environment. Furthermore, it is necessary to improve knowledge of the marine world, and stimulate innovation by facilitating collection, free sharing, re-use and dissemination of data concerning the status of oceans and seas **and the status of fisheries, making it available to end-users and the general public.**

**Amendment 111**  
**Proposal for a regulation**  
**Recital 80**

Text proposed by the Commission

- (80) The EMFF should also support sustainable economic growth, employment, innovation and competitiveness within maritime sectors and in coastal regions. It is particularly important to identify regulatory barriers and skill deficiencies hindering growth in emerging and prospective maritime sectors, as well as operations aimed at fostering investment in technological innovation necessary to enhance the business potential of marine and maritime applications.

Amendment

- (80) The EMFF should also support sustainable economic growth, employment, innovation and competitiveness within maritime sectors and in coastal regions. It is particularly important to identify regulatory barriers and skill deficiencies hindering growth in emerging and prospective maritime sectors, as well as operations aimed at fostering investment in technological innovation necessary to enhance the business potential of marine and maritime applications. **The EMFF should support measures to develop the education and vocational training system in the sector, including the acquisition of the equipment and tools needed to improve the quality of education and training services.**

Wednesday 23 October 2013

**Amendment 112**  
**Proposal for a regulation**  
**Recital 81**

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*Text proposed by the Commission*

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- (81) The EMFF should be complementary and coherent with existing and future financial instruments made available by the Union and the Member States, at national and sub-national level, for promoting the protection and sustainable use of the oceans, seas and coasts, helping to foster more effective cooperation between the Member States and their coastal, island, and outermost regions, and taking into account the prioritisation and progress of national and local projects. The Fund will tie in with other Union policies that may encompass a maritime dimension, in particular the European Regional Development Fund, the Cohesion Fund and the European Social Fund as well the Horizon 2020 Programme for Research and energy policy

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*Amendment*

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- (81) The EMFF should be complementary and coherent with existing and future financial instruments made available by the Union and the Member States, at national and sub-national level, for promoting **sustainable economic and social development**, the protection and sustainable use of the oceans, seas and coasts, helping to foster more effective cooperation between the Member States and their coastal, island, and outermost regions, and taking into account the prioritisation and progress of national and local projects. The Fund will tie in with other Union policies that may encompass a maritime dimension, in particular the European Regional Development Fund, the Cohesion Fund and the European Social Fund as well the Horizon 2020 Programme for Research and energy policy

**Amendment 113**  
**Proposal for a regulation**  
**Recital 84**

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*Text proposed by the Commission*

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- (84) By way of technical assistance the EMFF should provide preparatory, administrative and technical support as well as support for information measures, networking, evaluations, audits, studies and exchanges of experience in order to facilitate the implementation of the operational programme and to promote innovative approaches and practices for simple and transparent implementation. Technical assistance should also include the setting up of a European network of Fisheries Local Action Groups aiming at capacity building, disseminating information, exchanging experience and supporting cooperation between the local partnerships.

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*Amendment*

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- (84) By way of technical assistance the EMFF should provide preparatory, administrative and technical support as well as support for information measures, networking, evaluations, audits, studies and exchanges of experience in order to facilitate the implementation of the operational programme and to promote innovative approaches and practices for simple and transparent implementation, **including those which will benefit operators' and fishermen's organisations**. Technical assistance should also include the setting up of a European network of Fisheries Local Action Groups aiming at capacity building, disseminating information, exchanging experience and supporting cooperation between the local partnerships.

Wednesday 23 October 2013

**Amendment 114**  
**Proposal for a regulation**  
**Recital 88**

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*Text proposed by the Commission*

- (88) Conscious of the importance of ensuring conservation of marine biological and protecting fish stocks in particular from illegal fishing and in the spirit of the conclusions drawn in the Green Paper on the Reform of the CFP, those operators who do not comply with the rules of the CFP, and particularly jeopardise the sustainability of the stocks concerned and constitute therefore a serious threat to the sustainable exploitation of living marine biological resources ***that restores and maintains populations of harvested species above levels which can produce the MSY, and*** those who are involved in IUU fishing should be excluded from support under the EMFF. Union funding should not at any stage from the selection to the implementation of an operation be used to undermine the public interest of conservation of marine biological resources expressed in the objectives of the CFP Regulation.

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*Amendment*

- (88) Conscious of the importance of ensuring conservation of marine biological ***resources*** and protecting fish stocks in particular from illegal fishing and in the spirit of the conclusions drawn in the Green Paper on the Reform of the CFP, those operators who do not comply with the rules of the CFP, and particularly jeopardise the sustainability of the stocks concerned and, ***specifically, the goals of restoring and maintaining populations of harvested species above levels which can produce MSY by 2015 and achieving and maintaining a good environmental status by 2020***, constitute therefore a serious threat to the sustainable exploitation of living marine biological resources, ***along*** with those who are involved in IUU fishing, ***and*** should be excluded from support under the EMFF. Union funding should not at any stage from the selection to the implementation of an operation be used to undermine the public interest of conservation of marine biological resources expressed in the objectives of the CFP Regulation.

**Amendment 115**  
**Proposal for a regulation**  
**Recital 88 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (88a) ***There should be a possibility to freeze funding from the EMFF if a Member State is unable to tackle problems with IUU-fishing within its waters and within its fishing fleet.***

Wednesday 23 October 2013

**Amendment 116**  
**Proposal for a regulation**  
**Recital 91**

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*Text proposed by the Commission*

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- (91) In order to address the specific needs of the CFP mentioned in Articles 50 and 51 of the [CFP Regulation] and contribute to the compliance with the CFP rules, additional provisions to the rules on interruption of the payment deadline [Regulation (EU) No [...] laying down Common Provisions] should be laid down. Where a Member State or an operator has failed to comply with its obligations under the CFP or where the Commission has evidence to **suggest** this lack of compliance, as a precautionary measure, the Commission should be allowed to interrupt payments.

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*Amendment*

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- (91) In order to address the specific needs of the CFP mentioned in Articles 50 and 51 of the [CFP Regulation] and contribute to the compliance with the CFP rules, additional provisions to the rules on interruption of the payment deadline [Regulation (EU) No [...] laying down Common Provisions] should be laid down. Where a Member State or an operator has failed to comply with its obligations under the CFP or where the Commission has evidence to **verify** this lack of compliance, as a precautionary measure, the Commission should be allowed to interrupt payments.

**Amendment 117**  
**Proposal for a regulation**  
**Recital 93**

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*Text proposed by the Commission*

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- (93) The operational programme should be subject to monitoring and evaluation in order to improve its quality and demonstrate its achievements. The Commission should set up a framework for a common monitoring and evaluation ensuring among others that relevant data is available **on** a timely manner. In this context a list of indicators should be determined and the impact of the EMFF policy assessed by the Commission in relation to specific objectives.

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*Amendment*

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- (93) The operational programme should be subject to monitoring and evaluation in order to improve its quality and demonstrate its achievements. The Commission should set up a framework for a common monitoring and evaluation ensuring among others that relevant data is **made publicly** available **in** a timely manner. In this context a list of indicators should be determined and the impact of the EMFF policy assessed by the Commission in relation to specific objectives.

Wednesday 23 October 2013

**Amendment 118**  
**Proposal for a regulation**  
**Recital 95**

Text proposed by the Commission

- (95) With a view to strengthening accessibility and transparency of information about funding opportunities and project beneficiaries, in each Member State a single website or website portal providing information on operational programme, including the lists of operations supported under each operational programme, should be made available. This information should give a reasonable, tangible and concrete idea to the wider public and in particular to Union taxpayers on how Union funding is spent in the framework of the EMFF. In addition to this objective, the publication of relevant data should serve the purpose of further publicising the possibility of applying for Union funding. However in full respect of the fundamental right to data protection and in line with the judgment of the Court in the Joined Cases Schecke, the publication of the names of natural persons should not be requested.

Amendment

- (95) With a view to strengthening accessibility and transparency of information about funding opportunities and project beneficiaries, in each Member State a single website or website portal providing information on operational programme, including the lists of operations supported under each operational programme, should be made available. ***The dedicated websites of all Member States should also be accessible from an official Union website in order to help citizens from different Member States to get easier access to published information from all Member States.*** This information should give a reasonable, tangible and concrete idea to the wider public and in particular to Union taxpayers on how Union funding is spent in the framework of the EMFF. In addition to this objective, the publication of relevant data should serve the purpose of further publicising the possibility of applying for Union funding. However in full respect of the fundamental right to data protection and in line with the judgment of the Court in the Joined Cases Schecke, the publication of the names of natural persons should not be requested.

**Amendment 119**  
**Proposal for a regulation**  
**Recital 96 a (new)**

Text proposed by the Commission

Amendment

- (96a) ***It is particularly important to ensure that ex-ante conditionalities concerning the administrative capacity to comply with the data requirements for fisheries management and the implementation of a Union control inspection and enforcement system are respected.***

**Amendment 120**  
**Proposal for a regulation**  
**Recital 96 b (new)**

Text proposed by the Commission

Amendment

- (96b) ***It is particularly important to ensure that ex-ante conditionalities concerning the administrative capacity to comply with the data requirements for fisheries management and the implementation of a Union control inspection and enforcement system are respected.***

Wednesday 23 October 2013

## Amendment 121

## Proposal for a regulation

## Article 1 — point c

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*Text proposed by the Commission*

(c) the sustainable development of fisheries areas **and** inland fishing,

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*Amendment*

(c) the sustainable development of fisheries **and aquaculture** areas, **of** inland fishing **and of related activities as defined in this Regulation**,

## Amendment 122

## Proposal for a regulation

## Article 1 — paragraph 1 — point d

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*Text proposed by the Commission*

(d) and the Integrated Maritime Policy (IMP).

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*Amendment*

(d) and the Integrated Maritime Policy (IMP), **including the Marine Strategy Framework Directive**.

## Amendment 123

## Proposal for a regulation

## Article 2 — paragraph 1

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*Text proposed by the Commission*

This Regulation shall apply to operations carried out in the territory of the Union unless otherwise expressly provided for in this Regulation.

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*Amendment*

This Regulation shall apply to operations carried out in the territory, **waters and fleets** of the Union unless otherwise expressly provided for in this Regulation.

## Amendment 124

## Proposal for a regulation

## Article 3 — paragraph 2 — point - 1 (new)

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*Text proposed by the Commission*

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*Amendment*

(-1) ‘**closed aquaculture system**’ means aquaculture facilities where fish and other aquatic products are farmed in closed recirculation systems which retain and treat the water within the system, minimising water use. Such systems are usually land-based and re-use virtually all of the water initially put into the system;

Wednesday 23 October 2013

**Amendment 125****Proposal for a regulation****Article 3 — paragraph 2 — point 2 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(2a) *'diversification' means practices that render fisheries or aquaculture activities more versatile and which are directly complementary to or dependent on such activities;*

**Amendment 583****Proposal for a regulation****Article 3 — paragraph 2 — point 4 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(4a) *'alien species' means any alien species within the meaning of Council Regulation (EC) No 708/2007 <sup>(1)</sup>;*

<sup>(1)</sup> *Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture (OJ L 168, 28.6.2007, p. 1).*

**Amendment 127****Proposal for a regulation****Article 3 — paragraph 2 — point 4 b (new)**

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*Text proposed by the Commission*

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*Amendment*

(4b) *'extensive aquaculture' means aquaculture production which receives no intentional nutritional inputs but depends instead on natural food in the culture facility, including that brought in by water flow such as currents and tidal exchange. Extensive aquaculture largely depends on a single nutritional input, namely seed;*

Wednesday 23 October 2013

## Amendment 128

## Proposal for a regulation

## Article 3 — paragraph 2 — point 5

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*Text proposed by the Commission*

- (5) 'fisheries area' means an area with sea or lake shore or including ponds or a river estuary **with** a significant level of employment in fisheries **or** aquaculture and designated as such by the Member State;

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*Amendment*

- (5) 'fisheries **and aquaculture** area' means an area with sea, **river** or lake shore, or including ponds or a river estuary, **with** a significant level of employment in **the** fisheries **or** aquaculture **sector** and designated as such by the Member State;

## Amendment 129

## Proposal for a regulation

## Article 3 — paragraph 2 — point 5 a (new)

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*Text proposed by the Commission*

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*Amendment*

- (5a) 'fish stock recovery area' means a geographically defined sea area in which all fishing activities are prohibited, in order to improve the exploitation and conservation of living aquatic resources or the protection of marine ecosystems, as referred to in Regulation (EU) No .../.. [laying down Common Provisions];

## Amendment 130

## Proposal for a regulation

## Article 3 — paragraph 2 — point 5 b (new)

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*Text proposed by the Commission*

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*Amendment*

- (5b) 'fisheries sector' means the economic sector covering all activities relating to the production, processing and marketing of fisheries and aquaculture products;

Wednesday 23 October 2013

## Amendment 131

## Proposal for a regulation

## Article 3 — paragraph 2 — point 5 c (new)

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Text proposed by the Commission

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Amendment

- (5c) **'management and fisheries access systems'** means mechanisms for the attribution of and access to fishing rights or for the management of the fisheries effort, developed at national, regional or local level or at the level of the sea basins, on species under quota or out of quota within the 12-mile coastal strip or beyond and focusing on healthy stocks. These systems are implemented by the public authorities or fisheries organisations;

## Amendment 132

## Proposal for a regulation

## Article 3 — paragraph 2 — point 6

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Text proposed by the Commission

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Amendment

- (6) 'fisherman' means any person engaging in professional fishing, as recognised by the Member State, on board of an operational fishing vessel or engaging in professional harvesting of marine organisms, as recognised by the Member State, without a vessel;

- (6) 'fisherman' means any person engaging in professional fishing, **including employees**, as recognised by the Member State, on board of an operational fishing vessel or engaging in professional harvesting of **freshwater or** marine organisms, as recognised by the Member State, without a vessel;

## Amendment 133

## Proposal for a regulation

## Article 3 — paragraph 2 — point 6 a (new)

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Text proposed by the Commission

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Amendment

- (6a) **'fishing tourism'** means a complementary activity carried out by professional fishermen whereby persons who are not crew members board fishing vessels as tourists or researchers;

Wednesday 23 October 2013

Amendment 134

Proposal for a regulation

Article 3 — paragraph 2 — point 6 b (new)

Text proposed by the Commission

Amendment

(6b) *'ancillary fishing and aquaculture activities' means those activities carried out by anyone providing a professional service to fishermen which is required for their activity and designated as such by the Member State;*

Amendment 135

Proposal for a regulation

Article 3 — paragraph 2 — point 8 a (new)

Text proposed by the Commission

Amendment

(8a) *'intensive aquaculture' means aquaculture production which depends on nutritionally complete diets added to the nutritional system of either fresh, wild, marine or freshwater fish, or which depends on formulated diets. It is largely dependant on complete and commercially available feed and is characterised by high stocking densities;*

Amendment 136

Proposal for a regulation

Article 3 — paragraph 2 — point 10

Text proposed by the Commission

Amendment

(10) 'inland fishing' means fishing carried out for commercial purposes **by vessels operating** exclusively in inland waters or by other devices used for ice fishing;

(10) 'inland fishing' means fishing carried out for commercial purposes, **from a vessel or otherwise**, exclusively in inland waters or by other devices used for ice fishing;

Wednesday 23 October 2013

## Amendment 137

## Proposal for a regulation

## Article 3 — paragraph 2 — point 12

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*Text proposed by the Commission*

- (12) 'integrated maritime governance' means the coordinated management of all sectoral policies **of the** EU affecting the oceans, seas, and coastal regions;

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*Amendment*

- (12) 'integrated maritime governance' means the coordinated management of all sectoral policies **at Union level** affecting the oceans, seas, and coastal regions;

## Amendment 138

## Proposal for a regulation

## Article 3 — paragraph 2 — point 13

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*Text proposed by the Commission*

- (13) '**marine regions**' means the geographical areas set out in Annex I to Council Decision 2004/585/EC and the areas established by the regional fisheries management organisations;

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*Amendment*

*deleted*

## Amendment 139

## Proposal for a regulation

## Article 3 — paragraph 2 — point 16

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*Text proposed by the Commission*

- (16) 'sea basin strategy' means a structured framework of cooperation in respect to a given geographical area, developed by European Institutions, Member States, their regions and where appropriate third countries sharing a sea basin; the strategy takes into account the geographic, climatic, economic and political specificities of the sea basin;

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*Amendment*

- (16) 'sea basin strategy' means a structured framework of cooperation in respect to a given geographical area, developed by European Institutions, Member States, their regions **and local authorities** and where appropriate third countries sharing a sea basin; the strategy takes into account the geographic, climatic, economic and political specificities of the sea basin;

Wednesday 23 October 2013

**Amendment 140**

**Proposal for a regulation**

**Article 3 — paragraph 2 — point 16 a (new)**

*Text proposed by the Commission*

*Amendment*

(16a) ‘semi intensive aquaculture’ means aquaculture that depends largely on natural food but where the naturally present food levels are increased through the use of supplementary feed that complements that natural food. Culture densities are kept at lower levels than those typical for intensive aquaculture production;

**Amendment 142**

**Proposal for a regulation**

**Article 3 — paragraph 2 — point 18 a (new)**

*Text proposed by the Commission*

*Amendment*

(18a) ‘shellfish catcher/grower’ means any individual carrying out extraction, cultivation or semi-cultivation, whether on foot or on board a vessel, exclusively and using selective, specific gear for the capture of one or more species of molluscs, crustaceans, tunicates, echinoderms or other marine invertebrates;

**Oral Amendment**

**Proposal for a regulation**

**Article 3 — paragraph 2 — point 18 b (new)**

*Text proposed by the Commission*

*Amendment*

(18b) ‘tuna trap’ means traditional extractive fishing technique based on fixed nets anchored to the bottom for several months, which consists of a group of vessels, nets, fishing wires and anchors located near the coastline to intercept migratory fisheries (tuna and tunalike species) and lead them to an enclosed area where they are extracted;

Wednesday 23 October 2013

## Amendment 143

## Proposal for a regulation

## Article 5 — paragraph 1 — point a

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*Text proposed by the Commission*

- (a) promoting sustainable **and competitive** fisheries **and** aquaculture;

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*Amendment*

- (a) promoting **environmentally** sustainable, **economically viable and socially responsible** fisheries, aquaculture **and related activities of processing or marketing**;

## Amendment 144

## Proposal for a regulation

## Article 5 — paragraph 1 — point c

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*Text proposed by the Commission*

- (c) promoting a balanced and inclusive territorial development of fisheries areas;

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*Amendment*

- (c) promoting a balanced and inclusive territorial development of fisheries **and aquaculture** areas;

## Amendment 145

## Proposal for a regulation

## Article 5 — paragraph 1 — point d

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*Text proposed by the Commission*

- (d) fostering the implementation of the CFP.

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*Amendment*

- (d) fostering the implementation of the CFP, **including its regionalisation and the implementation of the common organisation of the markets**.

## Amendment 146

## Proposal for a regulation

## Article 5 — paragraph 1 — point d a (new)

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*Text proposed by the Commission*

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*Amendment*

- (da) **Fostering job creation in order to prevent the disappearance of fishing communities and delivering improved qualifications and working conditions in the fisheries sector.**

Wednesday 23 October 2013

## Amendment 147

## Proposal for a regulation

## Article 5 — paragraph 2 (new)

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Text proposed by the Commission

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Amendment

2. ***In achieving these objectives, the EMFF shall take into account the principles of intergenerational and gender equity.***

## Amendment 148

## Proposal for a regulation

## Article 5 — paragraph 3 (new)

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Text proposed by the Commission

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Amendment

3. ***These objectives shall be pursued without increasing fishing capacity.***

## Amendment 149

## Proposal for a regulation

## Article 6 — paragraph 1 — introductory part

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Text proposed by the Commission

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Amendment

The achievement of the objectives of the EMFF shall contribute to the Europe 2020 strategy for smart, sustainable and inclusive growth. It shall be pursued through the following six Union priorities, which translate the relevant Thematic Objectives of the Common Strategic Framework (hereinafter CSF):

The achievement of the objectives of the EMFF shall contribute to the Europe 2020 strategy for smart, sustainable and inclusive growth ***as well as to the implementation of the CFP***. It shall be pursued through the following six Union priorities ***for fisheries, sustainable aquaculture and related activities***, which translate the relevant Thematic Objectives of the Common Strategic Framework (hereinafter CSF):

## Amendment 150

## Proposal for a regulation

## Article 6 — paragraph 1 — point 1 — introductory part

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Text proposed by the Commission

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Amendment

(1) Increasing employment and territorial cohesion through the following objectives:

(1) Increasing employment and ***social and*** territorial cohesion through the following objectives:

Wednesday 23 October 2013

## Amendment 151

## Proposal for a regulation

## Article 6 — paragraph 1 — point 1 — point a

*Text proposed by the Commission*

- (a) promotion of economic growth, social inclusion, creation of jobs and **supporting labour** mobility in coastal and inland communities depending on fishing and aquaculture;

*Amendment*

- (a) promotion of economic growth **and** social inclusion, **including through the** creation of jobs **and the development of employability** and mobility in coastal and inland communities depending on fishing and aquaculture, **including in outermost regions**;

## Amendment 152

## Proposal for a regulation

## Article 6 — paragraph 1 — point 1 — point b

*Text proposed by the Commission*

- (b) diversification of fisheries activities **into** other sectors of maritime economy and growth of maritime economy, including mitigation of climate change.

*Amendment*

- (b) diversification of fisheries activities **in both the fisheries sector and** other sectors of **the** maritime economy **that are closely connected to the fishing sector**, and growth of maritime economy, including mitigation of climate change.

## Amendment 153

## Proposal for a regulation

## Article 6 — paragraph 1 — point 1 — point b a (new)

*Text proposed by the Commission**Amendment*

- (ba) promoting the implementation of harmonised social rules at Union level.**

## Amendment 154

## Proposal for a regulation

## Article 6 — paragraph 1 — point 2 — point a

*Text proposed by the Commission*

- (a) support to strengthening technological development, innovation and knowledge transfer;

*Amendment*

- (a) support to strengthening technological development, innovation, **including increasing energy efficiency**, and knowledge transfer;

Wednesday 23 October 2013

## Amendment 155

## Proposal for a regulation

## Article 6 — paragraph 1 — point 2 — point a (new)

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Text proposed by the Commission

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Amendment

(aa) *reducing the negative impact of fishing on animal welfare;*

## Amendment 156

## Proposal for a regulation

## Article 6 — paragraph 1 — point 2 — point b

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Text proposed by the Commission

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Amendment

(b) enhancement of the competitiveness and viability of fisheries, *in particular of small scale coastal fleet*, and improvement of safety *or* working conditions;

(b) enhancement of the competitiveness and viability of fisheries and improvement of *their health, hygiene*, safety *and* working conditions;

## Amendment 157

## Proposal for a regulation

## Article 6 — paragraph 1 — point 2 — point c

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Text proposed by the Commission

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Amendment

(c) development of new professional skills and lifelong learning;

(c) development of *professional training*, new professional skills and lifelong learning, *in particular for young fishermen*;

## Amendment 158

## Proposal for a regulation

## Article 6 — paragraph 1 — point 2 — point c a (new)

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Text proposed by the Commission

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Amendment

(ca) *developing small scale coastal fishing, especially its competitiveness and sustainability;*

Wednesday 23 October 2013

## Amendment 159

## Proposal for a regulation

## Article 6 — paragraph 1 — point 3 — introductory part

Text proposed by the Commission

- (3) Fostering innovative, competitive **and** knowledge **based aquaculture** through the focus on the following areas:

Amendment

- (3) Fostering **sustainable**, innovative, competitive **aquaculture based on** knowledge **and the ecosystem** through the focus on the following areas:

## Amendment 160

## Proposal for a regulation

## Article 6 — paragraph 1 — point 3 — point a

Text proposed by the Commission

- (a) support to strengthening technological development, innovation and knowledge transfer;

Amendment

- (a) support to strengthening technological development, **technical, social and economic** innovation and knowledge transfer;

## Amendment 161

## Proposal for a regulation

## Article 6 — paragraph 1 — point 3 — point b

Text proposed by the Commission

- (b) enhancement of the competitiveness and viability of aquaculture enterprises, SMEs in particular;

Amendment

- (b) enhancement of the competitiveness and viability of **extensive and semi intensive** aquaculture enterprises, SMEs in particular;

## Amendment 162

## Proposal for a regulation

## Article 6 — paragraph 1 — point 3 — point c

Text proposed by the Commission

- (c) development of new professional skills and lifelong learning;

Amendment

- (c) development of new professional skills **and encouragement of professional training** and lifelong learning, **in particular for young aquaculture farmers**;

Wednesday 23 October 2013

**Amendment 163**

**Proposal for a regulation**

**Article 6 — paragraph 1 — point 3 — point d**

*Text proposed by the Commission*

(d) improved market organisation for aquaculture products.

*Amendment*

(d) improved market organisation for aquaculture products **and encouragement of investment in the processing and marketing sectors.**

**Amendment 164**

**Proposal for a regulation**

**Article 6 — paragraph 1 — point 3 — point d a (new)**

*Text proposed by the Commission*

*Amendment*

**(da) limiting the ecological footprint by aquaculture.**

**Amendment 165**

**Proposal for a regulation**

**Article 6 — paragraph 1 — point 4 — point a**

*Text proposed by the Commission*

(a) **reduction of the impact** of fisheries on the marine environment;

*Amendment*

(a) **prevention, minimisation and, as far as possible, elimination of unwanted catches and of negative impacts** of fisheries on the marine environment, **especially through better selectivity of fishing gears;**

**Amendment 166**

**Proposal for a regulation**

**Article 6 — paragraph 1 — point 4 — point a a (new)**

*Text proposed by the Commission*

*Amendment*

**(aa) ensuring a balance between fishing capacity and available fishing opportunities;**

Wednesday 23 October 2013

**Amendment 167****Proposal for a regulation****Article 6 — paragraph 1 — point 4 — point b a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ba) implementation of the Marine Strategy Framework Directive and achievement of good environmental status by 2020;**

**Amendment 168****Proposal for a regulation****Article 6 — paragraph 1 — point 5 — point a**

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*Text proposed by the Commission*

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*Amendment*

**(a) enhancement of ecosystems related to aquaculture and**  
promotion of resource efficient aquaculture;

**(a) promotion of resource efficient aquaculture, including by reducing dependence on fish food and oil and reducing the use of chemicals and antibiotics;**

**Amendment 169****Proposal for a regulation****Article 6 — paragraph 1 — point 5 — point a a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(aa) assessment, reduction and, where possible, elimination of the impacts of aquaculture activities on marine, terrestrial and freshwater ecosystems;**

**Amendment 170****Proposal for a regulation****Article 6 — paragraph 1 — point 6 — introductory part**

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*Text proposed by the Commission*

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*Amendment*

**(6) Fostering the implementation of the CFP through:**

**(6) Fostering the implementation of the CFP and strengthening its links and coherence with the Integrated Maritime Policy through:**

Wednesday 23 October 2013

## Amendment 171

## Proposal for a regulation

## Article 6 — paragraph 1 — point 6 — point a

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Text proposed by the Commission(a) the **supply of** scientific knowledge **and collection of data**;

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Amendment(a) the **support for the collection and management of data, in order to improve** scientific knowledge;

## Amendment 172

## Proposal for a regulation

## Article 6 — paragraph 1 — point 6 — point b

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Text proposed by the Commission(b) the support **to** control and enforcement, enhancing institutional capacity and an efficient public administration.

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Amendment(b) the support **for monitoring**, control and enforcement, enhancing institutional capacity and an efficient public administration **without increasing the administrative burden**;

## Amendment 173

## Proposal for a regulation

## Article 6 — paragraph 1 — point 6 — point b a (new)

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Text proposed by the Commission

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Amendment(ba) **the support for the regionalisation of the CFP, especially through Regional Advisory Councils.**

## Amendment 174

## Proposal for a regulation

## Article 8 — paragraph 1

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Text proposed by the Commission1. **Without prejudice to paragraph 2 of this Article**, Articles 107, 108 and 109 of the Treaty shall apply to aid granted by the Member States to enterprises in fisheries **and** aquaculture.

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Amendment1. Articles 107, 108 and 109 of the Treaty shall apply to aid granted by the Member States to enterprises in **the** fisheries **and** aquaculture **sector**.

Wednesday 23 October 2013

## Amendment 175

## Proposal for a regulation

## Article 8 — paragraph 2

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Text proposed by the Commission

2. **However** Articles 107, 108 and 109 of the Treaty shall not apply to payments made by Member States pursuant to, and in conformity with, this Regulation within the scope of Article 42 of the Treaty.

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Amendment

2. **By way of derogation from paragraph 1**, Articles 107, 108 and 109 of the Treaty shall not apply to payments made by Member States pursuant to, and in conformity with, this Regulation within the scope of Article 42 of the Treaty.

## Amendment 176

## Proposal for a regulation

## Article 10 — paragraph 1

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Text proposed by the Commission

In addition to the principles enounced in Article 4 of the [Regulation (EU) No [...] laying down Common Provisions], the Commission and the Member States shall ensure coordination and complementarity between support from the EMFF and from other Union policies and financial instruments, including **the Regulation (EC) No [establishing the Framework Programme for Environment and Climate Change Action (LIFE Framework Programme)]** and those in the framework of the Union's external action. **Coordination between assistance from the EMFF and LIFE Framework Programme shall be achieved in particular, by promoting the funding of activities that complement integrated projects funded under LIFE Framework Programme, as well as by promoting the use of solutions, methods and approaches validated under LIFE Framework Programme.**

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Amendment

In addition to the principles enounced in Article 4 of the [Regulation (EU) No [...] laying down Common Provisions], the Commission and the Member States shall ensure coordination and complementarity between support from the EMFF and from other Union policies and financial instruments, including those in the framework of the Union's external action. **This coordination and complementarity requirement shall be included in the operational programmes.**

## Amendment 177

## Proposal for a regulation

## Article 11

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Text proposed by the Commission

The ex ante conditionalities referred to in Annex III of this Regulation shall apply for the EMFF.

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Amendment

The **specific** ex ante conditionalities referred to in Annex III of this Regulation shall apply for the EMFF.

Wednesday 23 October 2013

**Amendment 178**  
**Proposal for a regulation**  
**Article 11 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 11a**

***Assessment of compliance with capacity ceilings***

**1. By ... (\*), the Commission, in collaboration with the Member States, shall carry out an assessment of Member States' compliance with fishing capacity ceilings, set out in Annex II to Regulation (EU) No .../..... [on the CFP].**

**2. When the assessment referred to in paragraph 1 indicates that a Member State is not complying with its capacity ceilings, the Commission may adopt implementing acts suspending all or part of the payments and commitments for the operational programme of the Member State concerned.**

**3. The Commission shall lift the suspension of payments and commitments as soon as the Member State implements measures aimed at complying with its capacity ceilings and these are approved by the Commission.**

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**(\*) Three years after the date of entry into force of this Regulation.**

**Amendment 180**  
**Proposal for a regulation**  
**Article 12 — paragraph 1 — point b a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ba) operators involved in the operation, management or ownership of fishing vessels flagged to countries identified as non-cooperating third countries pursuant to Article 33 of Regulation (EC) No 1005/2008;**

**Amendment 181**  
**Proposal for a regulation**  
**Article 12 — paragraph 1 — point b b (new)**

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*Text proposed by the Commission*

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*Amendment*

**(bb) operators found guilty, in criminal or administrative proceedings, of having committed a serious infringement of the applicable national legislation in the following areas:**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

- *pay and employment conditions in the trade;*
- *professional liability;*
- *human or drug trafficking;*

**Amendment 182****Proposal for a regulation****Article 12 — paragraph 1 — point b c (new)**

Text proposed by the Commission

Amendment

- (bc) *operators found guilty, in criminal or administrative proceedings, of having committed, in one ore more Member States, a serious infringement of Union legislation, particularly concerning:*
- *working hours and rest periods for fishermen;*
  - *health and safety legislation;*
  - *pay and employment conditions in the trade;*
  - *the initial qualification and continuous training of fishermen;*

**Amendment 184****Proposal for a regulation****Article 12 — paragraph 1 — point c a (new)**

Text proposed by the Commission

Amendment

- (ca) *operators who have failed to comply with the provisions of the Council Regulation (EC) No 199/2008 of 25 February 2008 concerning the establishment of a Community framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the CFP <sup>(1)</sup>.*

<sup>(1)</sup> OJ L 60, 5.3.2008, p. 1.

Wednesday 23 October 2013

#### Amendment 571

#### Proposal for a regulation

#### Article 12 — paragraph 3 — point a

*Text proposed by the Commission*

- (a) the identification of the period of time referred to in paragraphs 1 and 2 which shall be proportionate to the gravity of the infringement or non-compliance;

*Amendment*

- (a) the identification of the period of time referred to in paragraphs 1 and 2 which shall be proportionate to the gravity of the infringement or non-compliance **in question, taking into account criteria such as the damage done, its value, the extent of the infringement or non-compliance and its repetition, and which shall be of at least one year;**

#### Amendment 185

#### Proposal for a regulation

#### Article 12 — paragraph 4

*Text proposed by the Commission*

4. Member States shall require that operators submitting an application under the EMFF provide to the managing authority a signed statement confirming that they respect the criteria listed in paragraph 1 and **have not committed an irregularity under the EEF or the EMFF as referred to in** paragraph 2. Member States shall verify the veracity of the statement before the approval of the operation

*Amendment*

4. Member States shall require that operators submitting an application under the EMFF provide to the managing authority a signed statement confirming that they respect the criteria listed in paragraph 1 and paragraph 2. Member States shall verify the veracity of the statement before the approval of the operation, **by reference to the information provided in the national register of infringements established under Article 93 of Regulation (EC) No 1224/2009, or to other data provided for this purpose.**

#### Amendment 610

#### Proposal for a regulation

#### Article 12 a (new)

*Text proposed by the Commission*

*Amendment*

#### Article 12a

#### *Suspension of payments*

***In the case of operators being under investigation for having committed an infringement described in Article 12(1), any payments under the EMFF to the operators concerned shall be suspended. Should an operator be found to have committed a infringement under Article 12(1), the application of the operators concerned shall be considered inadmissible.***

Wednesday 23 October 2013

## Amendment 186

## Proposal for a regulation

## Article 13 — paragraph 1 — point a

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*Text proposed by the Commission*

(a) operations increasing the fishing capacity of the vessel;

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*Amendment*(a) operations increasing the fishing capacity of the vessel **or its ability to catch fish;**

## Amendment 187

## Proposal for a regulation

## Article 13 — paragraph 1 — point a a (new)

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*Text proposed by the Commission*

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*Amendment***(aa) operations jeopardising the sustainability of marine biological resources and ecosystems;**

## Amendment 188

## Proposal for a regulation

## Article 13 — paragraph 1 — point a b (new)

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*Text proposed by the Commission*

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*Amendment***(ab) destructive employment measures;**

## Amendment 190

## Proposal for a regulation

## Article 13 — paragraph 1 — point b a (new)

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*Text proposed by the Commission*

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*Amendment***(ba) investments on board for vessels belonging to a fleet segment for which the capacity report, referred to in Article 34(1) of Regulation (EU) No .../... [on CFP], has demonstrated that there is no sustainable balance between fishing opportunities and fleet capacity;**

Wednesday 23 October 2013

**Amendment 191****Proposal for a regulation****Article 13 — paragraph 1 — point c***Text proposed by the Commission**Amendment*(c) **temporary cessation of fishing activities;****deleted****Amendment 192****Proposal for a regulation****Article 13 — paragraph 1 — point d***Text proposed by the Commission**Amendment*(d) **experimental** fishing;(d) **exploratory** fishing;**Amendment 611****Proposal for a regulation****Article 15 — paragraphs 2 to 4***Text proposed by the Commission**Amendment*

2. **EUR 4 535 000 000** of the resources referred to in paragraph (1) shall be allocated to the sustainable development of fisheries, aquaculture and fisheries areas under Chapters I, II and III of Title V.

2. **A maximum of 71,86 %** of the resources referred to in paragraph (1) shall be allocated to the sustainable development of fisheries, aquaculture and fisheries areas under Chapters I, II and III of Title V.

3. **EUR 477 000 000** of the resources referred to in paragraph (1) shall be allocated to control and enforcement measures referred to in Article 78.

3. **A minimum of 12,5 %** of the resources referred to in paragraph (1) shall be allocated to control and enforcement measures referred to in Article 78.

4. **EUR 358 000 000** of the resources referred to in paragraph (1) shall be allocated to measures on data collection referred to in Article 79.

4. **A minimum of 12,97 %** of the resources referred to in paragraph (1) shall be allocated to measures on data collection referred to in Article 79.

**Amendment 198****Proposal for a regulation****Article 15 — paragraph 5 — introductory part***Text proposed by the Commission**Amendment*

5. The resources allocated to compensation of outermost regions under Chapter V of Title V, shall not exceed **per year**:

5. The resources allocated to compensation of outermost regions under Chapter V of Title V, shall not exceed:

Wednesday 23 October 2013

**Amendment 199****Proposal for a regulation****Article 15 — paragraph 5 — indent 1***Text proposed by the Commission*— EUR **4 300 000** for the Azores and Madeira;*Amendment*— EUR **X per year** for the Azores and Madeira;**Amendment 200****Proposal for a regulation****Article 15 — paragraph 5 — indent 2***Text proposed by the Commission*— EUR **5 800 000** for the Canary Islands;*Amendment*— EUR **X per year** for the Canary Islands;**Amendment 201****Proposal for a regulation****Article 15 — paragraph 5 — indent 3***Text proposed by the Commission*— EUR **4 900 000** for the French **Guiana and Réunion**.*Amendment*— EUR **X per year** for the French **outermost regions**.**Amendment 202****Proposal for a regulation****Article 15 — paragraph 6***Text proposed by the Commission*

6. EUR **45 000 000** of the resources referred to in paragraph (1) shall be allocated to the storage aid referred to in Article 72 **from 2014 to 2018 included**.

*Amendment*

6. EUR **X** of the resources referred to in paragraph (1) shall be allocated to the **production and marketing plans referred to in Article 69 and to the** storage aid referred to in Article 70.

Wednesday 23 October 2013

## Amendment 616

## Proposal for a regulation

## Article 15 — paragraph 6 a (new)

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Text proposed by the Commission

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Amendment

**6a.** Member States shall have the opportunity to use resources available under Article 15(2), 15(5) and 15(6) for measures under Article 15(3) and Article 15(4).

## Amendment 204

## Proposal for a regulation

## Article 16 a (new)

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Text proposed by the Commission

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Amendment**Article 16a****[Annual reference amounts and annual appropriations]**

1. The overall indicative financial reference amount, as defined in point [17] of the Interinstitutional Agreement of xx/201z between the European Parliament, the Council and the Commission on cooperation in budgetary matters and sound financial management for the implementation of the Programme for the period 2014 to 2020 shall be EUR X in constant 2011 prices.

2. Annual appropriations shall be authorised by the European Parliament and the Council without prejudice to the provisions of the Regulation laying down the multiannual financial framework for the years 2014–2020 and the Interinstitutional Agreement xxx/201z between the European Parliament, Council and the Commission on cooperation in budgetary matters and sound financial management.

## Amendment 205

## Proposal for a regulation

## Article 17 — paragraph 1 — point a — point i

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Text proposed by the Commission

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Amendment

(i) the level of employment in fisheries **and** aquaculture,

(i) the level of employment in fisheries, **in** aquaculture **and in the processing industry**,

Wednesday 23 October 2013

## Amendment 206

## Proposal for a regulation

## Article 17 — paragraph 1 — point a — point ii

Text proposed by the Commission

(ii) the level of production in fisheries and aquaculture,

Amendment

(ii) the level of production in fisheries, **in** aquaculture **and in the processing industry**,

## Amendment 207

## Proposal for a regulation

## Article 17 — paragraph 1 — point b — point iii

Text proposed by the Commission

(iii) the extent of data **collections** tasks of the Member State concerned, approximated by the size of the national fishing fleet, the amount of landings, the amount of scientific monitoring activities at sea and the number of surveys the Member State is taking part in, and

Amendment

(iii) the extent of **the** data **collection and management** tasks of the Member State concerned, approximated by the size of the national fishing fleet, the amount of landings, the amount of scientific monitoring activities at sea and the number of surveys the Member State is taking part in, and

## Amendment 208

## Proposal for a regulation

## Article 17 — paragraph 1 — point b — point iv

Text proposed by the Commission

(iv) the **available** data collection resources compared to the extent of the data collection tasks of the Member State, where available means are approximated to **the number of observers at sea and the amount of** human resources and technical means needed to implement the national sampling programme for data collection.

Amendment

(iv) the data collection **and management** resources **that are available** compared to the extent of the data collection **and management** tasks of the Member State, where available means are approximated to human resources and technical means needed to implement the national sampling programme for data collection.

## Amendment 209

## Proposal for a regulation

## Article 17 — paragraph 1 — point c

Text proposed by the Commission

c) As regards all measures, the **historical allocations** under Council Regulation (EC) No 1198/2006 and the historical consumption under Council Regulation (EC) No 861/2006.

Amendment

c) As regards all measures, the **previous allocation of funds** under Council Regulation (EC) No 1198/2006 **for the 2007–2013 period** and the **previous** consumption under Council Regulation (EC) No 861/2006.

Wednesday 23 October 2013

#### Amendment 210

##### Proposal for a regulation

##### Article 18 — paragraph 1

*Text proposed by the Commission*

1. Each Member State shall draw up a single operational programme to implement the Union priorities to be co-financed by the EMFF.

*Amendment*

1. Each Member State shall draw up a single operational programme to implement the Union priorities **referred to in Article 6 of this Regulation** to be co-financed by the EMFF.

#### Amendment 211

##### Proposal for a regulation

##### Article 18 — paragraph 3

*Text proposed by the Commission*

3. For the section of the operational programme referred to in Article 20(1)(n) the Commission shall adopt **by means of implementing act** the priorities of the Union for enforcement and control policy by 31 May 2013 at the latest.

*Amendment*

3. For the section of the operational programme referred to in Article 20(1)(n), the Commission shall **be empowered to adopt delegated acts, in accordance with Article 127, setting** the priorities of the Union for enforcement and control policy by 31 May 2013 at the latest.

#### Amendment 212

##### Proposal for a regulation

##### Article 19 — paragraph 2 (new)

*Text proposed by the Commission*

*Amendment*

(2) **Each Member State shall include a production and marketing plan as referred to in Article 32 of Regulation (EU) No .../....[on the common organisation of the markets in fishery and aquaculture products].**

#### Amendment 213

##### Proposal for a regulation

##### Article 19 — paragraph 1 — point c

*Text proposed by the Commission*

(c) appropriate action is envisaged to simplify and facilitate the implementation of the programme;

*Amendment*

(c) appropriate action is envisaged to simplify and facilitate the implementation of the programme, **in particular facilitating access by small scale coastal fishing operators and their organisations to the available financial support;**

Wednesday 23 October 2013

## Amendment 214

## Proposal for a regulation

## Article 19 — point d a (new)

Text proposed by the Commission

Amendment

(da) *where applicable, consistency of the measures under Union priorities for EMFF referred to in point d of Article 38(1) of this Regulation and the prioritised action frameworks for Natura 2000 referred to in Article 8(4) of Council Directive 92/43/EEC as well as the achievement of good environmental status as defined in Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive).*

## Amendment 215

## Proposal for a regulation

## Article 20 — paragraph 1 — point b

Text proposed by the Commission

Amendment

(b) an analysis of the situation in terms of SWOT and identification of the needs that have to be addressed in the geographical area covered by the programme;

(b) an analysis of the situation in terms of SWOT and identification of the needs that have to be addressed in the geographical **and environmental** area covered by the programme;

The analysis shall be structured around the Union priorities. Specific needs concerning climate change mitigation and adaptation and promotion of innovation shall be assessed **across** Union priorities, in view of identifying relevant responses **in these two areas** at the level of each **priority; a synthesis of the situation of the policy areas eligible for support in terms of strengths and weaknesses;**

The analysis shall be structured around the Union priorities **as laid down in Article 6**. Specific needs concerning climate change mitigation and adaptation and promotion of innovation shall be assessed **in relation to** Union priorities, **with a view to** identifying **the most** relevant responses at the level of each of the **priorities related to those** areas;

**This analysis shall also cover the effects on each coastal region or area of implementation of the CFP.**

## Amendment 216

## Proposal for a regulation

## Article 20 — paragraph 1 — point b a (new)

Text proposed by the Commission

Amendment

(ba) **an analysis of the consequences for jobs, throughout the whole value chain, of implementing the CFP and innovative proposals for jobs in the affected areas;**

Wednesday 23 October 2013

## Amendment 217

## Proposal for a regulation

## Article 20 — paragraph 1 — point c

Text proposed by the Commission

- (c) **a demonstration of a pertinent approach integrated into** the programme **towards innovation**, the environment, **including** the specific needs of Natura 2000 areas, and climate change mitigation and adaptation;

Amendment

- (c) **an analysis showing that** the programme **takes account of the effects of fishing and aquaculture on** the environment **and, where appropriate**, the specific needs of Natura 2000 areas, **as well as the achievement of good environmental status, the establishment of a coherent network of fish recovery areas** and climate change mitigation and adaptation;

## Amendment 218

## Proposal for a regulation

## Article 20 — paragraph 1 — point c a (new)

Text proposed by the Commission

Amendment

- (ca) **an assessment of the balance between fishing capacity and available fishing opportunities, as required under Regulation (EU) No .../.... [on the CFP] and a description of the measures taken to comply with fishing capacity ceilings set out in Annex II to that Regulation;**

## Amendment 219

## Proposal for a regulation

## Article 20 — paragraph 1 — point h

Text proposed by the Commission

Amendment

- (h) a clear indication of the **operations** under Chapter III of Title V that may be undertaken collectively and therefore may benefit from higher aid intensity according to Article 95 (3);

- (h) a clear indication of the **measures** under Chapter III of Title V that may be undertaken collectively and therefore may benefit from higher aid intensity according to Article 95 (3);

## Amendment 220

## Proposal for a regulation

## Article 20 — paragraph 1 — point h a (new)

Text proposed by the Commission

Amendment

- (ha) **an action plan for small-scale and coastal fishing setting out a strategy for the development, competitiveness and sustainability of small-scale and coastal fishing;**

Wednesday 23 October 2013

## Amendment 221

## Proposal for a regulation

## Article 20 — paragraph 1 — point h b (new)

Text proposed by the Commission

Amendment

(hb) **a detailed description of the measures concerning the preparation and implementation of production and marketing plans benefiting from support under Article 69;**

## Amendment 222

## Proposal for a regulation

## Article 20 — paragraph 1 — point i

Text proposed by the Commission

Amendment

(i) **an analysis of needs relating to monitoring and** evaluation requirements and the evaluation plan referred to in Article 49 of the [Regulation (EU) No [...] laying down Common Provisions]. **The Member States shall provide sufficient resources and capacity building activities** to address the identified needs;

(i) **the** evaluation requirements and the evaluation plan referred to in Article 49 of the [Regulation (EU) No [...] laying down Common Provisions] **and the measures to be taken** to address the identified needs;

## Amendment 223

## Proposal for a regulation

## Article 20 — paragraph 1 — point j — point ii

Text proposed by the Commission

Amendment

(ii) a table setting out the applicable EMFF resources and co-financing rate for the **objectives under the** Union priorities of Article 6 and the technical assistance. Where applicable, this table shall indicate separately the EMFF resources and the co-financing rates which apply by way of derogation to the general rule of Article 94(1) for support referred to in Article 72, Article 73, Article 78(2)(a) to (d) and (f) to (j), Article 78(2)(e) and Article 79.

(ii) a table setting out the applicable EMFF resources and co-financing rate for the Union priorities of Article 6 and the technical assistance. Where applicable, this table shall indicate separately the EMFF resources and the co-financing rates which apply by way of derogation to the general rule of Article 94(1) for support referred to in Article 72, Article 73, Article 78(2)(a) to (d) and (f) to (j), Article 78(2)(e) and Article 79.

## Amendment 224

## Proposal for a regulation

## Article 20 — paragraph 1 — point k

Text proposed by the Commission

Amendment

(k) information on **the** complementarity with measures financed through other **CSF Funds or the LIFE Framework Programme;**

(k) information on complementarity with measures financed through other **Union policies and financial instruments;**

Wednesday 23 October 2013

## Amendment 225

## Proposal for a regulation

## Article 20 — paragraph 1 — point 1 — point ia (new)

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Text proposed by the Commission

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Amendment

- 
- (ia) **a clear description of the roles to be performed by the FLAGs and by the management authority or body appointed for setting strategy implementation tasks;**

## Amendment 226

## Proposal for a regulation

## Article 20 — paragraph 1 — point 1 — point ii

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Text proposed by the Commission

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Amendment

- 
- (ii) a description of the monitoring and evaluation procedures, as well as the composition of the Monitoring Committee;
- 
- (ii) a description of the monitoring and evaluation procedures, as well as the **general** composition of the Monitoring Committee;

## Amendment 227

## Proposal for a regulation

## Article 20 — paragraph 1 — point m

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Text proposed by the Commission

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Amendment

- 
- (m) the designation of the partners referred to in Article 5 of the [Regulation (EU) No [...] laying down Common Provisions] and the results of the consultation of the partners;
- 
- (m) the **procedure for** designation of the partners referred to in Article 5 of the [Regulation (EU) No [...] laying down Common Provisions] and the results of the consultation of the partners; **changes with regard to partners may be implemented during the programme with the agreement of the Monitoring Committee;**

## Amendment 228

## Proposal for a regulation

## Article 20 — paragraph 1 — point n — point i

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Text proposed by the Commission

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Amendment

- 
- (i) a list of bodies implementing the control, inspection and enforcement system and a brief description of their human and financial resources available for fisheries control, inspection and enforcement, their equipment available for fisheries control, inspection and enforcement in particular the number of vessels, aircraft and helicopters;
- 
- (i) a list of bodies implementing the control, inspection and enforcement system and a brief description of their human and financial resources available for fisheries control, inspection and enforcement, their **main** equipment available for fisheries control, inspection and enforcement in particular the number of vessels, aircraft and helicopters;

Wednesday 23 October 2013

**Amendment 229****Proposal for a regulation****Article 20 — paragraph 1 — point o — introductory part***Text proposed by the Commission*

- (o) for the objective of collection of data for sustainable fisheries management referred in under Articles 6(6) and 18(4) and in accordance with the multiannual Union programme referred to in Article 37(5) of the [Regulation on Common Fisheries Policy]:

*Amendment*

- (o) for the objective of collection of data for sustainable **ecosystem-based** fisheries management referred in under Articles 6(6) and 18(4) and in accordance with the multiannual Union programme referred to in Article 37(5) of the [Regulation on Common Fisheries Policy] **and for the analysis of the socio-economic situation of the processing and marketing industry for fisheries and aquaculture products:**

**Amendment 230****Proposal for a regulation****Article 20 — paragraph 1 — point o — point i***Text proposed by the Commission*

- (i) a description of activities of data collection to be carried out to allow the following:

*Amendment*

- (i) a description of activities of data collection, to be carried out **in consultation with stakeholders** to allow the following:

**Amendment 231****Proposal for a regulation****Article 20 — paragraph 1 — point o — point i — indent 1***Text proposed by the Commission*

- an evaluation of the fishing sector (biological, **economical** and transversal variables as well as research surveys at sea),

*Amendment*

- an evaluation of the fishing sector (biological, **economic, social** and transversal variables **throughout the value chain**, as well as research surveys at sea),

**Amendment 232****Proposal for a regulation****Article 20 — paragraph 1 — point o — point i — indent 2***Text proposed by the Commission*

- an evaluation of the economic situation of aquaculture and processing industries,

*Amendment*

- an evaluation of the economic **and social** situation of aquaculture and processing industries,

Wednesday 23 October 2013

#### Amendment 233

##### Proposal for a regulation

##### Article 20 — paragraph 1 — point o — point i — indent 3

###### Text proposed by the Commission

— an evaluation of the effects of the fishing **sector** on the ecosystem.

###### Amendment

— an evaluation of the effects of the fishing **and aquaculture sectors** on the ecosystem **to enable comparisons to be made between types of fishing and aquaculture activities and fleet segments according to the requirements of Regulation (EU) No .../.... [on the CFP]**.

#### Amendment 234

##### Proposal for a regulation

##### Article 20 — paragraph 1 — point o — point iii

###### Text proposed by the Commission

(iii) a **demonstration** of the capability to achieve sound financial and administrative management of the data collected.

###### Amendment

(iii) a **justification** of the capability to achieve sound financial and administrative management of the data collected.

#### Amendment 235

##### Proposal for a regulation

##### Article 20 — paragraph 4

###### Text proposed by the Commission

4. The Commission shall **lay down, by means of** implementing acts, rules for the presentation of the elements described in paragraphs 1, 2 and 3. These implementing acts shall be adopted in accordance with the **advisory** procedure referred to in Article 128(2).

###### Amendment

4. The Commission shall **adopt** implementing acts, **laying down** rules for the presentation of the elements described in paragraphs 1, 2 and 3. These implementing acts shall be adopted in accordance with the **examination** procedure referred to in Article 128(3).

#### Amendment 236

##### Proposal for a regulation

##### Article 21 — paragraph 2

###### Text proposed by the Commission

2. The Commission shall **approve** the operational programme **by means of implementing act**.

###### Amendment

2. The Commission shall adopt implementing acts approving the operational programme **when it is satisfied that the requirements of paragraph 1 have been met. Once approved the operational programmes shall be made available to the public.**

Wednesday 23 October 2013

**Amendment 237****Proposal for a regulation****Article 22 — paragraph 2 — subparagraph 2***Text proposed by the Commission*

For this purpose, the Commission shall adopt **a decision, by means of implementing act, detailing** the changes in the priorities of the Union in the enforcement and control policy mentioned in Article 18(3) and the corresponding eligible operations to be prioritised.

*Amendment*

For this purpose, the Commission shall **be empowered to adopt delegated acts, in accordance with Article 127, detailing** the changes in the priorities of the Union in the enforcement and control policy mentioned in Article 18(3) and the corresponding eligible operations to be prioritised.

**Amendment 238****Proposal for a regulation****Article 22— paragraph 2 — subparagraph 3***Text proposed by the Commission*

**Taking** into account the new priorities laid down in the decision mentioned in the second sub-paragraph of this paragraph, Member States shall submit to the Commission by 31 October of the year preceding the year of implementation concerned, the amendment to the Operational Programme.

*Amendment*

**Member States may amend their operational programme, taking** into account the new priorities laid down in the decision mentioned in the second sub-paragraph of this paragraph. Member States shall submit **any such amendments** to the Commission by 31 October of the year preceding the year of implementation concerned.

**Amendment 239****Proposal for a regulation****Article 23 — paragraph 1***Text proposed by the Commission*

1. For the purpose of application of Article 20(1)(o), Member States shall submit to the Commission **an annual work plan** before 31 October each year. Annual work plans shall contain a description of the procedures and methods to be used in collecting and analysing data and in estimating their accuracy and precision.

*Amendment*

1. For the purpose of application of Article 20(1)(o), Member States shall submit to the Commission, before 31 October each year, **an annual work plan or shall notify the Commission of the continuation of the plan that was in force the previous year.** Annual work plans shall **be drawn up within the framework of a multiannual national programme, in accordance with the Union programme and shall** contain a description of the procedures and methods to be used in collecting and analysing data and in estimating their accuracy and precision.

**Amendment 240****Proposal for a regulation****Article 24 — paragraph 1 — subparagraph 2 — point b***Text proposed by the Commission*

(b) introduction or withdrawal of measures or types of operations;

*Amendment*

(b) introduction or withdrawal of measures or types of **relevant** operations **and the information and indicators related to them;**

Wednesday 23 October 2013

#### Amendment 241

#### Proposal for a regulation

#### Article 24 — paragraph 2

*Text proposed by the Commission*

2. These implementing acts shall be adopted in accordance with the **advisory** procedure referred to in Article 128(2).

*Amendment*

2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the **examination** procedure referred to in Article 128(3).

#### Amendment 242

#### Proposal for a regulation

#### Article 25 — title

*Text proposed by the Commission*

Annual work **programme**

*Amendment*

**Multiannual operational programme and annual work programmes**

#### Amendment 243

#### Proposal for a regulation

#### Article 25 — paragraph 1

*Text proposed by the Commission*

1. **To implement** Chapters I and II of Title VI and Article 92, the Commission shall, **by means of implementing** acts, **adopt** annual work **programme** in accordance with objectives set out in those Chapters. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 128(3).**

*Amendment*

1. **In order to establish the details for the application of** Chapters I and II of Title VI and Article 92, the Commission shall **adopt delegated** acts, **in accordance with Article 127, setting up a multiannual operational programme, one of the tasks of which shall be to establish** annual work **programmes**, in accordance with **the** objectives set out in those Chapters.

#### Amendment 244

#### Proposal for a regulation

#### Article 25 — paragraph 2

*Text proposed by the Commission*

2. The annual work **programme** shall set out the objectives pursued, the expected results, the method of implementation and its total amount. It shall also contain a description of the activities to be financed, an indication of the amount allocated to each activity, an indicative implementation timetable, as well as information on their implementation. It shall include for grants the priorities, the essential evaluation criteria and the maximum rate of co-financing.

*Amendment*

2. The **multiannual operational programme and the** annual work **programmes** shall set out the objectives pursued, the expected results, the method of implementation and its total amount. **They** shall also contain a description of the activities to be financed, an indication of the amount allocated to each activity **and** an indicative implementation timetable, as well as information on their implementation. **For grants, they** shall include the priorities, the essential evaluation criteria and the maximum rate of co-financing. **They shall furthermore include a requirement for annual reports on budget implementation.**

Wednesday 23 October 2013

## Amendment 245

## Proposal for a regulation

## Article 27 — paragraph 1

*Text proposed by the Commission*

1. The owner of a fishing vessel having received support under Articles 32(1)(b), 36, 39(1)(a), or 40(2) of this Regulation shall not transfer the vessel to a third country outside the Union **during** at least **5** years following the date of actual payment to the beneficiary.

*Amendment*

1. The owner of a fishing vessel having received support under Articles 32, 36, 39 or 40 of this Regulation shall not transfer the vessel to a third country outside the Union **for** at least **five** years following the date of actual payment **of that support** to the beneficiary, **unless that support is reimbursed by the beneficiary on a pro rata temporis basis before such transfer. The first sentence of this paragraph shall be without prejudice to Article 135 of the [Financial Regulation].**

## Amendment 618

## Proposal for a regulation

## Article 27 — paragraph 1 a (new)

*Text proposed by the Commission**Amendment*

**1a. The total financial contribution from the EMFF to the measures on Sustainable Young Employment Programmes in the small scale fisheries referred to in Article 32(-1), temporary cessation referred to in Article 33A, the replacement or modernisation of main or ancillary engines referred to in Article 39 and permanent cessation shall not exceed 20 % of the Union financial assistance allocated per Member State.**

## Amendment 246

## Proposal for a regulation

## Article 28 — paragraph 1

*Text proposed by the Commission*

1. In order to stimulate innovation in fisheries, the EMFF may support projects aiming at developing or introducing new or substantially improved products **compared to the state of art, new** or improved processes, new or improved management and organisation systems.

*Amendment*

1. In order to stimulate innovation in fisheries **and the processing industry**, the EMFF may support projects aiming at developing or introducing new or substantially improved **techniques, equipment or products, for example through designing innovative vessels, as well as** new or improved processes **and** new or improved management and organisation systems, **provided that such projects contribute to the objectives listed in Article 2 of Regulation (EU) No .../.... [on the CFP].**

Wednesday 23 October 2013

**Amendment 247**

**Proposal for a regulation**

**Article 28 — paragraph 2**

*Text proposed by the Commission*

2. Operations financed under this Article must be carried out in collaboration with a scientific or technical body recognised by the Member State which shall validate the results of such operations.

*Amendment*

2. Operations financed under this Article must be carried out **by or** in collaboration with a scientific or technical body recognised by the Member State **or the Union** which shall validate the results of such operations.

**Amendment 248**

**Proposal for a regulation**

**Article 28 — paragraph 3**

*Text proposed by the Commission*

3. The results of operations financed under this Article shall be subject **to** adequate publicity by the Member State according to Article 120.

*Amendment*

3. The results of operations financed under this Article shall be **the** subject **of publicly accessible reports, as well as** adequate publicity by the Member State according to Article 120.

**Amendment 249**

**Proposal for a regulation**

**Article 28 — paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3a. The application procedure for innovation support shall be made more accessible in order to encourage more projects.**

**Amendment 250**

**Proposal for a regulation**

**Article 29 — paragraph 1 — introductory part**

*Text proposed by the Commission*

1. In order to improve the overall performance and competitiveness of operators, the EMFF may support:

*Amendment*

1. In order to improve the overall performance and competitiveness of operators **and to promote more sustainable fisheries**, the EMFF may support:

Wednesday 23 October 2013

## Amendment 251

## Proposal for a regulation

## Article 29 — paragraph 1 — point a a (new)

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Text proposed by the Commission

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Amendment

- (aa) *the provision of professional advice on the development of more sustainable fishing practices, with a focus on limiting and, where possible, eliminating the impact of such activities on marine, terrestrial and freshwater ecosystems;*

## Amendment 252

## Proposal for a regulation

## Article 29 — paragraph 1 — point a b (new)

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Text proposed by the Commission

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Amendment

- (ab) *the provision of technical, legal or economic advisory services linked to projects potentially eligible for support under this Chapter;*

## Amendment 253

## Proposal for a regulation

## Article 29 — paragraph 1 — point b

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Text proposed by the Commission

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Amendment

- (b) the provision of professional advice on business and marketing strategies.

- (b) the provision of professional advice on business and marketing strategies, *including advice on promotion, marketing and public relations.*

## Amendment 254

## Proposal for a regulation

## Article 29 — paragraph 2

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Text proposed by the Commission

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Amendment

2. The feasibility studies *and* advice referred to *respectively* in paragraph 1(a) and (b) shall be provided by recognised scientific or technical bodies with the required advisory competences as recognised by the national law of each Member State.

2. The feasibility studies, advice *and services* referred to in *points (a), (aa), (ab) and (b) of paragraph 1* shall be provided by recognised scientific, *academic, professional* or technical bodies with the required advisory competences as recognised by the national law of each Member State.

Wednesday 23 October 2013

## Amendment 255

## Proposal for a regulation

## Article 29 — paragraph 3

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*Text proposed by the Commission*

3. The support referred to in paragraph 1 shall be granted to operators **or** organisations of fishermen, recognised by the Member State, who commissioned the feasibility study referred to in paragraph 1.

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*Amendment*

3. The support referred to in paragraph 1 shall be granted to operators, organisations of fishermen **or public law bodies** recognised by the Member State, who commissioned the feasibility study **or who requested the advice or advisory services** referred to **under points (a), (aa), (ab) and (b) of** paragraph 1.

## Amendment 256

## Proposal for a regulation

## Article 29 — paragraph 4

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*Text proposed by the Commission*

4. Member States shall ensure that operations to be financed under this Article are selected through an accelerated procedure.

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*Amendment*

4. Member States shall ensure that operations to be financed under this Article are selected through an accelerated procedure, **in particular in the case of small scale coastal fisheries and inland fishing.**

## Amendment 257

## Proposal for a regulation

## Article 30 — paragraph 1 — introductory part

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*Text proposed by the Commission*

1. In order to foster the transfer of knowledge between scientists and fishermen, the EMFF may support:

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*Amendment*

1. In order to foster the **improved collection, promotion and** transfer of knowledge between scientists and fishermen, the EMFF may support:

## Amendment 258

## Proposal for a regulation

## Article 30 — paragraph 1 — point a

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*Text proposed by the Commission*

(a) the creation of **a network composed by** one or more independent scientific bodies and fishermen or one or more organisations of fishermen;

---

*Amendment*

(a) the creation of **networks, partnership agreements, contracts or associations between** one or more independent scientific bodies and fishermen or one or more organisations of fishermen, **with the participation of those public bodies of Member States that wish to participate;**

Wednesday 23 October 2013

## Amendment 259

## Proposal for a regulation

## Article 30 — paragraph 1 — point b

Text proposed by the Commission

- (b) the activities carried out **by a network as referred in** point (a).

Amendment

- (b) the activities carried out **in the framework of the networks, partnership agreements, contracts or associations created in accordance with** point (a).

## Amendment 260

## Proposal for a regulation

## Article 30 — paragraph 2

Text proposed by the Commission

2. Activities referred to in paragraph 1(b) may cover data collection activities, studies, dissemination of knowledge and best practices.

Amendment

2. Activities referred to in paragraph 1(b) may cover data collection **and management** activities, **joint research projects**, studies, **pilot projects, seminars**, dissemination of knowledge and best practices.

## Amendment 261

## Proposal for a regulation

## Article 31 — paragraph 1 — point a

Text proposed by the Commission

- (a) lifelong learning, dissemination of scientific knowledge and innovative practices, and acquisition of new professional skills in particular linked to **the sustainable management of marine ecosystems, activities in the maritime sector, innovation and entrepreneurship**;

Amendment

- (a) **actions and operations to promote professional training**, lifelong learning, dissemination of scientific, **technical, economic or legal** knowledge and innovative practices, and acquisition of new professional skills, in particular **those** linked to:
- **the sustainable management of marine and inland water ecosystems;**
  - **activities in the maritime sector;**
  - **innovation;**
  - **entrepreneurship, especially access by young people to fishing professions;**
  - **hygiene, health and safety;**
  - **training fishermen to implement the provisions of the CFP;**
  - **the prevention of occupational risks.**

Wednesday 23 October 2013

## Amendment 262

## Proposal for a regulation

## Article 31 — paragraph 1 — point b

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*Text proposed by the Commission*

- (b) networking and exchange of experience and best practice between stakeholders including among organisations **promoting** equal opportunities between men and women;

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*Amendment*

- (b) networking and exchange of experience and best practice between stakeholders including among **training** organisations **and those organisations that promote** equal opportunities between men and women **and the promotion and recognition of the crucial role performed by women in fishing communities;**

## Amendment 263

## Proposal for a regulation

## Article 31 — paragraph 1 — point c

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*Text proposed by the Commission*

- (c) **promoting the** social dialogue at national, regional **or** local level involving **fishermen** and other relevant stakeholders.

---

*Amendment*

- (c) **the promotion of** social dialogue at **Union**, national, regional **and** local level involving **operators, the social partners** and other relevant stakeholders, **with particular reference to under-represented groups such as those involved in small scale coastal fishing and in on-foot fishing.**

## Amendment 264

## Proposal for a regulation

## Article 32 — title

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*Text proposed by the Commission*

Facilitating diversification and job creation

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*Amendment*

Facilitating **entrepreneurship**, diversification and job creation

## Amendment 619

## Proposal for a regulation

## Article 32 — paragraph - 1 c (new)

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*Text proposed by the Commission*

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*Amendment*

**-1c. In order to facilitate job creation for young people in the small scale fisheries sector, the EMFF may support:**

- (a) traineeship programmes on board small scale coastal fleet;**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

*(b) training on sustainable fishing such as sustainable fishing techniques, selectivity, marine biology, conservation of marine biological resources;*

**Amendment 620****Proposal for a regulation****Article 32 — paragraph - 1 b (new)**

Text proposed by the Commission

Amendment

*-1b. People younger than 30 years of age and registered as unemployed and recognised as such by the relevant administration of a Member State shall be eligible for support under paragraph 1. The trainee shall be accompanied on board by a professional fisherman of at least 50 years of age;*

**Amendment 621****Proposal for a regulation****Article 32 — paragraph - 1 a (new)**

Text proposed by the Commission

Amendment

*-1 a. Support under paragraph 1 shall be granted to each beneficiary for a maximum period of two years during the programming period and for a maximum of EUR 40 000;*

**Amendment 622****Proposal for a regulation****Article 32 — paragraph - 1 (new)**

Text proposed by the Commission

Amendment

*-1. Two-thirds of the traineeship programme shall comprise training on board and one-third shall comprise courses of theory.*

Wednesday 23 October 2013

## Amendment 266

## Proposal for a regulation

## Article 32 — paragraph 1 — introductory part

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Text proposed by the Commission

1. In order to facilitate diversification *and job creation outside fishing*, the EMFF may support:

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Amendment

1. In order to facilitate diversification, the EMFF may *also* support *complementary activities related to the core fishing business through*:

## Amendment 267

## Proposal for a regulation

## Article 32 — paragraph 1 — point a

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Text proposed by the Commission

(a) *business start-ups outside fishing*;

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Amendment

(a) *investments on board in activities that complement fishing, such as environmental services and educational or tourism activities*;

## Amendment 268

## Proposal for a regulation

## Article 32 — paragraph 1 — point b

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Text proposed by the Commission

(b) retrofitting of small scale coastal fishing vessels in order to reassign them *for* activities outside fishing.

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Amendment

(b) retrofitting of small scale coastal fishing vessels in order to reassign them *to* activities outside *commercial* fishing.

## Amendment 269

## Proposal for a regulation

## Article 32 — paragraph 1 — point b

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Text proposed by the Commission

(b) retrofitting of small scale coastal fishing vessels in order to reassign them for activities outside fishing.

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Amendment

(Does not affect English version.)

Wednesday 23 October 2013

## Amendment 270

## Proposal for a regulation

## Article 32 — paragraph 2 — introductory part

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*Text proposed by the Commission*

2. Support under paragraph 1 (a) shall be granted to fishermen who:

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*Amendment*

2. Support under **paragraph –1 and** paragraph 1 (a) shall be granted to fishermen who:

## Amendment 271

## Proposal for a regulation

## Article 32 — paragraph 2 — point a

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*Text proposed by the Commission*

(a) submit a business plan for the development of their **new** activities;

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*Amendment*

(a) submit a business plan for the development of their activities;

## Amendment 272

## Proposal for a regulation

## Article 32 — paragraph 3

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*Text proposed by the Commission*

3. Support under paragraph 1(b) shall be granted to small scale coastal fishermen owning a Union fishing vessel registered as active and which have carried out fishing activities at sea at least 60 days during the two years preceding the date of submission of the application. ***The fishing licence associated with the fishing vessel shall be permanently withdrawn.***

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*Amendment*

3. Support under paragraph 1(b) shall be granted to small scale coastal fishermen owning a Union fishing vessel registered as active and which have carried out fishing activities at sea at least 60 days during the two **calendar** years preceding the date of submission of the application.

## Amendment 273

## Proposal for a regulation

## Article 32 — paragraph 3 a (new)

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*Text proposed by the Commission*

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*Amendment*

***3a. Support under paragraph 1(c) shall be granted only to fishermen provided that the complementary activities to fishing relate to the core fishing business, such as angling tourism, restaurants, fishing environmental services or educational activities on fishing.***

Wednesday 23 October 2013

## Amendment 274

## Proposal for a regulation

## Article 32 — paragraph 4

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Text proposed by the Commission

4. Beneficiaries of the support referred to in paragraph 1 shall not engage in professional fishing in the five years following the reception of the last payment of the support.

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Amendment

*deleted*

## Amendment 276

## Proposal for a regulation

## Article 32 a (new)

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Text proposed by the Commission

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Amendment**Article 32a****Start-up support for young fishermen**

1. The EMFF may grant individual support to young fishermen on condition that they:

- are younger than 35 years;
- demonstrate that they have worked for at least five years as fisherman or have equivalent professional training;
- acquired, for the first time, ownership of a small scale coastal fishing vessel which is between five and 20 years old and has carried out fishing activities during the five previous years.

2. The fishing vessel referred to in paragraph 1 shall belong to a fleet segment for which the capacity report, referred to in Article 34(1) of Regulation (EU) No .../.... [on CFP], shows that fishing opportunities and fleet capacity are in equilibrium.

3. The amount of the support referred to in paragraph 1 shall not exceed EUR 100 000.

Wednesday 23 October 2013

**Amendment 278**  
**Proposal for a regulation**  
**Article 33 — title**

Text proposed by the Commission

Health and safety on board

Amendment

Health, *hygiene* and safety on board

**Amendment 279**  
**Proposal for a regulation**  
**Article 33 — paragraph 1**

Text proposed by the Commission

1. In order to improve working conditions on board for fishermen the EMFF may support investments on board or in individual equipments **providing** that these investments go beyond standards required under national or Union law.

Amendment

1. In order to improve **health, hygiene, safety, working and living** conditions on board for fishermen, the EMFF may support investments on board or in individual equipments **provided** that these investments go beyond standards required under national or Union law **and do not increase the fishing capacity of the vessel.**

**Amendment 280**  
**Proposal for a regulation**  
**Article 33 — paragraph 1 a (new)**

Text proposed by the Commission

Amendment

**1a. In order to improve care for fishermen in the event of an accident, the EMFF may promote joint projects to make medical training widely available to entire crews.**

**Amendment 281**  
**Proposal for a regulation**  
**Article 33 a (new)**

Text proposed by the Commission

Amendment

Article 33a

**Temporary cessation of fishing activities**

**1. The EMFF shall only contribute to financing measures for the temporary cessation of fishing activities in the following cases:**

**(a) acting within the scope of a multiannual plan as defined in Regulation (EU) No .../.... [on the CFP];**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

(b) *when the Commission has adopted emergency pursuant to Article 13 of Regulation (EU) No .../.... [on the CFP];*

(c) *during biological recovery periods at given critical phases of the life cycles of species, where such measures are necessary for the sustainable exploitation of fishery resources, helping to sustain stocks and allowing fishing to continue outside such rest periods.*

*Support shall be granted by means of financial compensation for the period of inactivity.*

2. *The duration of the measures referred to in paragraph 1 shall be determined on the basis of the best available scientific research concerning the status of stocks.*

3. *The recurrent seasonal suspension of fishing periods which is not covered by paragraph 1(c) shall not be taken into account when granting compensation or making payments under this Article.*

4. *The EMFF may contribute to the financing of the measures referred to in paragraph 1 for affected fishermen and owners of fishing vessels, for a maximum period of six months per vessel throughout the programming period. The support shall be granted to:*

(a) *the owners of fishing vessels included in the Union Fleet Register who have engaged in fishing activities for at least 120 days preceding the submission of the application for support; and*

(b) *crew members who have worked on board a fishing vessel affected by temporary cessation of activities under the conditions referred to in point (a) of this paragraph.*

5. *During periods when the support referred to in paragraph 1 is being received, the fishing vessel and the crew members affected shall not engage in any fishing activity. Member States shall ensure that activity has ceased.*

Wednesday 23 October 2013

**Amendment 623**  
**Proposal for a regulation**  
**Article 33 b (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 33 b**

**Mutual funds for the purpose of insurance**

1. *The EMFF may contribute to mutual funds recognised by a Member State in accordance with its national law which enable fishermen who are affiliated members to insure themselves against losses caused by:*

- (a) natural disasters;*
- (b) environmental or health incidents;*
- (c) the rescue costs for fishing vessels which had accidents during their activities or sank, resulting in the loss of victims at sea;*
- (d) specific social and economic measures proposed by the Member States for fishermen onboard vessels which sank as a result of accidents at sea.*

2. *Events shall be formally recognised as natural disasters or environmental or health incidents by the Member State concerned or, if they so require, by the internal rules of the mutual fund. Member States may, where appropriate, establish criteria in advance based on which such formal recognition shall be deemed to be granted.*

**Amendment 624**  
**Proposal for a regulation**  
**Article 33 c (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 33 c**

**Permanent cessation of fishing activities**

1. *The EMFF may contribute to the financing of measures for permanent cessation of fishing activities only through scrapping of fishing vessels on the condition that the decommissioning scheme:*

- (a) is included in the operational programme as established in Article 20; and*

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

(b) concerns vessels included in a segment where fishing capacity is not effectively balanced with fishing opportunities available to that segment for the period of the long term management plan; and

2. Support under paragraph 1 shall be granted to:

(a) owners of Union fishing vessels registered as active and which have carried out fishing activities at sea at least 120 days per year during the last two calendar years preceding the date of submission of the application, or

(b) fishermen who have worked at sea on board a Union fishing vessel concerned by the permanent cessation for at least 120 days per year during the last two calendar years preceding the date of submission of the application.

3. The fisherman, owner or enterprise concerned shall effectively cease all fishing activities. The proof of the effective cessation of fishing activities shall be provided to the competent national authority by the beneficiaries of such aid. The compensation shall be refunded on a pro rata temporis basis where a fisherman or an enterprise returns to a fishing activity within a period of less than two years from the date of submission of the application.

4. Public aid under this Article may be granted until 31 December 2016.

5. Support under this Article shall be paid only after the equivalent capacity has been permanently removed from the Union fishing vessel register and the fishing licenses and authorisations have been also permanently removed. The beneficiary of such aid cannot register a new fishing vessel within five years following the receipt of such aid. The decrease in capacity shall result in the permanent equivalent reduction of the capacity ceiling of the fleet segment.

6. Traditional and wooden vessels shall not be eligible for support under this Article.

Wednesday 23 October 2013

**Amendment 283**  
**Proposal for a regulation**  
**Article 34**

Text proposed by the Commission

Amendment

**Article 34***deleted*

**Support to systems of transferable fishing concessions of the CFP**

1. In order to establish or modify systems of transferable fishing concessions under Article 27 of the [Regulation on the CFP], the EMFF may support:

- a) the design and development of technical and administrative means necessary for the creation or functioning of a transferable fishing concessions system;
- b) stakeholder participation in designing and developing transferable fishing concessions systems;
- c) the monitoring and evaluation of transferable fishing concessions systems;
- d) the management of transferable concessions systems.

2. Support under paragraph 1 (a), (b) and (c) shall only be granted to public authorities. Support under paragraph 1 (d) of this Article shall be granted to public authorities legal or natural persons or recognized producer organizations involved in collective management of pooled transferable fishing concessions in accordance with Article 28(4) of the Regulation on Common Fisheries.

**Amendment 284**  
**Proposal for a regulation**  
**Article 35 — title**

Text proposed by the Commission

Amendment

Support **to** the implementation of conservation measures under the CFP

Support **for** the **design and** implementation of conservation measures under the CFP

Wednesday 23 October 2013

## Amendment 285

## Proposal for a regulation

## Article 35 — paragraph 1 — introductory part

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Text proposed by the Commission

1. In order to ensure efficient implementation of conservation measures under **Articles 17 and 21 of** the [Regulation on Common Fisheries Policy] the EMFF may support:

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Amendment

1. In order to ensure efficient **design and** implementation of **the CFP's priorities on regionalisation and** conservation measures **adopted** under the [Regulation on Common Fisheries Policy], **including the multiannual plans**, the EMFF may support:

## Amendment 286

## Proposal for a regulation

## Article 35 — paragraph 1 — point a

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Text proposed by the Commission

(a) the design **and** development of technical and administrative means necessary for the implementation of conservation measures in the meaning of **Articles 17 and 21 of** the [Regulation on Common Fisheries Policy];

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Amendment

(a) the design, development **and monitoring** of technical and administrative means necessary for the **drafting and** implementation of **the multiannual plans and** conservation measures in the meaning of the [Regulation on Common Fisheries Policy];

## Amendment 287

## Proposal for a regulation

## Article 35 — paragraph 1 — point a a (new)

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Text proposed by the Commission

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Amendment

(aa) **the establishment of a coherent network of fish stock recovery areas pursuant to Regulation (EU) No .../... [on CFP];**

## Amendment 288

## Proposal for a regulation

## Article 35 — paragraph 1 — point a b (new)

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Text proposed by the Commission

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Amendment

(ab) **the implementation of biological recovery periods;**

Wednesday 23 October 2013

## Amendments 289 and 612

## Proposal for a regulation

## Article 35 — paragraph 1 — point b

Text proposed by the Commission

(b) stakeholder participation in designing and implementing conservation measures in the meaning **of Articles 17 and 21** of the [Regulation on Common Fisheries Policy]

Amendment

(b) stakeholder participation **and cooperation between Member States** in designing and implementing **the multiannual plans and** conservation measures in the meaning of the [Regulation on Common Fisheries Policy], **including through multi-stakeholder co-management committees.**

## Amendment 640

## Proposal for a regulation

## Article 35 — paragraph 1 — point b a (new)

Text proposed by the Commission

Amendment

(ba) **the design, development and implementation of allocation criteria under Article 16a (new) of the [Regulation on Common Fisheries Policy].**

## Amendment 291

## Proposal for a regulation

## Article 36 — paragraph 1 — introductory part

Text proposed by the Commission

1. In order to reduce the impact of fishing on the marine environment, foster the elimination of discards and facilitate the transition to exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the MSY, the EMFF may support investments in equipment:

Amendment

1. In order to reduce the impact of fishing on the marine environment, foster the elimination of discards and facilitate the transition to **a sustainable** exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the MSY, the EMFF may support **research and** investments in equipment, **instruments or systems:**

## Amendment 292

## Proposal for a regulation

## Article 36 — paragraph 1 — point a a (new)

Text proposed by the Commission

Amendment

(aa) **replacing the fishing gear provided that the new gear has a more appropriate size, a better species selectivity, a limited impact on the marine environment and vulnerable marine ecosystems and does not increase the capacity of the fishing vessel to catch fish;**

Wednesday 23 October 2013

## Amendment 293

## Proposal for a regulation

## Article 36 — paragraph 1 — point b

---

Text proposed by the Commission

- (b) reducing unwanted catches of commercial stocks or other by-catches;

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Amendment

- (b) reducing unwanted **or unauthorised** catches of commercial stocks or other by-catches, **with an emphasis on the development and introduction of devices to reduce these catches**;

## Amendment 294

## Proposal for a regulation

## Article 36 — paragraph 1 — point c

---

Text proposed by the Commission

- (c) limiting the physical and biological impacts of fishing on the ecosystem or the sea bed.

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Amendment

- (c) limiting **and, where possible, eliminating** the physical and biological impacts of fishing on the ecosystem or the sea bed, **particularly in areas identified as biogeographically sensitive**;

## Amendment 295

## Proposal for a regulation

## Article 36 — paragraph 1 — point c a (new)

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Text proposed by the Commission

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Amendment

- (ca) **protecting gear and catches from mammals and birds protected by Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora <sup>(1)</sup> or Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds <sup>(2)</sup> , provided that it does not undermine the selectivity of the fishing gear and that all appropriate measures are taken to avoid physical damage to the predators.**

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<sup>(1)</sup> OJ L 206, 22.7.1992, p. 7.

<sup>(2)</sup> OJ L 20, 26.1.2010, p. 7.

## Amendment 296

## Proposal for a regulation

## Article 36 — paragraph 1 — point c b (new)

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Text proposed by the Commission

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Amendment

- (cb) **reducing the negative impact of fishing activities on animal welfare.**

Wednesday 23 October 2013

## Amendment 297

## Proposal for a regulation

## Article 36 — paragraph 1 — point c c (new)

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Text proposed by the Commission

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Amendment

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(cc) *contributing to the assessment of fish stocks.*

## Amendment 298

## Proposal for a regulation

## Article 36 — paragraph 1 a (new)

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Text proposed by the Commission

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Amendment

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*1a. In the outermost regions, the support referred to in paragraph 1 may be granted to anchored fish aggregating devices (FADs) only if they contribute to sustainable and selective fishing.*

## Amendment 299

## Proposal for a regulation

## Article 36 — paragraph 3

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Text proposed by the Commission

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Amendment

3. Support shall only be granted when the gear or other equipment referred under paragraph 1 has demonstrably better size-selection **or** lower impact on non-target species than the standard gear or other equipment permitted under Union law or relevant national law of Member States adopted in the context of regionalisation as referred to in the [Regulation on the CFP].

3. Support shall only be granted when the gear or other equipment referred under paragraph 1 demonstrably **has a substantially** better size-selection **and a** lower impact on **the ecosystem and on** non-target species than the standard gear or other equipment, **instruments or systems** permitted under Union law or relevant national law of Member States adopted in the context of regionalisation as referred to in the [Regulation on the CFP].

## Amendment 300

## Proposal for a regulation

## Article 36 — paragraph 4 — point b

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Text proposed by the Commission

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Amendment

(b) fishermen who own the gear to be replaced and who have worked on board of a Union fishing vessel for at least 60 days during the two years preceding the date of submission of the application;

(b) fishermen who own the gear, **instruments or systems** to be replaced and who have worked on board of a Union fishing vessel for at least 60 days during the two years preceding the date of submission of the application;

Wednesday 23 October 2013

**Amendment 301**  
**Proposal for a regulation**  
**Article 36 a (new)**

Text proposed by the Commission

Amendment

**Article 36a**

**Support to mitigate the economic impact of exceptional events**

*In order to mitigate the economic impact of an exceptional event that prevents normal fishery from being conducted, support may be granted under the EMFF to fishing vessel owners and fishermen for the temporary suspension of fisheries activities. The implementation of fish stock conservation measures shall not be considered to be an exceptional event.*

**Amendment 574/REV**  
**Proposal for a regulation**  
**Article 37 — paragraph 1**

Text proposed by the Commission

Amendment

1. In order to contribute to the elimination of discards and by-catches and facilitate the transition to exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the MSY, the EMFF may support projects **aiming at developing or introducing** new technical or organisational knowledge reducing impacts of fishing activities on the environment **or achieving** a more sustainable use of marine biological resources.

1. In order to contribute to the elimination of discards and by-catches and facilitate the transition to exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the MSY **and to reduce the impact of fishing on the marine environment and the impact of protected predators**, the EMFF may support **schemes and projects that aim to develop, improve or introduce** new technical or organisational knowledge reducing impacts of fishing activities on the environment, **including improved fishing techniques and improved selectivity of fishing operations, or to achieve** a more sustainable use of marine biological resources **and coexistence with protected predators, based on an ecosystem-approach to fisheries management.**

**Amendment 303**  
**Proposal for a regulation**  
**Article 37 — paragraph 2**

Text proposed by the Commission

Amendment

2. Operations financed under this Article **must** be carried out in collaboration with a scientific or technical body recognised by **the national law of** each Member State which shall validate the results of such operations.

2. Operations financed under this Article, **which may be implemented by organisations of fishermen recognised by a Member State, shall** be carried out in collaboration with a scientific or technical body recognised by each Member State which shall validate the results of such operations.

Wednesday 23 October 2013

**Amendment 304****Proposal for a regulation****Article 37 — paragraph 3**

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*Text proposed by the Commission*

3. The results of operations financed under this Article shall be **the subject to adequate publicity** by the Member State according to Article 120.

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*Amendment*

3. The results of operations financed under this Article shall be **made publicly available** by the Member State according to Article 120.

**Amendment 305****Proposal for a regulation****Article 37 — paragraph 4**

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*Text proposed by the Commission*

4. Fishing vessels involved in projects financed under this Article shall not exceed 5 % of the vessels of the national fleet or 5 % of the national fleet tonnage in gross tonnage, calculated at the time of submission of the application.

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*Amendment*

4. Fishing vessels involved in projects financed under this Article shall not exceed 5 % of the vessels of the national fleet or 5 % of the national fleet tonnage in gross tonnage, calculated at the time of submission of the application. **At the request of a Member State, in duly justified circumstances and on the basis of a recommendation by the STECF, the Commission may approve projects that exceed the limits set in this paragraph.**

**Amendment 306****Proposal for a regulation****Article 37 — paragraph 5**

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*Text proposed by the Commission*

5. Operations consisting of testing new fishing gear or techniques shall be carried out within the limits of the fishing opportunities allocated to the Member State.

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*Amendment*

5. Operations consisting of testing new fishing gear or techniques shall be carried out within the limits of the fishing opportunities allocated to the Member State **or within the quota for scientific research pursuant to Article 33(6) of Regulation (EC) No 1224/2009.**

**Amendment 625****Proposal for a regulation****Article 38 — paragraph 1 — introductory part**

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*Text proposed by the Commission*

1. In order to stimulate the **participation of fishermen in the** protection and restoration of marine biodiversity and ecosystems including the services they provide in the framework of sustainable fishing activities, the EMFF may support the following operations:

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*Amendment*

1. In order to stimulate the protection and restoration of marine biodiversity and ecosystems including the services they provide in the framework of sustainable fishing activities, **and, where relevant, the participation of fishermen,** the EMFF may support the following operations **which have a direct effect on the activities of the fishing sector:**

Wednesday 23 October 2013

## Amendment 626

## Proposal for a regulation

## Article 38 — paragraph 1 — point a

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Text proposed by the Commission

- (a) collection of waste from the sea such as the removal of lost fishing gears and marine litter;

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Amendment

- (a) collection, **by fishermen**, of waste from the sea such as the removal of lost fishing gears and marine litter;

## Amendment 627

## Proposal for a regulation

## Article 38 — paragraph 1 — point b

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Text proposed by the Commission

- (b) the construction **or** installation of static or movable facilities intended to protect and enhance marine fauna and flora;

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Amendment

- (b) the construction, installation **or modernisation** of static or movable facilities **that can be easily dismantled and which are** intended to protect and enhance marine fauna and flora, **and scientific studies and evaluations of such facilities**;

## Amendment 628

## Proposal for a regulation

## Article 38 — paragraph 1 — point c

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Text proposed by the Commission

- (c) the contribution to a better management or conservation of resources;

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Amendment

- (c) the contribution to a better management or conservation of **marine biological** resources;

## Amendment 629

## Proposal for a regulation

## Article 38 — paragraph 1 — point d

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Text proposed by the Commission

- (d) **management, restoration and monitoring NATURA 2000 sites in accordance with Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora and Council and European Parliament Directive 2009/147/EC of 30 November 2009 on the conservation of wild birds, in accordance with prioritised action frameworks established pursuant to Council Directive 92/43/EEC;**

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Amendment

- (d) **the identification, selection, management, restoration and monitoring of:**

Wednesday 23 October 2013

**Amendment 630****Proposal for a regulation****Article 38 — paragraph 1 — point d — point i (new)**

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*Text proposed by the Commission*

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*Amendment*

- (i) **NATURA 2000 sites in accordance with Council Directive 92/43/EEC and Directive 2009/147/EC or in accordance with prioritised action frameworks established pursuant to Council Directive 92/43/EEC, where operations are related to fishing activities,**

**Amendment 631****Proposal for a regulation****Article 38 — paragraph 1 — point d — point ii (new)**

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*Text proposed by the Commission*

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*Amendment*

- (ii) **marine protected areas in view of the implementation of the spatial protection measures related to fishing activities referred to in Article 13(4) of Directive 2008/56/EC;**

**Amendment 632****Proposal for a regulation****Article 38 — paragraph 1 — point e**

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*Text proposed by the Commission*

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*Amendment*

- (e) **management, restoration and monitoring of marine protected areas in view of the implementation of the spatial protection measures referred to in Article 13(4) of the European Parliament and Council Directive 2008/56/EC;**

- (e) **the participation in other actions aimed at maintaining and enhancing biodiversity and ecosystem services, in connection with Union action in the field of marine environment policy and consistent with an ecosystem-based approach to fisheries management, such as the restoration of specific marine and coastal habitats in support of sustainable fish stocks, including the preparation of such actions and their scientific evaluation;**

**Amendment 633****Proposal for a regulation****Article 38 — paragraph 1 — point e a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (ea) **environmental awareness involving fishermen with regard to protection and restoration of marine biodiversity.**

Wednesday 23 October 2013

**Amendment 575/REV**

**Proposal for a regulation**

**Article 38 — paragraph 1 — point e b (new)**

*Text proposed by the Commission*

*Amendment*

(eb) *schemes for the compensation of damage to catches caused by mammals and birds protected by the Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora or Council and European Parliament Directive 2009/147/EC of 30 November 2009 on the conservation of wild birds;*

**Amendment 308**

**Proposal for a regulation**

**Article 38 — paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. Operations under this Article shall be implemented by public law bodies and shall involve fishermen **or** organisations of fishermen, recognised by the Member State, or non-governmental organisation in partnership with organisations of fishermen or FLAGs as defined under Article 62.

2. Operations under this Article shall be implemented by **technical or scientific** public law bodies and shall involve fishermen, **Advisory Councils**, organisations of fishermen recognised by the Member State, or non-governmental organisation in partnership with organisations of fishermen or FLAGs as defined under Article 62

**Amendment 309**

**Proposal for a regulation**

**Article 39 — title**

*Text proposed by the Commission*

*Amendment*

**Mitigation of climate change**

**Energy efficiency and reduction of capacity**

**Amendment 310**

**Proposal for a regulation**

**Article 39 — paragraph 1 — introductory part**

*Text proposed by the Commission*

*Amendment*

1. In order to **mitigate the effects of climate change** the EMFF may support:

1. In order to **improve the energy efficiency of fishing vessels**, the EMFF may support:

Wednesday 23 October 2013

## Amendment 311

## Proposal for a regulation

## Article 39 — paragraph 1 — point a

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*Text proposed by the Commission*

- (a) investments on board aimed at reducing the emission of pollutants or green-house gases and increasing energy efficiency of fishing vessels;

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*Amendment*

- (a) investments **in equipment or** on board, aimed at reducing the emission of pollutants or green-house gases and increasing energy efficiency of fishing vessels, **including the withdrawal, replacement or modernisation of main or ancillary engines, provided that the power of the new engine is at least 40 % lower than that of the engine replaced;**

## Amendment 312

## Proposal for a regulation

## Article 39 — paragraph 1 — point b

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*Text proposed by the Commission*

- (b) energy efficiency audits and schemes.

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*Amendment*

- (b) energy efficiency audits, **advice** and schemes, **provided that they do not lead to an increase in fishing effort.**

## Amendment 313

## Proposal for a regulation

## Article 39 — paragraph 1 — point b a (new)

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*Text proposed by the Commission*

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*Amendment*

- (ba) **the protection and restoration of seagrass beds and coastal wetlands which are carbon sinks of critical importance in mitigating the negative impact of climate change;**

## Amendment 314

## Proposal for a regulation

## Article 39 — paragraph 1 — point b b (new)

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*Text proposed by the Commission*

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*Amendment*

- (bb) **replacement of high energy consuming fishing gears with lower energy consuming ones, provided that changes do not result in an increase in the fishing capacity of the fishing unit and that the replaced fishing gear is confiscated and destroyed;**

Wednesday 23 October 2013

## Amendment 315

## Proposal for a regulation

## Article 39 — paragraph 1 — point b c (new)

Text proposed by the Commission

Amendment

(bc) *independent evaluations and audits of the energy footprint of fish products in the market place in order to allow consumers to differentiate fish products coming from fishing methods which are less energy intensive.*

## Amendment 641

## Proposal for a regulation

## Article 39 — paragraph 2

Text proposed by the Commission

Amendment

2. **Support shall not contribute to the replacement or modernisation of main or ancillary engines.** Support shall only be granted to owners of fishing vessels and not more than once during the programming period for the same fishing vessel.

2. Support shall only be granted to owners of **small-scale coastal** fishing vessels and not more than once during the programming period for the same fishing vessel.

## Amendment 317

## Proposal for a regulation

## Article 39 — paragraph 3

Text proposed by the Commission

Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 127 **in order to define** the investments eligible under paragraph 1(a).

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 127, **fixing** the investments eligible under paragraph 1(a) **and laying down detailed rules for the application of the criteria set out in this Article.**

## Amendment 318

## Proposal for a regulation

## Article 40 — paragraph 1

Text proposed by the Commission

Amendment

1. In order to improve the quality of **the fish caught** the EMFF may support **investments on board for this purpose.**

1. In order to improve the **added value and the** quality of **commercial catches**, the EMFF may support:

(a) **investments which add value to fishing products, in particular by allowing fishermen to carry out the processing, marketing and direct sale of their own catches;**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

(b) **innovative investments on board which improve the quality and conservation of fishing products;**

**Amendment 319****Proposal for a regulation****Article 40 — paragraph 2**

Text proposed by the Commission

Amendment

2. **In order to improve the use of unwanted catches the** EMFF may support investments on board to make the best use of unwanted catches of commercial stocks and valorise underused components of fish caught, in line with Article 15 of the [Regulation on Common Fisheries Policy] and Article 8(b) of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products].

2. **The** EMFF may support investments on board to **improve handling, storing and landing of unwanted catches, to** make the best use of unwanted catches of commercial stocks and **to** valorise underused components of fish caught, in line with Article 15 of the [Regulation on Common Fisheries Policy] and Article 8(b) of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products].

**Amendment 320****Proposal for a regulation****Article 40 — paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. **Support under paragraph 1(b) shall be conditional upon the use of selective gears to minimise unwanted catch.**

**Amendment 321****Proposal for a regulation****Article 40 — paragraph 4**

Text proposed by the Commission

Amendment

4. The support referred to in paragraph 1 shall only be granted to owners of Union fishing vessels whose vessels **are which** have carried a fishing activity for at least 60 days at sea during the two years preceding the date of submission of the application.

4. The support referred to in paragraph 1**(b)** shall only be granted to owners of Union fishing vessels whose vessels have carried **out** a fishing activity for at least 60 days at sea during the two **calendar** years preceding the date of submission of the application.

Wednesday 23 October 2013

**Amendment 603**  
**Proposal for a regulation**  
**Article 41 — title**

*Text proposed by the Commission*

Fishing ports, landing sites **and** shelters

*Amendment*

Fishing ports, landing sites, **auction halls**, shelters **and other land-based support infrastructure**

**Amendment 604**  
**Proposal for a regulation**  
**Article 41 — paragraph 1**

*Text proposed by the Commission*

1. ***For the purpose of increasing the quality of the product landed, increasing energy efficiency, contributing to environmental protection or improving safety and working conditions,*** the EMFF may support investments ***improving fishing port infrastructure or landing sites***, including investments in facilities for waste and marine litter collection.

*Amendment*

1. The EMFF may support investments ***improving existing infrastructure, such as fishing ports, landing sites, auction halls and other land-based support infrastructure***, including investments in facilities for waste and marine litter collection.

**Amendment 323**  
**Proposal for a regulation**  
**Article 41 — paragraph 2**

*Text proposed by the Commission*

2. ***In order to facilitate the use of unwanted catches the EMFF may support investments in fishing ports and landing sites which enable to make the best use of unwanted catches of commercial stocks and which valorise under-used components of the fish caught, in line with Article 15 of the [Regulation on Common Fisheries Policy] and Article 8(b) of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products].***

*Amendment*

2. ***Investments may concern:***

(a) ***the improvement of the quality, freshness and traceability of landed products;***

(b) ***the improvement of landing, processing, storage and auction conditions;***

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

- (c) *the use of unwanted catches of commercial stocks and the putting to better use of under-used components of catches, in line with Article 15 of the Regulation (EU) No .../.... [on CFP] and Article 8(b) of Regulation (EU) No .../.... [on the common organisation of the markets in fishery and aquaculture products];*
- (d) *energy efficiency;*
- (e) *environmental protection, notably the collection, storage and treatment of waste and marine litter;*
- (f) *the improvement of hygiene, health and safety;*
- (g) *the improvement of working conditions;*
- (h) *the supply of ice, water and electricity;*
- (i) *equipment for repairing and maintenance of fishing vessels;*
- (j) *the construction, modernisation and extension of quays to improve safety during landing or loading;*
- (k) *the computerised management of fishing activities;*
- (l) *the networking of fishing ports, landing sites and auction halls.*

**Amendment 324****Proposal for a regulation****Article 41 a (new)**

Text proposed by the Commission

Amendment

**Article 41 a****Protection of maritime heritage**

1. In order to support and promote traditional maritime crafts related to fisheries and to preserve or maintain operational vessels that are covered by the protection of the maritime heritage of a Member State, the EMFF may support:
- (a) *training and investments for the support of traditional shipyards and traditional maritime crafts;*
  - (b) *investments on board that aim to restore traditional wooden fishing vessels without increasing the fishing capacity of those vessels;*

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

(c) *Investments for the safekeeping and maintenance of traditional fishing vessels that are covered by the protection of maritime heritage and that have been decommissioned.*

2. *Support shall be granted only to the owners of shipyards and fishing vessels and only once during the programming period for the same fishing vessel.*

3. *Member States shall ensure that vessels receiving support under paragraph 1 (b) continue to operate.*

#### Amendment 325

##### Proposal for a regulation

##### Article 42 — paragraph 1 — introductory part

Text proposed by the Commission

1. In order to reduce the impact of inland fishing on the environment, increase energy efficiency, increase the quality of fish landed, or to improve safety **or** working conditions, the EMFF may support the following investments:

Amendment

1. In order to reduce the impact of inland fishing on the environment, **to** increase energy efficiency, **to** increase the quality of fish landed, or to improve **health**, safety, working conditions, **human capital and training**, the EMFF may support the following investments:

#### Amendment 326

##### Proposal for a regulation

##### Article 42 — paragraph 1 — point a a (new)

Text proposed by the Commission

Amendment

(aa) ***promotion of human capital and social dialogue subject to the conditions set out in Article 31;***

#### Amendment 327

##### Proposal for a regulation

##### Article 42 — paragraph 1 — point b

Text proposed by the Commission

(b) in equipment as referred to in Article 36 and under the conditions set out in **that Article**;

Amendment

(b) in equipment **and projects** as referred to in Article 36 **and Article 37** and under the conditions set out in **those Articles**;

Wednesday 23 October 2013

**Amendment 328****Proposal for a regulation****Article 42 — paragraph 1 — point d**

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*Text proposed by the Commission*

(d) on **existing** ports and landing sites as referred to in Article 41 and under the conditions set out in that Article.

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*Amendment*

(d) on **fishing** ports, **shelters** and landing sites as referred to in Article 41 and under the conditions set out in that Article;

**Amendment 329****Proposal for a regulation****Article 42 — paragraph 1 — point d a (new)**

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*Text proposed by the Commission*

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*Amendment*

(da) **in improvements of the value or quality of fish caught as referred to in Article 40 and subject to the conditions set out in that Article.**

**Amendment 330****Proposal for a regulation****Article 42 — paragraph 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**1a. The EMFF may support investments relating to entrepreneurship as referred to in Article 32 and subject to the same conditions as set out in that Article.**

**Amendment 331****Proposal for a regulation****Article 42 — paragraph 1 b (new)**

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*Text proposed by the Commission*

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*Amendment*

**1b. The EMFF may support the development and facilitation of innovation in accordance with Article 28, the advisory services in accordance with Article 29 and partnerships between scientists and fishermen in accordance with Article 30.**

Wednesday 23 October 2013

## Amendment 332

## Proposal for a regulation

## Article 42 — paragraph 2 — point a

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Text proposed by the Commission

- (a) References made in Articles 33, 36 and 39 to fishing vessels shall be understood as references to vessels operating exclusively in inland water;

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Amendment

- (a) References made in Articles 33, 36, **37**, 39 **and 40** to fishing vessels shall be understood as references to vessels operating exclusively in inland water;

## Amendment 333

## Proposal for a regulation

## Article 42 — paragraph 2 — point b

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Text proposed by the Commission

- (b) References made in Article 36 to the marine environment shall be understood as references to the environment in which the inland fishing vessel **operates**.

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Amendment

- (b) References made in Article 36 to the marine environment shall be understood as references to the environment in which inland fishing **is carried out**.

## Amendment 334

## Proposal for a regulation

## Article 42 — paragraph 3

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Text proposed by the Commission

3. In order to sustain diversification by inland fishermen, the EMFF may support the **reassignment** of **vessels operating in** inland fishing to other activities outside fishing **under** the conditions of Article 32 of this Regulation.

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Amendment

3. In order to sustain diversification by inland fishermen, the EMFF may support the **diversification** of inland fishing **activities complementary** to other activities outside fishing **subject to** the conditions of Article 32 of this Regulation.

## Amendment 634

## Proposal for a regulation

## Article 42 — paragraph 5

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Text proposed by the Commission

5. In order to protect and develop aquatic fauna and flora, the EMFF may support **the participation of inland fishermen in managing, restoring and monitoring NATURA 2000 sites where these areas directly concern fishing activities as well as the rehabilitation of inland waters, including spawning grounds and migration routes for migratory species, without prejudice of Article 38(1)(d).**

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Amendment

5. In order to protect and develop aquatic fauna and flora, the EMFF may support:

Wednesday 23 October 2013

**Amendment 635****Proposal for a regulation****Article 42 — paragraph 5 — point a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (a) *without prejudice to Article 38(1)(d), the management, restoration and monitoring of NATURA 2000 sites where these areas directly concern fishing activities as well as the rehabilitation of inland waters, including spawning grounds and migration routes for migratory species and where relevant including the participation of inland fishermen;*

**Amendment 636****Proposal for a regulation****Article 42 — paragraph 5 — point b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (b) *the construction, modernisation or installation of static or movable facilities intended to protect and enhance aquatic fauna and flora, including their scientific monitoring and evaluation.*

**Amendment 336****Proposal for a regulation****Article 42 — paragraph 6**

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*Text proposed by the Commission*

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*Amendment*

6. Member States shall ensure that vessels receiving support under this Article continue to operate exclusively in inland waters.

6. ***Without prejudice to paragraph 3,*** Member States shall ensure that vessels receiving support under this Article continue to operate exclusively in inland waters.

Wednesday 23 October 2013

Amendment 337

Proposal for a regulation

Article 44 — paragraph 1

Text proposed by the Commission

1. Support under this Chapter shall be limited to aquaculture enterprises unless otherwise expressly established.

Amendment

1. Support under this Chapter shall be limited to **sustainable** aquaculture enterprises, **including those operated by entrepreneurs entering the sector referred to in paragraph 1a, and to organisations made up of aquaculture producers and entrepreneurs**, unless otherwise expressly established. **Support shall not be granted to operators who have committed serious infringements of Union environmental law.**

Amendment 338

Proposal for a regulation

Article 44 — paragraph 1 a (new)

Text proposed by the Commission

Amendment

**1a. For the purposes of this Article, entrepreneurs entering the sector shall submit a business plan and, where the amount of the investment exceeds EUR 150 000, a feasibility study.**

Amendment 589

Proposal for a regulation

Article 44 — paragraph 2

Text proposed by the Commission

2. **Where operations consist of** investments in equipment or infrastructure **ensuring compliance with requirements on the environment**, human or animal health, hygiene or animal welfare under Union law, **and entering into force after 2014, may be granted until the date on which the standards become mandatory for the enterprises.**

Amendment

2. **Support shall be limited to** investments in equipment or infrastructure **which have demonstrably a lower impact on the environment or a better performance with respect to** human or animal health, hygiene or animal welfare **than is required** under Union law.

**Support shall not be granted to aquaculture operations using genetically modified organisms.**

**Support shall not be granted to any intensive aquaculture operation in marine protected areas or fish stock recovery areas.**

Wednesday 23 October 2013

## Amendment 340

## Proposal for a regulation

## Article 45 — paragraph 1 — introductory part

*Text proposed by the Commission*

1. In order to stimulate innovation in aquaculture, the EMFF may support operations:

- (a) **introducing new** technical or organisational knowledge in aquaculture farms which reduces **their** impact on the environment **or** fosters a **more** sustainable use of resources in aquaculture;
- (b) **developing or introducing** in the market new or substantially improved products **compared to the state of art**, new or improved processes, new or improved management and organisation systems.

*Amendment*

1. In order to stimulate innovation in **sustainable** aquaculture, the EMFF may support **projects that aim to**:

- (a) **develop** technical, **scientific** or organisational knowledge in aquaculture farms, which, **in particular**, reduces **the** impact on the environment, **reduces dependence on fish meal and oil**, fosters a sustainable use of resources in aquaculture **or facilitates new sustainable production methods**;
- (b) **develop or introduce** in the market new or substantially improved products, new or improved processes, new or improved management and organisation systems **as well as innovations or improvements in the production and processing of aquaculture products**;
- (ba) **explore the technical or economic feasibility of innovations, products or processes.**

## Amendment 341

## Proposal for a regulation

## Article 45 — paragraph 2

*Text proposed by the Commission*

2. Operations under this Article **must** be carried out in collaboration with a scientific or technical body as recognised by the national law of each Member State, which shall validate the results of such operations.

*Amendment*

2. Operations under this Article **shall** be carried out **by or** in collaboration with a **public or private** scientific, **academic** or technical body as recognised by the national law of each Member State which shall validate the results of such operations.

## Amendment 342

## Proposal for a regulation

## Article 45 — paragraph 3 a (new)

*Text proposed by the Commission**Amendment*

**3a. The EMFF shall provide a financial contribution for development and innovation in aquaculture, implemented under multiannual strategic plans drawn up by Member States.**

Wednesday 23 October 2013

**Amendment 343**  
**Proposal for a regulation**  
**Article 46 — title**

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*Text proposed by the Commission*

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Investments in ***off-shore and non-food*** aquaculture

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*Amendment*

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Investments in aquaculture

**Amendment 344**  
**Proposal for a regulation**  
**Article 46 — paragraph 1**

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*Text proposed by the Commission*

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1. In order to foster forms of aquaculture with high growth potential, the EMFF may support ***investment in the development of*** off-shore or non food aquaculture.

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*Amendment*

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1. In order to foster forms of ***sustainable*** aquaculture with high growth potential, the EMFF may support: –

(a) ***productive investments in aquaculture, including in*** off-shore or non food aquaculture;

(b) ***diversification of production and of the species exploited as well as studies on yield and location suitability.***

**Amendment 345**  
**Proposal for a regulation**  
**Article 46 — paragraph 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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***1a. Support under paragraph 1 may be granted for the increase in production and/or modernisation of existing aquaculture enterprises or the construction of new ones provided that the development is consistent with the multi-annual national strategic plan for the development of aquaculture.***

Wednesday 23 October 2013

## Amendment 346

## Proposal for a regulation

## Article 46 — paragraph 1 b (new)

Text proposed by the Commission

Amendment

**1b.** Support under this Article shall be granted only where it has been clearly demonstrated in an independent marketing report that good sustainable market prospects exist for the product. The enterprises created shall be economically viable and shall not contribute to overproduction in the sector.

## Amendment 347

## Proposal for a regulation

## Article 47 — paragraph 1 — introductory part

Text proposed by the Commission

Amendment

1. In order to foster entrepreneurship in aquaculture, the EMFF may support investments contributing to:

1. In order to foster entrepreneurship in **sustainable** aquaculture, the EMFF may support investments contributing to:

## Amendment 348

## Proposal for a regulation

## Article 47 — paragraph 1 — point a

Text proposed by the Commission

Amendment

(a) adding value to aquaculture products, **in particular** by **allowing** the aquaculture **enterprise to carry** out the processing, marketing and direct sale of its own aquaculture production;

(a) adding value to aquaculture products, **for example** by **supporting** the aquaculture **sector in carrying** out the processing, marketing and direct sale of its own aquaculture production, **or in establishing associations or association agreements for such processing**;

## Amendment 349

## Proposal for a regulation

## Article 47 — paragraph 1 — point b

Text proposed by the Commission

Amendment

(b) diversification of the income of aquaculture **enterprises** through the development of new aquaculture species with good market prospects;

(b) diversification of the income of **the** aquaculture **sector** through the development of new **native** aquaculture species **in their respective areas offering added value and** with good market **and environmental** prospects;

Wednesday 23 October 2013

## Amendment 350

## Proposal for a regulation

## Article 47 — paragraph 1 — point c

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*Text proposed by the Commission*

(c) diversification of the income of aquaculture enterprises through the development of complementary activities **outside aquaculture**.

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*Amendment*

(c) diversification of the income of aquaculture enterprises through the development of complementary activities.

## Amendment 351

## Proposal for a regulation

## Article 47 — paragraph 2

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*Text proposed by the Commission*

2. Support under paragraph 1(c) shall be granted only to aquaculture enterprises provided that the complementary activities outside aquaculture relate to the core aquaculture **business of enterprise**, such as angling tourism, aquaculture environmental services or educational activities on aquaculture.

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*Amendment*

2. Support under paragraph 1(c) shall be granted only to aquaculture enterprises provided that the complementary activities outside aquaculture relate to the core aquaculture **production or marketing**, such as angling tourism, aquaculture environmental services or educational activities on aquaculture.

## Amendment 352

## Proposal for a regulation

## Article 48 — paragraph 1 — introductory part

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*Text proposed by the Commission*

1. In order to improve the overall performance and competitiveness of aquaculture farms, the EMFF may support:

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*Amendment*

1. In order to improve the overall performance and competitiveness of aquaculture farms **and to reduce the environmental impact of their operations**, the EMFF may support:

## Amendment 353

## Proposal for a regulation

## Article 48 — paragraph 1 — point b

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*Text proposed by the Commission*

(b) the provision of farm advisory services of technical, scientific, legal or economic nature.

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*Amendment*

(b) the provision of farm advisory services of technical, scientific, legal, **environmental** or economic nature.

Wednesday 23 October 2013

**Amendment 637****Proposal for a regulation****Article 48 — paragraph 1 — point b a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ba) the improvement of working conditions taking into account the ILO rules;**

**Amendment 638****Proposal for a regulation****Article 48 — paragraph 1 — point b b (new)**

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*Text proposed by the Commission*

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*Amendment*

**(bb) the promotion of professional training and access to work for young people and women in the fishing and aquaculture sector.**

**Amendment 354****Proposal for a regulation****Article 48 — paragraph 2 — point d**

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*Text proposed by the Commission*

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*Amendment*

(d) health and safety standards based on Union and national legislation;

(d) health, **hygiene** and safety standards based on Union and national legislation;

**Amendment 355****Proposal for a regulation****Article 48 — paragraph 2 — point e a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ea) the promotion of equal opportunities, especially with regard to gender equality and the integration of disabled people;**

Wednesday 23 October 2013

## Amendment 356

## Proposal for a regulation

## Article 48 — paragraph 3

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Text proposed by the Commission

3. Support under paragraph (1)(a) shall only be granted to public law bodies selected to set up the farm advisory services. Support under paragraph (1)(b) shall only be granted to aquaculture SMEs **or** aquaculture producer's organisations.

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Amendment

3. Support under paragraph (1)(a) shall only be granted to public law bodies selected to set up the farm advisory services **or to professional organisations recognised by the Member State.** Support under paragraph (1)(b) shall only be granted to aquaculture SMEs, **aquaculture professional organisations recognised by the Member State,** aquaculture producer's organisations **or associations of aquaculture producer organisations.**

## Amendment 357

## Proposal for a regulation

## Article 48 — paragraph 3 a (new)

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Text proposed by the Commission

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Amendment

**3a. When the support to be granted does not exceed EUR 4 000, the beneficiary may be selected through an accelerated procedure.**

## Amendment 358

## Proposal for a regulation

## Article 48 — paragraph 4

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Text proposed by the Commission

**4. Aquaculture farms shall not receive support for the advisory services more than once for each category of services covered under paragraph 2 (a) to (e) during the programming period.**

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Amendment

**deleted**

## Amendment 359

## Proposal for a regulation

## Article 49 — paragraph 1 — point a

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Text proposed by the Commission

(a) lifelong learning, dissemination of scientific knowledge and innovative practices **and** acquisition of new professional skills in aquaculture;

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Amendment

(a) **professional training,** lifelong learning, **the** dissemination of scientific **and technical** knowledge and innovative practices, **the** acquisition of new professional skills in aquaculture, **the improvement of working conditions, the promotion of occupational safety and the reduction of the environmental impact of aquaculture operations;**

Wednesday 23 October 2013

## Amendment 360

## Proposal for a regulation

## Article 49 — paragraph 1 — point b

Text proposed by the Commission

- (b) networking and exchange of experience and best practice among aquaculture enterprises or professional organisations and other stakeholders, including scientific bodies or those promoting equal opportunities between men and women.

Amendment

- (b) networking and exchange of experience and best practice among aquaculture enterprises or professional organisations and other **private or public** stakeholders, including scientific, **technical and training** bodies or those promoting equal opportunities between men and women.

## Amendment 361

## Proposal for a regulation

## Article 49 — paragraph 2

Text proposed by the Commission

2. **Support referred to in paragraph 1(a) shall not be granted to large aquaculture enterprises.**

Amendment

**deleted**

## Amendment 362

## Proposal for a regulation

## Article 50 — paragraph 1 — introductory part

Text proposed by the Commission

1. In order to contribute to the development of the aquaculture sites and infrastructures, the EMFF may support:

Amendment

1. In order to contribute to the development of the aquaculture sites and infrastructures **and to reduce the environmental impact of the operations**, the EMFF may support:

## Amendment 363

## Proposal for a regulation

## Article 50 — paragraph 1 — point a

Text proposed by the Commission

- (a) identification and mapping of most suitable areas for developing aquaculture, **and** where applicable, taking into account maritime spatial planning processes;

Amendment

- (a) **the** identification and mapping of most suitable areas for developing **sustainable** aquaculture **with low environmental impact**, where applicable, taking into account maritime spatial planning processes, **as well as follow-up actions for environmental interactions during the production phase of aquaculture activities**;

Wednesday 23 October 2013

## Amendment 364

## Proposal for a regulation

## Article 50 — paragraph 1 — point a a (new)

Text proposed by the Commission

Amendment

- (aa) *the identification and mapping of areas, such as nursery grounds, coastal spawning areas, marine protected areas, Natura 2000 sites or fish stock recovery areas where intensive aquaculture activities should be excluded in order to maintain the role of such areas in the functioning of the ecosystem;*

## Amendment 365

## Proposal for a regulation

## Article 50 — paragraph 1 — point b

Text proposed by the Commission

Amendment

- (b) improvement of infrastructures of aquaculture **areas** including through land consolidation, energy supply or water management;
- (b) *the* improvement and development of *the* support installations and infrastructures necessary for increasing the potential of aquaculture sites and decreasing the ecological footprint of aquaculture, including through investment in land consolidation, energy supply or water management;

## Amendment 366

## Proposal for a regulation

## Article 50 — paragraph 1 — point c

Text proposed by the Commission

Amendment

- (c) action taken **and implemented** by competent authorities under **of Article 9(1) of** Directive 2009/147/EC or **Article 16 (1) of** Directive 92/43/EEC with the aim of preventing serious damages to aquaculture.
- (c) action taken by competent authorities **aiming to mitigate conflicts with wild species protected** under Directive 2009/147/EC or Directive 92/43/EEC, with the aim of preventing serious damages to aquaculture.

## Amendment 367

## Proposal for a regulation

## Article 50 — paragraph 2

Text proposed by the Commission

Amendment

2. **Beneficiaries of** support under this Article shall only be public law bodies.
2. **Eligibility for** support under this Article shall be **limited to** public law bodies **or private organisations entrusted by a Member State to carry out the activities referred to in points (a), (aa) and (b) of paragraph 1.**

Wednesday 23 October 2013

**Amendment 368**  
**Proposal for a regulation**  
**Article 51 — title**

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*Text proposed by the Commission*

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Encouraging new aquaculture **farmers**

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*Amendment*

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Encouraging new **farmers in the sector of sustainable** aquaculture **and aquaculture processing**

**Amendment 369**  
**Proposal for a regulation**  
**Article 51 — paragraph 1**

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*Text proposed by the Commission*

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1. In order to foster entrepreneurship in aquaculture, the EMFF may support the setting up of aquaculture enterprises by new starting farmers.

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*Amendment*

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1. In order to foster entrepreneurship in aquaculture, the EMFF may support the setting up of **sustainable** aquaculture enterprises **or cooperatives** by new starting farmers, **including in the related processing sector, with particular focus on young aquaculturists and gender equality.**

**Amendment 370**  
**Proposal for a regulation**  
**Article 51 — paragraph 2 — introductory part**

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*Text proposed by the Commission*

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2. Support 1 shall be granted to aquaculture farmers entering the sector provided that they:

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*Amendment*

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2. Support **under paragraph** 1 shall be granted to aquaculture farmers entering the sector provided that they:

**Amendment 371**  
**Proposal for a regulation**  
**Article 51 — paragraph 2 — point b**

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*Text proposed by the Commission*

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(b) are setting up for the first time **an aquaculture** micro or small enterprise as heads of such enterprise;

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*Amendment*

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(b) are setting up for the first time **a** micro or small enterprise **in the sector of aquaculture or in the related processing sector,** as heads of such enterprise;

Wednesday 23 October 2013

#### Amendment 372

#### Proposal for a regulation

#### Article 51 — paragraph 2 — point c

*Text proposed by the Commission*

(c) submit **a** business plan for the development of their aquaculture activities.

*Amendment*

(c) submit **an economically and environmentally credible** business plan for the development of their aquaculture activities, **including a plan on how to minimise the ecological footprint of their activity.**

#### Amendment 373

#### Proposal for a regulation

#### Article 52 — title

*Text proposed by the Commission*

Promotion of aquaculture with high level of environmental protection

*Amendment*

Promotion of **sustainable** aquaculture with high level of environmental protection

#### Amendment 374

#### Proposal for a regulation

#### Article 52 — paragraph 1 — introductory part

*Text proposed by the Commission*

In order to substantially reduce the impact of aquaculture on the environment the EMFF may support investments:

*Amendment*

In order to substantially reduce the impact of aquaculture on the environment the EMFF may support **the following** investments:

#### Amendment 375

#### Proposal for a regulation

#### Article 52 — paragraph 1 — point a

*Text proposed by the Commission*

(a) allowing **for** a substantial reduction of impact of aquaculture enterprises on water, in particular through reducing the amount of water used or improving the output water quality, including through the deployment of multi-trophic aquaculture systems;

*Amendment*

(a) allowing a substantial reduction of **the** impact of aquaculture enterprises on water **usage and quality**, in particular through reducing the amount of water **or chemicals, antibiotics and other medicines** used, or improving the output water quality, including through the deployment of multi-trophic aquaculture systems;

Wednesday 23 October 2013

## Amendment 376

## Proposal for a regulation

## Article 52 — paragraph 1 — point a a (new)

Text proposed by the Commission

Amendment

*(aa) promotion of closed aquaculture systems;*

## Amendment 377

## Proposal for a regulation

## Article 52 — paragraph 1 — point b

Text proposed by the Commission

Amendment

(b) limiting the negative impact of aquaculture enterprises on nature or biodiversity;

(b) limiting the negative impact of aquaculture enterprises on nature **and promoting environmental protection and biodiversity, in particular limiting the impact on wild fish stocks, the interactions with predator species, the use of toxic chemicals and antibiotics and other environmental impacts linked to intensive aquaculture;**

## Amendment 378

## Proposal for a regulation

## Article 52 — paragraph 1 — point c

Text proposed by the Commission

Amendment

(c) the purchase of **the** equipment protecting aquaculture farms from wild predators **benefitting from protection under Council and European Parliament Directive 2009/147/EC and Council Directive 92/43/EEC;**

(c) the purchase of equipment protecting aquaculture farms from wild predators;

## Amendment 379

## Proposal for a regulation

## Article 52 — paragraph 1 — point e

Text proposed by the Commission

Amendment

(e) the restoration of existing aquaculture ponds or lagoons through removal of silt, **or possible measures aimed at the prevention of silt deposition.**

(e) the restoration of **estuaries**, existing aquaculture ponds or lagoons **and connected habitats** through removal of silt or prevention of silt deposition.

Wednesday 23 October 2013

#### Amendment 380

##### Proposal for a regulation

##### Article 53 — paragraph 1 — introductory part

*Text proposed by the Commission*

1. In order to promote the development of organic or energy efficient aquaculture, the EMFF may support:

*Amendment*

1. In order to promote the development of organic or **more** energy efficient aquaculture, the EMFF may support:

#### Amendment 381

##### Proposal for a regulation

##### Article 53 — paragraph 1 — point a a (new)

*Text proposed by the Commission*

*Amendment*

**(aa) the conversion of operations for the farming of carnivorous species into operations for the farming of herbivorous species which do not rely for feeding on fresh, wild, marine or freshwater fish, fishmeal or fish oil products;**

#### Amendment 382

##### Proposal for a regulation

##### Article 53 — paragraph 1 — point a b (new)

*Text proposed by the Commission*

*Amendment*

**(ab) promotion of closed system aquaculture where fish and other aquatic products are farmed in closed recirculation systems, minimizing water use.**

#### Amendment 383

##### Proposal for a regulation

##### Article 53 — paragraph 1 — point b

*Text proposed by the Commission*

(b) the participation in the Union eco-management and audit schemes established by Regulation (EC) No 761/2001 of the European **parliament** and of the **council** of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS).

*Amendment*

(b) the participation in the Union eco-management and audit schemes **such as those** established by Regulation (EC) No 761/2001 of the European **Parliament** and of the **Council** of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) **or participation in nationally recognised environmental management schemes;**

Wednesday 23 October 2013

**Amendment 384****Proposal for a regulation****Article 53 — paragraph 2***Text proposed by the Commission*

2. Support shall only be granted to beneficiaries who commit themselves for a minimum of **3** years to participate in the EMAS or **for a minimum of 5 years** to comply with the requirements of organic production.

*Amendment*

2. Support shall only be granted to beneficiaries who commit themselves for a minimum of **five** years to participate in the EMAS or **for a minimum of five years** to comply with the requirements of organic production.

**Amendment 385****Proposal for a regulation****Article 53 — paragraph 3***Text proposed by the Commission*

3. Support shall take the form of compensation for a maximum of **two** years during the period of the conversion of the enterprise to organic production or during the preparation for participation in the EMAS scheme.

*Amendment*

3. Support shall take the form of compensation for a maximum of **five** years during the period of the conversion of the enterprise to organic production or during the preparation for participation in the EMAS scheme.

**Amendment 386****Proposal for a regulation****Article 53 — paragraph 4 — point a***Text proposed by the Commission*

(a) the loss of revenue or additional costs incurred during the period of transition from conventional into organic production for operations eligible under paragraph 1(a) of this Article;

*Amendment*

(a) the loss of revenue or additional costs incurred during the period of transition from conventional into organic production **or the maintenance of organic production** for operations eligible under paragraph 1(a) of this Article;

**Amendment 387****Proposal for a regulation****Article 54 — paragraph 1 — introductory part***Text proposed by the Commission*

1. In order to foster the development of aquaculture providing environmental services, the EMFF may support:

*Amendment*

1. In order to foster the development of **sustainable** aquaculture providing environmental services, the EMFF may support:

Wednesday 23 October 2013

**Amendment 388****Proposal for a regulation****Article 54 –paragraph 1 — point a***Text proposed by the Commission*

- (a) aquaculture methods compatible with specific environmental needs and subject to specific management requirements resulting from the designation of NATURA 2000 areas in accordance with Council Directive 92/43/EEC and **Council and European Parliament** Directive 2009/147/EC;

*Amendment*

- (a) **extensive and semi-intensive** aquaculture methods compatible with specific environmental needs and subject to specific management requirements resulting from the designation of NATURA 2000 areas in accordance with Council Directive 92/43/EEC and Directive 2009/147/EC;

**Amendment 389****Proposal for a regulation****Article 54 –paragraph 1 — point b***Text proposed by the Commission*

- (b) participation in ex-situ conservation and reproduction of aquatic animals, within the framework of conservation and biodiversity restoration programmes developed by public authorities, or under their supervision;

*Amendment*

- (b) **the costs directly related to** participation in ex-situ conservation and reproduction of aquatic animals, within the framework of conservation and biodiversity restoration programmes developed by public authorities, or under their supervision;

**Amendment 390****Proposal for a regulation****Article 54 –paragraph 1 — point c***Text proposed by the Commission*

- (c) forms of extensive aquaculture including conservation and improvement of the environment, biodiversity, and management of the landscape and traditional features of aquaculture zones.

*Amendment*

- (c) forms of extensive **and semi-intensive** aquaculture, **both in coastal zones and in inland waters**, including conservation and improvement of the environment, biodiversity, and management of the landscape and traditional features of aquaculture zones.

**Amendment 391****Proposal for a regulation****Article 54 –paragraph 2***Text proposed by the Commission*

2. Support under paragraph 1 (a) shall take the form of annual compensation for the additional costs incurred or income foregone resulting from management requirements in the areas concerned, related to the implementation of Council Directive 92/43/EEC or Council and European Parliament Directive 2009/147/EC.

*Amendment*

2. Support under paragraph 1(a) shall take the form of annual compensation for the additional costs incurred **and/or** income foregone resulting from management requirements in the areas concerned, related to the implementation of Council Directive 92/43/EEC or Council and European Parliament Directive 2009/147/EC.

Wednesday 23 October 2013

**Amendment 392****Proposal for a regulation****Article 54 — paragraph 4***Text proposed by the Commission*

4. Support provided under paragraph 1 (c) shall take the form of annual compensation for the additional costs incurred.

*Amendment*

4. Support provided under paragraph 1(c) shall take the form of annual compensation for the additional costs incurred **and compensation for losses caused to aquaculture stocks by protected species, on the condition that protection measures have been taken.**

**Amendment 393****Proposal for a regulation****Article 55 — paragraph 1***Text proposed by the Commission*

1. The EMFF **shall** support compensation to mollusc farmers for the temporary suspension of harvesting of farmed molluscs exclusively for reasons of public health.

*Amendment*

1. The EMFF **may** support compensation to mollusc farmers for the temporary suspension of harvesting of farmed molluscs exclusively for reasons of public health.

**Amendment 395****Proposal for a regulation****Article 55 — paragraph 2 — point b***Text proposed by the Commission*

(b) the loss, resulting from the suspension of the harvest, amounts to more than **35 %** of the annual turnover of the business concerned, calculated on the basis of the average turnover of the business over the preceding three years.

*Amendment*

(b) the loss, resulting from the suspension of the harvest, amounts to more than **15 %** of the annual turnover of the business concerned, calculated on the basis of the average turnover of the business over the preceding three years, **or, when the company has a lower implementation period, in the prior activity period. Member States may establish special calculation rules for use in respect of companies with less than one year of activity.**

**Amendment 396****Proposal for a regulation****Article 55 — paragraph 3***Text proposed by the Commission*

3. **The duration for which compensation may be granted shall be of maximum 12 months over the entire programming period.**

*Amendment*

**deleted**

Wednesday 23 October 2013

#### Amendment 397

#### Proposal for a regulation

#### Article 56 — paragraph 1 — introductory part

##### Text proposed by the Commission

1. In order to foster animal health and welfare in aquaculture enterprises, particularly in terms of prevention and bio-security, the EMFF may support:

##### Amendment

1. In order to foster animal health and welfare in aquaculture enterprises, particularly in terms of prevention and bio-security, the EMFF may support **aquaculture farms and professional aquaculture organisations in respect of the following operations:**

#### Amendment 398

#### Proposal for a regulation

#### Article 56 — paragraph 1 — point a

##### Text proposed by the Commission

(a) the control and eradication of diseases in aquaculture under the terms of Council Decision 2009/470/EC on expenditure in the veterinary field;

##### Amendment

(a) the **costs of** control and eradication of diseases in aquaculture under the terms of Council Decision 2009/470/EC on expenditure in the veterinary field, **including the necessary operating costs to fulfil the obligations laid down in an eradication plan;**

#### Amendment 399

#### Proposal for a regulation

#### Article 56 — paragraph 1 — point b

##### Text proposed by the Commission

(b) the development of general and species specific best practices or codes of conducts on bio-security **or on** animal welfare needs in aquaculture;

##### Amendment

(b) the development of general and species specific best practices or codes of conducts on bio-security, animal **health and animal** welfare needs in aquaculture;

#### Amendment 400

#### Proposal for a regulation

#### Article 56 — paragraph 1 — point c

##### Text proposed by the Commission

(c) **increasing the availability of** veterinary medicines **for its use in aquaculture and promoting appropriate use of such medicines** through the commissioning of pharmaceutical studies and the dissemination and exchange of information.

##### Amendment

(c) **initiatives aimed at reducing the dependence of aquaculture on** veterinary medicines;

Wednesday 23 October 2013

**Amendment 401****Proposal for a regulation****Article 56 — paragraph 1 — c a (new)**

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*Text proposed by the Commission*

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*Amendment*

(ca) ***the establishment and operation of health protection groups in the aquaculture sector as recognised by Member States.***

**Amendment 402****Proposal for a regulation****Article 57 — paragraph 1 — introductory part**

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*Text proposed by the Commission*

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*Amendment*

1. In order to safeguard the income of aquaculture producers the EMFF may support the contribution to an aquaculture stock insurance which shall cover the losses due to:

1. In order to safeguard the income of aquaculture producers the EMFF may support the contribution to an aquaculture stock insurance ***or a mutual fund recognised by a Member State*** which shall cover the losses due to ***at least one of the following:***

**Amendment 403****Proposal for a regulation****Article 57 — paragraph 1 — point a**

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*Text proposed by the Commission*

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*Amendment*

(a) natural disasters;

(a) natural disasters ***or extensive pollution of the marine environment;***

**Amendment 404****Proposal for a regulation****Article 57 — paragraph 1 — point c**

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*Text proposed by the Commission*

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*Amendment*

(c) sudden water quality changes;

(c) sudden water quality ***and quantity*** changes;

Wednesday 23 October 2013

**Amendment 405**

**Proposal for a regulation**

**Article 57 — paragraph 1– point d**

*Text proposed by the Commission*

(d) diseases in aquaculture or destruction of production facilities.

*Amendment*

(d) diseases in aquaculture, **predation, mechanical failures** or destruction of production facilities, **for which the operator is not responsible;**

**Amendment 406**

**Proposal for a regulation**

**Article 57 — paragraph 1 — point d a (new)**

*Text proposed by the Commission*

*Amendment*

(da) **severe damage to facilities caused by wild animals, including infestation of aquaculture farms by invasive species;**

**Amendment 407**

**Proposal for a regulation**

**Article 57 — paragraph 1 — point d b (new)**

*Text proposed by the Commission*

*Amendment*

(db) **environmental pollution caused by an incident external to the aquaculture farm;**

**Amendment 408**

**Proposal for a regulation**

**Article 57 — paragraph 1 — point d c (new)**

*Text proposed by the Commission*

*Amendment*

(dc) **collection and destruction of animals that have died on the farm as a result of natural causes or farm accidents for which the operator is not responsible, or have been slaughtered and buried on the farm itself for animal health reasons with prior authorisation by the relevant authorities.**

Wednesday 23 October 2013

**Amendment 409****Proposal for a regulation****Article 57 — paragraph 2 –subparagraph 1***Text proposed by the Commission*

2. The occurrence of an adverse climatic event or **the outbreak of disease** in aquaculture shall be formally recognised as such by the Member State concerned.

*Amendment*

2. The occurrence of an adverse climatic event, **disease, extensive pollution or any of the relevant circumstances provided for in paragraph 1** in aquaculture shall be formally recognised as such by the Member State concerned.

**Amendment 410****Proposal for a regulation****Article 57 — paragraph 3***Text proposed by the Commission*

3. Support shall only be granted for aquaculture stock insurance contracts which cover economic losses under paragraph 1 exceeding **30%** of the average annual production of the aquaculture farmer.

*Amendment*

3. Support shall only be granted for aquaculture stock insurance contracts **or mutual funds** which cover economic losses under paragraph 1 exceeding **25 %** of the average annual production of the aquaculture farmer.

**Amendment 411****Proposal for a regulation****Article 58***Text proposed by the Commission*

The EMFF shall support the sustainable development of fisheries areas following a community-led local development approach as set out in Article 28 of the [Regulation (EU) No [...] laying down Common Provisions].

*Amendment*

The EMFF shall support the sustainable development of fisheries **and aquaculture** areas following a community-led local development approach as set out in Article 28 of the [Regulation (EU) No [...] laying down Common Provisions].

**Amendment 412****Proposal for a regulation****Article 59 — paragraph 1***Text proposed by the Commission*

Financial support under this Chapter shall contribute to the achievement of the Union priorities identified in Article 6(1).

*Amendment*

Financial support under this Chapter shall contribute to the achievement of the Union priorities identified in Article 6(1), **(2) and (3)**.

Wednesday 23 October 2013

#### Amendment 413

#### Proposal for a regulation

#### Title V — chapter III — section 2 — title

*Text proposed by the Commission*

Fisheries areas, local partnerships and local development strategies

*Amendment*

Fisheries **and aquaculture** areas, local partnerships and local development strategies

#### Amendment 414

#### Proposal for a regulation

#### Article 60 — title

*Text proposed by the Commission*

Fisheries areas

*Amendment*

Fisheries **and aquaculture** areas

#### Amendment 415

#### Proposal for a regulation

#### Article 60 — paragraph 1 — introductory part

*Text proposed by the Commission*

1. **A fisheries** area eligible for support shall be:

*Amendment*

1. ***In order for an area to qualify as an area eligible for support, it shall be either a sea-fishing area, an inland fishing area or an aquaculture area. It shall be functionally coherent in geographical, biological, economic and social terms, taking specific account of the fisheries, aquaculture and related activities, and shall offer sufficient critical mass in terms of human, financial and economic resources to support a viable local development strategy.***

#### Amendment 416

#### Proposal for a regulation

#### Article 60 — paragraph 1 — point a

*Text proposed by the Commission*

(a) **limited in size and, as a general rule, shall be smaller than NUTS level 3 of the common classification of territorial units for statistics within the meaning of Regulation (EC) No 1059/2003 of 26 May 2003 of the European Parliament and of the Council on the establishment of a common classification of territorial units for statistics (NUTS); and**

*Amendment*

**deleted**

Wednesday 23 October 2013

## Amendment 417

## Proposal for a regulation

## Article 60 — paragraph 1 — point b

Text proposed by the Commission

(b) *functionally coherent in geographical, economic and social terms, taking specific account of the fisheries and aquaculture sectors and offer sufficient critical mass in terms of human, financial and economic resources to support a viable local development strategy.*

Amendment

deleted

## Amendment 418

## Proposal for a regulation

## Article 61 — paragraph 1

Text proposed by the Commission

1. For the purposes of the EMFF, the integrated local development strategy referred to in Article 28(1)(c) of [Regulation (EU) No [...] laying down Common Provisions] shall be based on the interaction between actors and projects of **different sectors of the local economy, in particular** the fisheries and aquaculture sectors;

Amendment

1. For the purposes of the EMFF, the integrated local development strategy referred to in Article 28(1)(c) of [Regulation (EU) No [...] laying down Common Provisions] shall be based on interaction **and consultations** between actors and projects of the fisheries and aquaculture sectors, **as well as other sectors of the local economy. In this regard, Advisory Councils shall be consulted.**

## Amendment 419

## Proposal for a regulation

## Article 61 — paragraph 2 — point a

Text proposed by the Commission

(a) maximise the participation of the fisheries and aquaculture sectors in the sustainable development of coastal and inland fisheries areas;

Amendment

(a) maximise the participation of the fisheries and aquaculture sectors in the sustainable development of coastal and inland fisheries **and aquaculture** areas;

## Amendment 420

## Proposal for a regulation

## Article 61 — paragraph 2 — point b

Text proposed by the Commission

(b) ensure that local communities fully exploit and benefit from the opportunities offered by maritime **and** coastal development.

Amendment

(b) ensure that local communities fully exploit and benefit from the opportunities offered by maritime, coastal **and inland water development and, in particular, help small and declining fishing ports to maximise their marine potential by developing a diversified infrastructure.**

Wednesday 23 October 2013

## Amendment 421

## Proposal for a regulation

## Article 61 — paragraph 3

Text proposed by the Commission

3. The strategy must be coherent with the opportunities and needs identified in the area and the Union priorities for the EMFF. Strategies **may range from those which** focus on fisheries **to broader strategies** directed at the diversification of fisheries areas. The strategy shall go beyond a mere collection of operations or juxtaposition of sectoral measures.

Amendment

3. The strategy must be coherent with the opportunities and needs identified in the area and the Union priorities for the EMFF. Strategies **shall** focus **mainly** on fisheries **or aquaculture, although they may be** broader, directed at the diversification of fisheries **and aquaculture** areas. The strategy shall go beyond a mere collection of operations or juxtaposition of sectoral measures.

## Amendment 422

## Proposal for a regulation

## Article 61 — paragraph 5

Text proposed by the Commission

5. **The Commission shall be empowered to adopt delegated acts in accordance with Article 127 concerning the content of the** action plan referred to in Article 29(1)(e) of the [Regulation (EU) No [...] laying down Common Provisions].

Amendment

5. **The integrated local development strategy shall include an** action plan referred to in Article 29(1)(e) of the [Regulation (EU) No [...] laying down Common Provisions]. **The action plan shall set out, inter alia, the list of actions envisaged for implementing the strategy and, for each action, it shall specify the objectives of that action, the eligible expenditure, the admissible beneficiaries, the financial envelope related to associated public funds, the criteria for selecting operations and the performance indicators.**

## Amendment 423

## Proposal for a regulation

## Article 62 — paragraph 3 — point b

Text proposed by the Commission

(b) ensure a **significant representation of** fisheries and aquaculture **sectors**.

Amendment

(b) ensure **that a majority of representatives come from the** fisheries and/or the aquaculture **sectors**.

## Amendment 424

## Proposal for a regulation

## Article 62 — paragraph 4

Text proposed by the Commission

4. If the local development strategy is supported by other Funds in addition to the EMFF **a specific** selection body for EMFF supported projects shall **be established according to the criteria** set out in paragraph (3).

Amendment

4. If the local development strategy is supported by other Funds in addition to the EMFF, **the** selection body **of the FLAG** for EMFF supported projects shall **fulfil the requirements** set out in paragraph (3).

Wednesday 23 October 2013

**Amendment 425****Proposal for a regulation****Article 62 — paragraph 7**

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*Text proposed by the Commission*

7. The respective roles of the FLAG, the managing authority for all implementation tasks relating to the strategy shall be clearly described in the operational programme.

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*Amendment*

7. The respective roles of the FLAG, the managing authority **and, where this differs from the managing authority, the implementing authority**, for all implementation tasks relating to the strategy, shall be clearly described in the operational programme.

**Amendment 426****Proposal for a regulation****Article 63 — paragraph 1**

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*Text proposed by the Commission*

1. The operations eligible under this Section are set out in Article 31 of the [Regulation (EU) No [...] laying down Common Provisions].

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*Amendment*

1. The operations **and costs** eligible under this Section are set out in Article 31 of the [Regulation (EU) No [...] laying down Common Provisions].

**Amendment 427****Proposal for a regulation****Article 64 — paragraph 1**

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*Text proposed by the Commission*

1. Preparatory support shall cover capacity building, training and networking with a view to preparing and implementing a local development strategy.

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*Amendment*

1. Preparatory support shall cover capacity building, **consultation**, training and networking with a view to preparing and implementing a local development strategy.

**Amendment 428****Proposal for a regulation****Article 65 — paragraph 1 — point a**

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*Text proposed by the Commission*

(a) adding value, creating jobs, and promoting innovation at all stages of the fisheries and aquaculture supply chain;

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*Amendment*

(a) adding value, creating jobs, **attracting young people** and promoting innovation at all stages of the fisheries, aquaculture **and processing** supply chain;

Wednesday 23 October 2013

## Amendment 429

## Proposal for a regulation

## Article 65 — paragraph 1 — point b

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Text proposed by the Commission

- (b) supporting diversification and job creation in fisheries areas,  
**in particular in other maritime sectors;**

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Amendment

- (b) supporting diversification and job creation in fisheries and aquaculture areas, **including diversification into maritime activities that complement fisheries and aquaculture activities;**

## Amendment 430

## Proposal for a regulation

## Article 65 — paragraph 1 — point b a (new)

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Text proposed by the Commission

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Amendment

- (ba) **strengthening training and improving working conditions in fisheries and aquaculture areas;**

## Amendment 431

## Proposal for a regulation

## Article 65 — paragraph 1 — point c

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Text proposed by the Commission

- (c) enhancing and capitalising on the environmental assets of the fisheries areas including operations to mitigate climate change;

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Amendment

- (c) enhancing and capitalising on the environmental assets of the fisheries **and aquaculture** areas including operations to **maintain biodiversity, to improve management of the coastal zone and to** mitigate climate change;

## Amendment 432

## Proposal for a regulation

## Article 65 — paragraph 1 — point d

---

Text proposed by the Commission

- (d) promoting social well being and cultural heritage in fisheries areas including maritime cultural heritage;

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Amendment

- (d) promoting social well being and cultural heritage in fisheries **and aquaculture** areas including **fisheries and** maritime cultural heritage;

Wednesday 23 October 2013

## Amendment 433

## Proposal for a regulation

## Article 65 — paragraph 2

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*Text proposed by the Commission*

2. The support given may include measures provided for Chapters I **and** II of this Title, provided there is a clear rationale for their management at local level. When assistance is granted for operations corresponding to these measures, the relevant conditions and the scales of contribution per operation laid down in Chapters I **and** II of this Title shall apply.

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*Amendment*

2. The support given may include measures provided for **in** Chapters I, II **and** IV of this Title, provided there is a clear rationale for their management at local level. When assistance is granted for operations corresponding to these measures, the relevant conditions and the scales of contribution per operation laid down in Chapters I, II **and** IV of this Title shall apply.

## Amendment 434

## Proposal for a regulation

## Article 66 — paragraph 2

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*Text proposed by the Commission*

2. **Apart** from other FLAGs, the partners of a FLAG under the EMFF may be a local public–private partnership that is implementing a local development strategy within or outside the Union.

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*Amendment*

2. **For the purposes of this Article, apart** from other FLAGs, the partners of a FLAG under the EMFF may be **the participants in a cooperation project with a non-FLAG territory based on a** local public–private partnership that is implementing a local development strategy within or outside the Union.

## Amendment 435

## Proposal for a regulation

## Article 66 — paragraph 3

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*Text proposed by the Commission*

3. In cases where co-operation projects are not selected by the FLAGs, Member States shall establish a system of ongoing **application** for cooperation projects. They shall make public the national or regional administrative procedures concerning the selection of transnational cooperation projects and a list of eligible costs at the latest two years after the date of approval of their operational programme.

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*Amendment*

3. In cases where co-operation projects are not selected by the FLAGs, Member States shall establish a system of ongoing **applications** for cooperation projects. They shall make public the national or regional administrative procedures concerning the selection of transnational cooperation projects and a list of eligible costs at the latest two years after the date of approval of their operational programme. **Advisory Councils may, due to their transnational character, be involved in that system of ongoing applications.**

Wednesday 23 October 2013

## Amendment 436

## Proposal for a regulation

## Article 66 — paragraph 4

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Text proposed by the Commission

4. **Approval of** cooperation projects shall take place no later than four months after the date of submission of the project.

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Amendment

4. **Administrative decisions concerning** cooperation projects shall take place no later than four months after the date of submission of the project.

## Amendment 437

## Proposal for a regulation

## Article 68

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Text proposed by the Commission

Support under this Chapter shall contribute to **achieve the specific objectives of Chapter I and Chapter II of this Title.**

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Amendment

Support under this Chapter shall contribute to:

- (a) **the achievement of the specific objectives of Chapter I and Chapter II of this Title;**
- (b) **the improvement of the competitiveness of the processing and marketing of fisheries and aquaculture products;**
- (c) **the improvement of food safety and product quality;**
- (d) **the development, production and marketing of new products and the use of new technologies and innovative production methods;**
- (e) **reducing the negative impact on the environment and increase energy efficiency;**
- (f) **a better use of minor species, of by-products and of waste;**
- (g) **the development, production and marketing of new products and the use of new technologies and innovative production methods;**
- (h) **the improvement of working conditions and worker training;**
- (i) **the opening and development of new markets.**

Wednesday 23 October 2013

**Amendment 438****Proposal for a regulation****Article 69 — paragraph 1***Text proposed by the Commission*

1. The EMFF **may** support the preparation and implementation of production and marketing plans referred to in Article 32 of [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products].

*Amendment*

1. The EMFF **shall** support the preparation and implementation of production and marketing plans referred to in Article 32 of [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products].

**Amendment 439****Proposal for a regulation****Article 70 — paragraph 1 — introductory part***Text proposed by the Commission*

1. The EMFF may **support** compensation to recognised producer organisations and associations of producers organisations which store fishery products listed in Annex II **of** Regulation No. [on the common organisation of the market in fishery and aquaculture products], provided that the products are stored in conformity with Articles 35 and 36 of Regulation **No ...[on the common organisation of the markets in fishery and aquaculture products]:**

*Amendment*

1. The EMFF may **co-finance a** compensation to recognised producer organisations and associations of producers organisations which store fishery **and aquaculture** products listed in Annex II **to** Regulation No. [on the common organisation of the market in fishery and aquaculture products], provided that the products are stored in conformity with Articles 35 and 36 of **that** Regulation:

**Amendment 440****Proposal for a regulation****Article 70 — paragraph 1 — point a***Text proposed by the Commission*

(a) the amount of the storage aid shall not exceed the amount of the technical and financial costs of the actions required for the stabilisation and storage of the products in question;

*Amendment*

(a) the amount of the storage aid shall not exceed the amount of the technical and financial costs of the actions required for the stabilisation, **preparation** and storage of the products in question;

Wednesday 23 October 2013

#### Amendment 441

#### Proposal for a regulation

#### Article 70 — paragraph 1 — point c

*Text proposed by the Commission*

(c) the financial assistance per year shall not exceed **the following percentages** of the average annual value of the marketed production at first sale of the members of producer organisation in the period 2009–2011. In the case that members of producer organisation did not have any marketed production in 2009–2011, the average annual value of marketed production in the first three years of production of such member shall be taken into account:

— 1 % in 2014

— 0,8 % in 2015

— 0,6 % in 2016

— 0,4 % in 2017

— 0,2 % in 2018.

*Amendment*

(c) the financial assistance per year shall not exceed **5 %** of the average annual value of the marketed production at first sale of the members of producer organisation in the period 2009–2011. In the case that members of producer organisation did not have any marketed production in 2009–2011, the average annual value of marketed production in the first three years of production of such member shall be taken into account.

#### Amendment 442

#### Proposal for a regulation

#### Article 70 — paragraph 2

*Text proposed by the Commission*

**2. By 2019 support referred to in paragraph 1 shall be phased out.**

*Amendment*

**deleted**

#### Amendment 443

#### Proposal for a regulation

#### Article 71 — paragraph 1 — introductory part

*Text proposed by the Commission*

1. The EMFF may support marketing measures for fishery and aquaculture products which aim at:

*Amendment*

1. The EMFF may support marketing measures for fishery, aquaculture **and inland fishery** products which aim at:

Wednesday 23 October 2013

## Amendment 444

## Proposal for a regulation

## Article 71 — paragraph 1 — point a — introductory part

Text proposed by the Commission

(a) improving the conditions for the placing on the market of:

Amendment

(a) **finding new markets and** improving the conditions for the placing on the market of **fishery and aquaculture species, including:**

## Amendment 445

## Proposal for a regulation

## Article 71 — paragraph 1 — point a — point i a (new)

Text proposed by the Commission

Amendment

(ia) **products marketed by organisations of fishermen, by their associations and via auction halls;**

## Amendment 446

## Proposal for a regulation

## Article 71 — paragraph 1 — point a — point ii

Text proposed by the Commission

(ii) unwanted catches landed in conformity with Article 15 of [Regulation on the Common Fisheries Policy] and Article 8 (b) second indent of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products];

Amendment

(ii) unwanted catches landed **from commercial stocks** in conformity with **technical measures**, Article 15 of [Regulation on the Common Fisheries Policy] and Article 8 (b) second indent of the [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products];

## Amendment 447

## Proposal for a regulation

## Article 71 — paragraph 1 — point a — point iii

Text proposed by the Commission

(iii) products obtained using methods with low impact on the environment or organic aquaculture products as defined in Council Regulation(EC) No 834/2007 on organic production.

Amendment

(iii) **fisheries or aquaculture** products obtained using methods with low impact on the environment, or organic aquaculture products as defined in Council Regulation(EC) No 834/2007 on organic production **or in closed aquaculture systems;**

Wednesday 23 October 2013

## Amendment 448

## Proposal for a regulation

## Article 71 — paragraph 1 — point a — point iii a (new)

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Text proposed by the Commission

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Amendment

(iiia) *local and seasonal products, including products covered by Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs;*

## Amendment 449

## Proposal for a regulation

## Article 71 — paragraph 1 — point a — point iii b (new)

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Text proposed by the Commission

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Amendment

(iiib) *new or upgraded products.*

## Amendment 450

## Proposal for a regulation

## Article 71 — paragraph 1 — point b — introductory part

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Text proposed by the Commission

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Amendment

(b) promoting **the** quality by facilitating:

(b) promoting quality **and added value** by facilitating:

## Amendment 451

## Proposal for a regulation

## Article 71 — paragraph 1 — point b — point ii

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Text proposed by the Commission

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Amendment

(ii) certification **and** promotion including **of** sustainable fishery and aquaculture products and of environmentally friendly processing methods;

(ii) **the** certification **of quality and the** promotion **and creation of specific labelling with regard to** sustainable fishery and aquaculture products, **small scale coastal fishing products, local and seasonal products** and environmentally friendly processing methods;

Wednesday 23 October 2013

**Amendment 452****Proposal for a regulation****Article 71 — paragraph 1 — point b — point ii a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(iia) the traceability of fishery and aquaculture products, including the development of a Union-wide ecolabel for fisheries and aquaculture products;*

**Amendment 453****Proposal for a regulation****Article 71 — paragraph 1 — point b — point ii b (new)**

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*Text proposed by the Commission*

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*Amendment*

*(iib) innovative processes and methods;*

**Amendment 454****Proposal for a regulation****Article 71 — paragraph 1 — point b — point iii**

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*Text proposed by the Commission*

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*Amendment*

(iii) direct marketing of fishery products by small scale coastal fishermen.

(iii) direct marketing of fishery products by small scale coastal fishermen *and on-foot fishermen;*

**Amendment 455****Proposal for a regulation****Article 71 — paragraph 1 — point b — point iii a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(iiia) presentation and packaging of products;*

Wednesday 23 October 2013

## Amendment 456

## Proposal for a regulation

## Article 71 — paragraph 1 — point b — point iii b (new)

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Text proposed by the Commission

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Amendment

(iiib) **achievement of the compliance and certification requirements for products covered by Regulation (EC) No 510/2006 by producers, processors and developers to which the control and certification systems apply.**

## Amendment 457

## Proposal for a regulation

## Article 71 — paragraph 1 — point c

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Text proposed by the Commission

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Amendment

(c) contributing to the transparency of production and the markets and conducting market surveys;

(c) contributing to the transparency of production and the markets and conducting market surveys **and studies on the Union's trade dependency;**

## Amendment 458

## Proposal for a regulation

## Article 71 — paragraph 1 — point e

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Text proposed by the Commission

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Amendment

(e) creating producers' organisations, associations of producer organisations or inter-branch organisations recognised under Chapter II, Section III of Regulation [on the Common Organisation of the markets in fisheries and aquaculture products];

(e) creating **and merging** producers' organisations, associations of producer organisations or inter-branch organisations recognised under Chapter II, Section III of Regulation [on the Common Organisation of the markets in fisheries and aquaculture products] **in order to foster their role in the management of fisheries and marketing measures;**

## Amendment 459

## Proposal for a regulation

## Article 71 — paragraph 1 — point f

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Text proposed by the Commission

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Amendment

(f) conducting regional, national or transnational promotional campaigns for fishery and aquaculture products.

(f) conducting regional, national or transnational promotional campaigns, **including exhibitions and media campaigns,** for **environmentally sustainable** fishery and aquaculture products.

Wednesday 23 October 2013

**Amendment 460****Proposal for a regulation****Article 72 — paragraph 1 — point -a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(-a) for innovation in order to develop new products with greater quality and added value, new or improved processes and in new or improved management and organisational systems;**

**Amendment 461****Proposal for a regulation****Article 72 — paragraph 1 — point -b (new)**

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*Text proposed by the Commission*

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*Amendment*

**(-b) increasing the added value of products;**

**Amendment 462****Proposal for a regulation****Article 72 — paragraph 1 — point a a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(aa) improving safety, hygiene, health and working conditions;**

**Amendment 463****Proposal for a regulation****Article 72 — paragraph 1 — point d**

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*Text proposed by the Commission*

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*Amendment*

(d) for the processing of organic aquaculture products as regulated in Article 6 and 7 of Council Regulation(EC) No 834/2007.

(d) for the processing **of sustainable aquaculture products and** of organic aquaculture products as regulated in Article 6 and 7 of Council Regulation(EC) No 834/2007.

Wednesday 23 October 2013

## Amendment 464

## Proposal for a regulation

## Article 72 — paragraph 1 a (new)

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Text proposed by the Commission

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Amendment

**1a.** The EMFF **may** support companies, associations and technology centres representing the processing sector to develop research and innovation activities related to those referred to in paragraph 1.

## Amendment 465

## Proposal for a regulation

## Article 73 — paragraph 1

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Text proposed by the Commission

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Amendment

1. The EMFF **may** support the compensation **regime** introduced by Council Regulation (EC) No 791/2007 for the additional costs incurred by the operators in the fishing, farming and marketing of certain fishery and aquaculture products from the **Azores, Madeira, the Canary Islands, French Guiana, and Réunion**.

1. The EMFF **shall** support the compensation **scheme** introduced **pursuant to Article 349 TFEU** by Council Regulation (EC) No 791/2007 **to compensate** for the additional costs incurred by the operators in the fishing, farming, **processing** and marketing of certain fishery and aquaculture products from the **outermost regions**. **That scheme shall apply to all additional costs incurred by operators engaged in the activities referred to in this paragraph.**

## Amendment 466

## Proposal for a regulation

## Article 73 — paragraph 2

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Text proposed by the Commission

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Amendment

2. Each Member State concerned shall determine for the regions referred to in paragraph 1 the list of fishery and aquaculture products and the quantity of those products eligible for the compensation.

2. Each Member State concerned shall determine, for the regions referred to in paragraph 1, the list of **additional costs incurred by operators engaged in the activities referred to in paragraph 1**. **It shall also draw up the list of** fishery and aquaculture products and the quantity of those products eligible for the compensation.

Wednesday 23 October 2013

**Amendment 467****Proposal for a regulation****Article 73 — paragraph 3**

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*Text proposed by the Commission*

3. When establishing the list and the quantities referred to in paragraph 2, Member States shall take into account all the relevant factors, in particular the need to ensure that the compensation is fully compatible with the rules of the CFP.

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*Amendment*

3. When establishing the list and the quantities referred to in paragraph 2, Member States shall take into account all the relevant factors, in particular the need to ensure that the compensation is fully compatible with the rules of the CFP **and that the fishing capacity of the fleets concerned is commensurate with the fishing opportunities that are available.**

**Amendment 468****Proposal for a regulation****Article 73 — paragraph 4 — point c a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ca) obtained by IUU fishing.**

**Amendment 469****Proposal for a regulation****Article 73 — paragraph 5 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**5a. The following operators who incur additional costs in the marketing of fishery products shall be eligible for compensation:**

- (a) natural or legal persons using means of production to obtain fishery or aquaculture products with a view to placing them on the market;**
- (b) the owners or operators of vessels that are registered in the ports of the regions referred to in paragraph 1 and that are operating in those regions, or associations of such owners or operators;**
- (c) the operators in the processing and marketing sector or associations of such operators.**

Wednesday 23 October 2013

**Amendment 470**  
**Proposal for a regulation**  
**Article 73 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 73a****Operators**

1. *Compensation shall be paid to operators carrying out fishing and aquaculture activities in the regions concerned.*
2. *The Member States concerned shall take the measures necessary to ensure that operators receiving the compensation remain economically viable.*

**Amendment 471**  
**Proposal for a regulation**  
**Article 74 — paragraph 1 — point a**

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*Text proposed by the Commission*

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*Amendment*

(a) for each fishery or aquaculture product the additional costs resulting from the specific handicaps of the regions concerned, and

(a) for each fishery or aquaculture product **or category of product** the additional costs resulting from the specific handicaps of the regions concerned, and

**Amendment 472**  
**Proposal for a regulation**  
**Article 74 — paragraph 1 — point b a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ba) any other support that the beneficiary continues to receive or has received for his activity.**

**Amendment 473**  
**Proposal for a regulation**  
**Article 75 — paragraph 1**

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*Text proposed by the Commission*

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*Amendment*

1. The Member States concerned shall submit to the Commission a compensation plan for each region concerned including the list and quantities referred to in Article 73, the level of compensation referred to in Article 74 and the competent authority as laid down in Article 99.

1. The Member States concerned shall submit to the Commission a compensation plan for each region concerned including the list and quantities **and the type of operators** referred to in Article 73, the level of compensation referred to in Article 74 and the competent authority as laid down in Article 99.

Wednesday 23 October 2013

## Amendment 474

## Proposal for a regulation

## Article 75 — paragraph 1 a (new)

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Text proposed by the Commission

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Amendment

**1a. Member States may amend the content of the compensation plan referred to in paragraph 1. Such amendments shall be submitted to the Commission.**

## Amendment 475

## Proposal for a regulation

## Article 75 — paragraph 2

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Text proposed by the Commission

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Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance **to** Article 127 **in order to define** the content of the compensation plan, including the criteria for the calculation of the additional costs resulting from the specific handicaps of the regions concerned.

2. The Commission shall be empowered to adopt delegated acts, in accordance **with** Article 127, **laying down** the content of the compensation plan, including the criteria for the calculation of the additional costs resulting from the specific handicaps of the regions concerned.

## Amendment 476

## Proposal for a regulation

## Article 75 a (new)

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Text proposed by the Commission

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Amendment**Article 75a****State aid**

**1. By way of derogation from Article 8, the Commission may authorise, in accordance with Article 108 TFEU, operating aid in the sectors producing, processing and marketing fishing and aquaculture products, with a view to alleviating the specific constraints in the outermost regions as a result of their isolation, insularity and extreme remoteness.**

**2. Member States may grant additional financing for the implementation of the compensation plans referred to in Article 75. In such cases, the Member States shall notify the Commission of the State aid which the Commission may approve in accordance with this Regulation as part of those plans. State aid that has been notified in accordance with this paragraph shall also be deemed to be notified within the meaning of the first sentence of Article 108(3) TFEU.**

Wednesday 23 October 2013

## Amendment 477

## Proposal for a regulation

## Article 78 — paragraph 1

*Text proposed by the Commission*

1. The EMFF may support the implementation of a Union control, inspection and enforcement system as provided for in Article 46 of the [Regulation on the Common Fisheries Policy] and specified in Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the Common Fisheries Policy.

*Amendment*

1. The EMFF may support the implementation of a Union control, inspection and enforcement system as provided for in Article 46 of the [Regulation on the Common Fisheries Policy] and specified in Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the Common Fisheries Policy, **as well as the installation of the components that are necessary to ensure the traceability of fisheries products pursuant to Article 58 of Council Regulation (EC) No 1224/2009. Such a system should result in a number of controls based on the size of fleets in different Member States.**

## Amendment 478

## Proposal for a regulation

## Article 78 — paragraph 2 — point a

*Text proposed by the Commission*

(a) purchase **or** development of technology, including hardware and software, vessel detection systems (VDS), CCTV systems and IT networks enabling the gathering, administration, validation, analysis and exchange of, and the development of sampling methods for, data related to fisheries, as well as interconnection to cross-sectoral data exchange systems;

*Amendment*

(a) purchase, **installation and** development of technology, including hardware and software, vessel detection systems (VDS), CCTV systems and IT networks enabling the gathering, administration, validation, analysis, **risk management, submission** and exchange of, and the development of sampling methods for, data related to fisheries, as well as interconnection to cross-sectoral data exchange systems, **on condition that such operations respect individual freedoms and ensure that personal data is protected;**

## Amendment 479

## Proposal for a regulation

## Article 78 — paragraph 2 — point b

*Text proposed by the Commission*

(b) purchase and installation of the components necessary to ensure data transmission from actors involved in fishing and the marketing of fishery products to the relevant Member State and EU authorities, including the necessary components for electronic recording and reporting systems (ERS), vessel monitoring systems (VMS), and automatic identification systems (AIS) used for control purposes;

*Amendment*

(b) **development,** purchase and installation of the components, **including computer hardware and software, that are** necessary to ensure data transmission from actors involved in fishing and the marketing of fishery products to the relevant Member State and EU authorities, including the necessary components for electronic recording and reporting systems (ERS), vessel monitoring systems (VMS), and automatic identification systems (AIS) used for control purposes;

Wednesday 23 October 2013

## Amendment 480

## Proposal for a regulation

## Article 78 — paragraph 2 — point c

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Text proposed by the Commission

- (c) purchase and installation of the components necessary to ensure traceability of fishery and aquaculture products, as defined in Article 58 of Council Regulation (EC) No 1224/2009;

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Amendment

- (c) **development**, purchase and installation of the components, **including computer hardware and software, which are** necessary to ensure traceability of fishery and aquaculture products, as defined in Article 58 of Council Regulation (EC) No 1224/2009;

## Amendment 481

## Proposal for a regulation

## Article 78 — paragraph 2 — point e

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Text proposed by the Commission

- (e) modernisation and purchase of patrol vessels, aircrafts and helicopters, provided they are used at least 60 % of the time **for fisheries control**;

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Amendment

- (e) modernisation and purchase of patrol vessels, aircrafts and helicopters, provided they are used **for fisheries control for** at least 60 % of the **total** time **that the equipment is used per year**;

## Amendment 482

## Proposal for a regulation

## Article 78 — paragraph 2 — point g

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Text proposed by the Commission

- (g) implementation of pilot projects related to fisheries control, including fish DNA analysis or the development of web-sites related to control;

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Amendment

- (g) **development of innovative control and monitoring systems and** implementation of pilot projects related to fisheries control, including fish DNA analysis or the development of web-sites related to control;

## Amendment 483

## Proposal for a regulation

## Article 78 — paragraph 2 — point j a (new)

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Text proposed by the Commission

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Amendment

- (ja) **programmes delivering tougher control for stocks subject to specific control and inspection programmes established in accordance with Article 95 of Council Regulation (EC) No 1224/2009, including any operational costs incurred;**

Wednesday 23 October 2013

#### Amendment 484

#### Proposal for a regulation

#### Article 78 — paragraph 2 — point j b (new)

*Text proposed by the Commission*

*Amendment*

(jb) programmes linked to the implementation of an action plan established in accordance with Article 102(4) of Regulation (EC) No 1224/2009, including any operational costs incurred.

#### Amendment 485

#### Proposal for a regulation

#### Article 78 — paragraph 3

*Text proposed by the Commission*

*Amendment*

3. The measures listed in points (h), (i) **and** (j) of paragraph 2 of this Article shall only be eligible for support if they relate to control activities carried out by a public authority.

3. The measures listed in points (h), (i), (j), **(ja) and (jb)** of paragraph 2 of this Article shall only be eligible for support if they relate to control activities carried out by a public authority.

#### Amendment 486

#### Proposal for a regulation

#### Article 78 a (new)

*Text proposed by the Commission*

*Amendment*

#### Article 78a

#### **Collective actions with a view to strengthening and standardising controls**

1. With a view to strengthening and standardising controls, the EMFF may support the implementation of transnational projects aimed at developing and testing the inter-State control, inspection and enforcement systems provided for under Article 46 of the Regulation (EU) No .../..... [on the CFP] and laid down in Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the CFP.

2. Eligible types of operation include in particular the following:

(a) international training programmes for personnel responsible for monitoring, control and surveillance of fisheries activities;

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

- (b) *initiatives, including seminars and media tools, for standardising the interpretation of regulations and associated controls in the Union.*

## Amendment 487

## Proposal for a regulation

## Article 79 — paragraph 1

Text proposed by the Commission

Amendment

1. The EMFF shall support the collection and management and use of primary biological, technical, environmental and socioeconomic data as in the multiannual Union programme referred to in Article 37(5) of the [Regulation on the Common Fisheries Policy].

1. The EMFF shall support the collection and management, **analysis** and use of primary biological, technical, environmental and socioeconomic data **necessary for sustainable ecosystem-based fisheries and aquaculture management** as in the multiannual Union programme referred to in Article 37(5) of the [Regulation on the Common Fisheries Policy].

## Amendment 488

## Proposal for a regulation

## Article 79 — paragraph 2 — point a

Text proposed by the Commission

Amendment

- (a) the management and use of data for the purpose of scientific analysis and CFP implementation;

- (a) the **collection**, management and use of data for the purpose of scientific analysis and CFP implementation;

## Amendment 489

## Proposal for a regulation

## Article 79 — paragraph 2 — point a (new)

Text proposed by the Commission

Amendment

- (aa) *the purchase or development of technology, including computer hardware and software, required for the collection, management and use of data;*

Wednesday 23 October 2013

**Amendment 490**

**Proposal for a regulation**

**Article 79 — paragraph 2 — point b**

*Text proposed by the Commission*

(b) national multi-annual sampling programmes;

*Amendment*

(b) national, **transnational and sub-national** multi-annual sampling programmes;

**Amendment 491**

**Proposal for a regulation**

**Article 79 — paragraph 2 — point c**

*Text proposed by the Commission*

(c) at-sea monitoring of commercial and recreational fisheries;

*Amendment*

(c) at-sea monitoring of commercial and recreational fisheries, **including the monitoring of by-catches of marine organisms and birds**;

**Amendment 492**

**Proposal for a regulation**

**Article 79 — paragraph 2 — point d a (new)**

*Text proposed by the Commission*

*Amendment*

(da) **management of annual work programmes with regard to technical and scientific expertise in fisheries, the processing of data communications and data sets and preparatory work for the provision of scientific advice**;

**Amendment 493**

**Proposal for a regulation**

**Article 79 — paragraph 2 — point d b (new)**

*Text proposed by the Commission*

*Amendment*

(db) **Organisation and management of fisheries expert meetings**;

Wednesday 23 October 2013

**Amendment 494****Proposal for a regulation****Article 79 — paragraph 2 — point e***Text proposed by the Commission*

(e) the participation **of** Member States' representatives in regional coordination meetings as referred to in Article 37 (4) of the [Regulation on the Common Fisheries Policy], meetings of regional fisheries management organisations of which the EU is a contracting partner or an observer or meetings of international bodies in charge of providing scientific advice.

*Amendment*

(e) the participation, **by representatives** of Member States **and their scientific experts, as well as by** representatives **of regional authorities**, in regional coordination meetings as referred to in Article 37(4) of the [Regulation on the Common Fisheries Policy], meetings of regional fisheries management organisations of which the EU is a contracting partner or an observer or meetings of international bodies in charge of providing scientific, **economic or technical** advice;

**Amendment 495****Proposal for a regulation****Article 79 — paragraph 2 — point e a (new)***Text proposed by the Commission**Amendment*

(ea) **the improvement of data collection and data management systems and the implementation of pilot studies to improve existing data collection and data management systems;**

**Amendment 496****Proposal for a regulation****Article 79 — paragraph 2 — point e b (new)***Text proposed by the Commission**Amendment*

(eb) **the operating costs incurred by the collection and processing of data.**

**Amendment 497****Proposal for a regulation****Article 79 a (new)***Text proposed by the Commission**Amendment***Article 79 a****Penalties**

**The Commission shall be empowered to adopt delegated acts, in accordance with Article 150, penalising a Member State by freezing and/or decreasing funds from the EMFF for failure:**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

(a) **to fulfil its data collection and transmission obligations or fail to report its actual fishing fleet capacity; or**

(b) **to tackle problems with IUU-fishing within its waters and/or within its fishing fleet.**

#### Amendment 498

##### Proposal for a regulation

##### Article 81 — paragraph 1 — introductory part

Text proposed by the Commission

Support under this Chapter shall contribute to the development and implementation of the Union's Integrated Maritime Policy. It shall:

Amendment

Support under this Chapter shall contribute to **enhancing** the development and implementation of the Union's Integrated Maritime Policy. It shall:

#### Amendment 499

##### Proposal for a regulation

##### Article 81 — paragraph 1 — point a — point i

Text proposed by the Commission

(i) promoting actions which encourage Member States and **EU** regions to develop introduce or implement integrated maritime governance;

Amendment

(i) promoting actions which encourage Member States and **their** regions to develop, introduce or implement integrated maritime governance;

#### Amendment 500

##### Proposal for a regulation

##### Article 81 — paragraph 1 — point a — point ii

Text proposed by the Commission

(ii) promoting dialogue and cooperation with and among Member States and stakeholders on marine and maritime issues, including by developing sea-basin strategies;

Amendment

(ii) promoting dialogue and cooperation with and among Member States and stakeholders on marine and maritime issues, including by developing **and implementing integrated** sea-basin strategies, **bearing in mind the need for a balanced approach in all sea basins and taking into account the specific characteristics of maritime basins and sub-basins and the relevant macroregional strategies, where appropriate;**

Wednesday 23 October 2013

## Amendment 501

## Proposal for a regulation

## Article 81 — paragraph 1 — point a — point iii

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*Text proposed by the Commission*

- (iii) promoting cross-sectoral cooperation platforms and networks, including representatives of public authorities, regional and local authorities, industry, the tourism sector, research stakeholders, citizens, civil society organisations and the social partners;

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*Amendment*

- (iii) promoting cross-sectoral cooperation platforms and networks, including representatives of **national** public authorities, regional and local authorities, industry, the tourism sector, research stakeholders, citizens, civil society organisations and the social partners, **including within sea basins strategies**;

## Amendment 502

## Proposal for a regulation

## Article 81 — paragraph 1 — point a — point iv

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*Text proposed by the Commission*

- (iv) promoting the exchange of best practices and dialogue at international level, including bilateral dialogue with third countries without prejudice to other agreements or arrangements which may exist between the EU and the third countries concerned;

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*Amendment*

- (iv) promoting the exchange of best practices and dialogue at international level, including bilateral dialogue with third countries, **taking into account the United Convention of the Law of the Sea (UNCLOS) and the relevant existing international conventions based on UNCLOS**, without prejudice to other agreements or arrangements which may exist between the EU and the third countries concerned;

## Amendment 503

## Proposal for a regulation

## Article 81 — paragraph 1 — point b — introductory part

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*Text proposed by the Commission*

- (b) **Contribute** to the development of cross-sectoral initiatives that are mutually beneficial to different maritime sectors and/or sectoral policies, taking into account and building upon existing tools and initiatives, such as:

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*Amendment*

- (b) **contribute** to the development of cross-sectoral initiatives that are mutually beneficial to different maritime **and marine** sectors and/or sectoral policies, taking into account and building upon existing tools and initiatives, such as:

Wednesday 23 October 2013

## Amendment 504

## Proposal for a regulation

## Article 81 — paragraph 1 — point b — point i

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Text proposed by the Commission

- (i) integrated maritime surveillance to enhance effectiveness and efficiency through information exchange across sectors and borders while taking due account of existing and future systems;

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Amendment

- (i) integrated maritime surveillance to enhance **security**, effectiveness and efficiency through information exchange across sectors and borders while taking due account of existing and future systems;

## Amendment 505

## Proposal for a regulation

## Article 81 — paragraph 1 — point b — point iii

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Text proposed by the Commission

- (iii) the progressive development of a comprehensive and publicly accessible high quality marine knowledge base **which shall** facilitate sharing, re-use and dissemination of these data and knowledge among various user groups.

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Amendment

- (iii) the progressive development of a comprehensive and publicly accessible high quality marine knowledge base **to reduce duplication**, facilitate sharing, re-use and dissemination of these data and knowledge among various user groups.

## Amendment 506

## Proposal for a regulation

## Article 81 — paragraph 1 — point b a (new)

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Text proposed by the Commission

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Amendment

- (ba) **improve the cooperation between Member States through the exchange of information and best practices among the various coast guard functions, with the aim of creating a European Coast Guard.**

## Amendment 507

## Proposal for a regulation

## Article 81 — paragraph 1 — point c

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Text proposed by the Commission

- (c) **Supporting** sustainable economic growth, employment, innovation and new technologies within emerging and prospective maritime sectors in coastal regions, in complementarity with established sectoral and national activities.

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Amendment

- (c) **support** sustainable economic growth, employment, innovation and new technologies within emerging and prospective maritime sectors, **as well as** in coastal, **insular and outermost regions of the Union**, in complementarity with established sectoral and national activities.

Wednesday 23 October 2013

## Amendment 508

## Proposal for a regulation

## Article 81 — paragraph 1 — point c a (new)

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Text proposed by the Commission

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Amendment

- (ca) **support the development of human capital in the maritime sector, in particular by promoting cooperation and exchanges in the field of training.**

## Amendment 509

## Proposal for a regulation

## Article 81 — paragraph 1 — point d

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Text proposed by the Commission

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Amendment

- (d) **promoting** the protection of the marine environment, in particular its biodiversity and marine protected areas such as Natura 2000 sites, and the sustainable use of marine and coastal resources **and to further define the boundaries of the sustainability** of human activities **that have an impact on the marine environment**, in **particular in the framework** of the Marine Strategy Framework Directive.

- (d) **promote** the protection of the marine environment, in particular its biodiversity and marine protected areas such as Natura 2000 sites, and the sustainable use of marine and coastal resources **by applying an ecosystem-based approach** to the **management** of human activities, in **accordance with the objectives of achieving and maintaining a good environmental status as required by** the Marine Strategy Framework Directive.

## Amendment 510

## Proposal for a regulation

## Article 82 — paragraph 1 — point b

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Text proposed by the Commission

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Amendment

- (b) projects, including test projects and cooperation projects;

- (b) projects, **from design to implementation**, including test **and pilot** projects and **national and cross-border** cooperation projects;

Wednesday 23 October 2013

## Amendment 511

## Proposal for a regulation

## Article 82 — paragraph 1 — point c

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*Text proposed by the Commission*

- (c) public information and sharing best practice, awareness raising campaigns and associated communication and dissemination activities such as publicity campaigns, events, the development and maintenance of websites, stakeholder platforms, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of this Regulation;

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*Amendment*

- (c) public information and sharing best practice, **including with regard to relevant effective European research programmes**, awareness raising campaigns and associated communication and dissemination activities such as publicity campaigns, events, the development and maintenance of websites, stakeholder platforms, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of this Regulation;

## Amendment 512

## Proposal for a regulation

## Article 82 — paragraph 1 — point d

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*Text proposed by the Commission*

- (d) conferences, seminars and workshops;

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*Amendment*

- (d) conferences, seminars, **forums** and workshops;

## Amendment 513

## Proposal for a regulation

## Article 82 — paragraph 1 — point e

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*Text proposed by the Commission*

- (e) exchange of best practices, coordination activities including information sharing networks and **steering mechanisms** for sea-basin strategies;

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*Amendment*

- (e) exchange of best practices, coordination activities including information sharing networks and **development support** for sea-basin strategies;

## Amendment 514

## Proposal for a regulation

## Article 82 — paragraph 1 — point f

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*Text proposed by the Commission*

- (f) the development, operation and maintenance of IT-systems and networks enabling the gathering, administration, validation, analysis and exchange of, and the development of sampling methods for, data **related to fisheries**, as well as interconnection to cross-sectoral data exchange systems;

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*Amendment*

- (f) the development, operation and maintenance of IT-systems and networks enabling the gathering, administration, validation, analysis and exchange of, and the development of sampling methods for data, as well as interconnection to cross-sectoral data exchange systems;

Wednesday 23 October 2013

**Amendment 515****Proposal for a regulation****Article 82 — paragraph 1 — point f a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(fa) training projects for the development of knowledge, professional qualifications and measures aimed to promote professional development in the maritime sector;*

**Amendment 516****Proposal for a regulation****Article 82 — paragraph 1 — point f b(new)**

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*Text proposed by the Commission*

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*Amendment*

*(fb) relevant instruments for integrated coastal areas management, maritime spatial planning and management of resources shared at sea-basin level;*

**Amendment 517****Proposal for a regulation****Article 82 — paragraph 1 — point f c(new)**

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*Text proposed by the Commission*

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*Amendment*

*(fc) technical assistance under Article 51 of Regulation (EU) No .../..... [laying down common provisions].*

**Amendment 518****Proposal for a regulation****Article 82 — paragraph 2 — introductory part**

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*Text proposed by the Commission*

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*Amendment*

2. In order to achieve the specific objective of developing cross-sectoral operations set out in Article 81 b), the EMFF may support:

2. In order to achieve the specific objective of developing **cross-border and** cross-sectoral operations set out in Article 81 b), the EMFF may support:

Wednesday 23 October 2013

## Amendment 519

## Proposal for a regulation

## Article 82 — paragraph 2 — point b

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Text proposed by the Commission

- (b) activities of coordination and cooperation among Member States to develop maritime spatial planning and integrated coastal zone management, including expenditure related to systems and practices of data sharing and monitoring, evaluation activities, the setting up and running of networks of experts, and the setting up of a programme aiming at building capacity for Member States to implement maritime spatial planning;

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Amendment

- (b) activities of coordination and cooperation among Member States **and, where appropriate, between Member States and regions**, to develop maritime spatial planning and integrated coastal zone management, including expenditure related to systems and practices of data sharing and monitoring, evaluation activities, the setting up and running of networks of experts, and the setting up of a programme aiming at building capacity for Member States to implement maritime spatial planning;

## Amendment 520

## Proposal for a regulation

## Article 82 — paragraph 2 — point c

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Text proposed by the Commission

- (c) the technical tools for setting up and running of an operational European Marine Observation and Data Network **aiming** to facilitate the collection, assembling, quality control, re-use and distribution of marine data through cooperation between the Member **states** institutions involved in the network.

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Amendment

- (c) the technical tools for setting up and running of an operational European Marine Observation and Data Network **which aims** to facilitate the collection, **acquisition**, assembling, quality control, re-use and distribution of marine data **and knowledge**, through cooperation between the Member **States'** institutions involved in the network.

## Amendment 521

## Proposal for a regulation

## Article 84 — paragraph 1 — introductory part

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Text proposed by the Commission

Measures under this Chapter shall facilitate the implementation of the CFP and IMP in particular **as** regard to:

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Amendment

Measures under this Chapter shall facilitate the implementation of the CFP and IMP in particular **with** regard to:

Wednesday 23 October 2013

**Amendment 522****Proposal for a regulation****Article 84 — paragraph 1 — point a**

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*Text proposed by the Commission*

(a) scientific advice under CFP;

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*Amendment*(a) **collection, management and dissemination of** scientific advice under **the** CFP;**Amendment 523****Proposal for a regulation****Article 84 — paragraph 1 — point b**

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*Text proposed by the Commission*

(b) specific control and enforcement measures under CFP;

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*Amendment*(b) specific control and enforcement measures under CFP, **including labour inspections;****Amendment 524****Proposal for a regulation****Article 84 — paragraph 1 — point d a (new)**

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*Text proposed by the Commission*

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*Amendment***(da) social dialogue and the involvement of social partners;****Amendment 525****Proposal for a regulation****Article 84 — paragraph 1 — point e**

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*Text proposed by the Commission*

(e) market intelligence;

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*Amendment*(e) market intelligence, **including the establishment of electronic markets;**

Wednesday 23 October 2013

**Amendment 526**  
**Proposal for a regulation**  
**Article 84 a (new)**

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*Text proposed by the Commission*

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*Amendment*

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**Article 84 a****Conservation measures**

*In order to ensure efficient implementation of conservation measures under Articles 17 and 21 of Regulation (EU) No .../..... [on CFP] the EMFF may support initiatives undertaken by Member States to cooperate and implement common measures to achieve objectives and targets agreed under multiannual plans established pursuant to Articles 9, 10 and 11 of Regulation (EU) No .../..... [on CFP];*

**Amendment 527**  
**Proposal for a regulation**  
**Article 85 — paragraph 1**

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*Text proposed by the Commission*

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*Amendment*

1. The EMFF may support the provision of scientific deliverables, particularly applied–research projects directly linked to the provision of scientific opinions and advice, for the purpose of sound and efficient fisheries management decisions under the CFP.

1. The EMFF may support the provision of scientific deliverables, particularly applied–research projects directly linked to the provision of scientific **and socio-economic** opinions and advice, for the purpose of sound and efficient fisheries management decisions under the CFP.

**Amendment 528**  
**Proposal for a regulation**  
**Article 85 — paragraph 2 — point a**

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*Text proposed by the Commission*

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*Amendment*

(a) studies and pilot projects needed for the implementation and development of the CFP, including on alternative types of sustainable fishing management techniques;

(a) studies and pilot projects needed for the implementation and development of the CFP, including on alternative types of sustainable fishing **and aquaculture** management techniques, **including within Advisory Councils;**

Wednesday 23 October 2013

**Amendment 529****Proposal for a regulation****Article 85 — paragraph 2 — point a a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(aa) studies necessary for the implementation and development of the CFP in biogeographically sensitive areas;**

**Amendment 530****Proposal for a regulation****Article 85 — paragraph 2 — point b**

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*Text proposed by the Commission*

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*Amendment*

(b) the preparation and provision of scientific opinions and advice by scientific bodies, including international advisory bodies in charge of stock assessments, by **independent** experts and by research institutions;

(b) the preparation and provision of scientific opinions and advice by scientific bodies, including international advisory bodies in charge of stock assessments, by experts and by research institutions;

**Amendment 531****Proposal for a regulation****Article 85 — paragraph 2 — point c**

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*Text proposed by the Commission*

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*Amendment*

(c) the participation of experts in the meetings on fisheries scientific and technical issues and expert working groups as well as in international advisory bodies and in meetings where contribution of fisheries experts will be required;

(c) the participation of experts in the meetings on fisheries scientific and technical issues and expert working groups as well as in international advisory bodies and in meetings where contribution of fisheries **and aquaculture** experts will be required;

**Amendment 532****Proposal for a regulation****Article 85 — paragraph 2 — point c a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ca) funding of research vessels conducting scientific research programmes in areas outside Union waters where the Union is operating under fisheries agreements;**

Wednesday 23 October 2013

## Amendment 533

## Proposal for a regulation

## Article 85 — paragraph 2 — point e

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*Text proposed by the Commission*

- (e) cooperation activities between the Member States in the field of data collection, including the setting-up and running of regionalized databases for storage, management and use of data which will benefit regional cooperation and improve data collection and management activities as well as the scientific expertise in support of fisheries management.

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*Amendment*

- (e) cooperation activities between the Member States in the field of data collection, including the **various regional stakeholders and including the** setting-up and running of regionalized databases for storage, management and use of data which will benefit regional cooperation and improve data collection and management activities as well as the scientific expertise in support of fisheries management;

## Amendment 534

## Proposal for a regulation

## Article 85 — paragraph 2 — point e a (new)

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*Text proposed by the Commission*

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*Amendment*

- (ea) **the establishment of electronic markets to better co-ordinate information between market operators and processors.**

## Amendment 535

## Proposal for a regulation

## Article 86 — paragraph 2 — point a

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*Text proposed by the Commission*

- (a) joint purchase by several Member States belonging to the same geographical area, of patrol vessels, aircrafts and helicopters, provided they are used at least 60 % of the time **for fisheries control**;

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*Amendment*

- (a) joint purchase by several Member States belonging to the same geographical area, of patrol vessels, aircrafts and helicopters, provided they are used **for fisheries control** at least 60 % of the **total** time **that the equipment is used, calculated on an annual basis**;

## Amendment 536

## Proposal for a regulation

## Article 86 — paragraph 2 — point b

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*Text proposed by the Commission*

- b) expenditure relating to the assessment and development of new control technologies;

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*Amendment*

- (b) expenditure relating to the assessment and development of new control technologies **as well as processes for the exchange of data between authorities and institutions with responsibilities in areas such as security, rescue and control in the Union**;

Wednesday 23 October 2013

**Amendment 537****Proposal for a regulation****Article 88 — paragraph 1***Text proposed by the Commission*

1. The EMFF **may** support operating costs of the Advisory Councils as set up by **Article 52 of** [Regulation on Common Fisheries Policy].

*Amendment*

1. The EMFF **shall** support **the necessary** operating **and expertise** costs of the Advisory Councils as set up by [Regulation on Common Fisheries Policy], **in order to ensure that they carry out their tasks fully and effectively.**

**Amendment 538****Proposal for a regulation****Article 88 — paragraph 1 a (new)***Text proposed by the Commission**Amendment*

**1a. The EMFF may support the operating costs of Advisory Councils where those costs promote the involvement and participation of organisations of fishermen and other stakeholders.**

**Amendment 539****Proposal for a regulation****Article 88 — paragraph 1 b (new)***Text proposed by the Commission**Amendment*

**1b. The EMFF shall support operating, technical and scientific costs associated with carrying out studies to underpin the recommendations of the Advisory Councils.**

**Amendment 540****Proposal for a regulation****Article 88 a (new)***Text proposed by the Commission**Amendment***Article 88 a****Social Dialogue**

**The EMFF may support the operational costs of structures that promote the social dialogue and the involvement of the social partners.**

Wednesday 23 October 2013

#### Amendment 541

#### Proposal for a regulation

#### Article 89 — paragraph 1

##### *Text proposed by the Commission*

The EMFF may support the development and dissemination of market intelligence for fishery and aquaculture products by the Commission in accordance with Article 49 of [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products].

##### *Amendment*

The EMFF may support the development and dissemination of market intelligence for fishery and aquaculture products by the Commission in accordance with Article 49 of [Regulation (EU) No on the common organisation of the markets in fishery and aquaculture products], **including establishing electronic markets to better coordinate information between market operators and processors;**

#### Amendment 542

#### Proposal for a regulation

#### Article 91 — paragraph 1 — point b

##### *Text proposed by the Commission*

(b) the **implementation** of sustainable fisheries agreements and the Union participation in regional fisheries management organisations;

##### *Amendment*

(b) the **preparation, monitoring and evaluation** of sustainable fisheries agreements and the Union participation in regional fisheries management organisations; **the measures in question shall consist of studies, meetings, expert involvement, temporary staff costs, information activities and any other administrative costs or costs arising from scientific or technical assistance by the Commission.**

#### Amendment 543

#### Proposal for a regulation

#### Article 92 — paragraph 1 — introductory part

##### *Text proposed by the Commission*

1. The EMFF may support, at the initiative of a Member State, subject to a ceiling of **5 %** of the total amount of the operational programme:

##### *Amendment*

1. The EMFF may support, at the initiative of a Member State, subject to a ceiling of **6 %** of the total amount of the operational programme:

#### Amendment 544

#### Proposal for a regulation

#### Article 94 — paragraph 3 — point a

##### *Text proposed by the Commission*

(a) **100 %** of the eligible public expenditure for the support under storage aid referred to in Article 70;

##### *Amendment*

(a) **50 %** of the eligible public expenditure for the support under storage aid referred to in Article 70;

Wednesday 23 October 2013

**Amendment 545****Proposal for a regulation****Article 94 — paragraph 3 — point a a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(aa) 100 % of the eligible public expenditure for the preparation of production and marketing plans referred to in Article 69;*

**Amendment 546****Proposal for a regulation****Article 94 — paragraph 3 — point d**

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*Text proposed by the Commission*

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*Amendment*

(d) **80** % of the eligible public expenditure for the support referred to in Article 78(2)(a) to (d) and (f) to (j);

(d) **90** % of the eligible public expenditure for the support referred to in Article 78(2)(a) to (d) and (f) to (j);

**Amendment 547****Proposal for a regulation****Article 94 — paragraph 3 — point e**

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*Text proposed by the Commission*

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*Amendment*

(e) **65** % of the eligible expenditure for the support referred to in Article 79.

(e) **80** % of the eligible expenditure for the support referred to in Article 79.

**Amendment 548****Proposal for a regulation****Article 94 — paragraph 3 — point e a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(ea) plus 10 percentage points, plus the maximum EMFF contribution rate, where operations are financed by the EMFF in the outlying Greek islands and in the outermost regions that, due to their remoteness, are at a disadvantage;*

Wednesday 23 October 2013

**Amendment 549**  
**Proposal for a regulation**  
**Article 95 — paragraph 1**

*Text proposed by the Commission*

1. Member States shall apply a maximum intensity of public aid of **50** % of the total eligible expenditure of the operation.

*Amendment*

1. Member States shall apply a maximum intensity of public aid of **60** % of the total eligible expenditure of the operation.

**Amendment 550**  
**Proposal for a regulation**  
**Article 95 — paragraph 2 — point a**

*Text proposed by the Commission*

(a) the beneficiary is a public law body;

*Amendment*

(a) the beneficiary is a public law body **or a private body performing public service tasks;**

**Amendment 551**  
**Proposal for a regulation**  
**Article 95 — paragraph 2 — point b**

*Text proposed by the Commission*

(b) **the operation is related to the storage aid referred to in Article 70;**

*Amendment*

**deleted**

**Amendment 552**  
**Proposal for a regulation**  
**Article 95 — paragraph 3 — introductory part**

*Text proposed by the Commission*

3. By way of derogation from paragraph 1, Member States may apply an intensity of public aid between **50** % and maximum100 % of the total eligible expenditure when the operation is implemented under **Chapter** III of Title V and fulfils **one** of the following criteria:

*Amendment*

3. By way of derogation from paragraph 1, Member States may apply an intensity of public aid between **60** % and maximum100 % of the total eligible expenditure when the operation is implemented under **Chapters I, II, III or IV** of Title V and fulfils **two or more** of the following criteria:

Wednesday 23 October 2013

## Amendment 553

## Proposal for a regulation

## Article 98 — paragraph 2 — subparagraph 2

*Text proposed by the Commission*

The Commission shall exercise the empowerment in full respect of the principle of proportionality and taking into account the risk that the non-compliance with the respective CFP rules constitutes a serious threats to the sustainable exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the MSY, the sustainability of the stocks concerned or the conservation of the marine environment.

*Amendment*

The Commission shall exercise the empowerment in full respect of the principle of proportionality and taking into account the risk that the non-compliance with the respective CFP rules constitutes a serious threats to the sustainable exploitation of living marine biological resources that restores and maintains populations of harvested species above levels which can produce the MSY, the sustainability of the stocks concerned or the conservation of the marine environment **or the achievement and maintenance of a good environmental status by 2020.**

## Amendment 576

## Proposal for a regulation

## Article 99 — paragraph 1

*Text proposed by the Commission*

1. In addition to the general rules set out in Article 114 of [Regulation (EU) No [...]] laying down Common Provisions] the managing authority shall

(a) provide the Commission, on a biannual basis, with relevant data on operations selected for funding, including key characteristics of the beneficiary and the operation itself. The Commission shall lay down, by means of implementing act, rules for the presentation of these data in accordance with the advisory procedure referred to in Article 128(2).

(b) ensure publicity for the programme by informing potential beneficiaries, professional organisations, the economic and social partners, bodies involved in promoting equality between men and women, and the non-governmental organisations concerned, including environmental organisations, of the possibilities offered by the programme and the rules for gaining access to programme funding;

(c) ensure publicity for the programme by informing beneficiaries of the Union contribution and the **general public on the role played by the Union in the programme.**

*Amendment*

1. In addition to the general rules set out in Article 114 of [Regulation (EU) No [...]] laying down Common Provisions] the managing authority shall

(a) provide the Commission, on a biannual basis, with relevant data on operations selected for funding, including key characteristics of the beneficiary and the operation itself. The Commission shall lay down, by means of implementing act, rules for the presentation of these data in accordance with the advisory procedure referred to in Article 128(2).

(b) ensure publicity for the programme by informing potential beneficiaries, professional organisations, the economic and social partners, bodies involved in promoting equality between men and women, and the non-governmental organisations concerned, including environmental organisations, of the possibilities offered by the programme, and the rules for gaining access to programme funding **and the obligation to comply with the rules of the Common Fisheries Policy;**

(c) ensure publicity for the programme by informing beneficiaries of the Union contribution and the **obligation to comply with the rules of the Common Fisheries Policy;**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

- (d) **ensure publicity for the programme by the general public on the role played by the Union in the programme as well as by the Member States in ensuring the compliance with the rules of the Common Fisheries Policy.**

#### Amendment 554

##### Proposal for a regulation

##### Article 100 — paragraph 1

Text proposed by the Commission

Amendment

1. In addition to Article 135 of [Regulation (EU) No [...] laying down Common Provisions], the Member States shall in the first instance be responsible also for investigating the cases of non-compliance with rules applicable under the Common Fisheries Policy.

(Does not affect English version.)

#### Amendment 555

##### Proposal for a regulation

##### Article 100 — paragraph 2

Text proposed by the Commission

Amendment

2. For the cases of financial corrections applied on expenditure directly linked to the non-compliance with Article 98, the Member States shall decide the amount of a correction taking into account the **gravity** of the non compliance by the beneficiary with CFP rules, the economic advantage derived from the non-compliance with CFP rules or the importance of the EMFF contribution to the economic activity of the beneficiary.

2. For the cases of financial corrections applied on expenditure directly linked to the non-compliance with Article 98, the Member States shall decide the amount of a correction taking into account the **gravity (including the extent, duration and any re-occurrence)** of the non compliance by the beneficiary with CFP rules, the economic advantage derived from the non-compliance with CFP rules or the importance of the EMFF contribution to the economic activity of the beneficiary.

#### Amendment 577

##### Proposal for a regulation

##### Article 102

Text proposed by the Commission

Amendment

1. In addition to Article 134 of [Regulation (EU) No [...] laying down Common Provisions], the Commission may suspend, by means of an implementing act, all or part of the interim payments of the operational programme where:

1. In addition to Article 134 of [Regulation (EU) No [...] laying down Common Provisions], the Commission may suspend, by means of an implementing act, all or part of the interim payments of the operational programme where:

- (a) **there is a serious deficiency in the management and control system of the operational programme for which corrective measures have not been taken;**
- (b) **expenditure in a certified statement of expenditure is linked to a serious irregularity or other case of non compliance which has not been corrected;**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

the Commission has adopted a decision by means of an implementing act recognising that a Member State has failed to comply with its obligations under the Common Fisheries Policy. Such non compliance shall be liable to affect the expenditure contained in a certified statement of expenditure for which the interim payment is requested.

2. The Commission may lay down, by means of implementing acts adopted in accordance with the examination procedure referred to in Article 128(3), detailed rules on the payments which may be suspended. **The amounts of those payments** shall be proportionate to the nature and importance of the non-compliance by the Member State.

(c) **the Member State has failed to take the necessary action to remedy the situation giving rise to an interruption under Article 118;**

(d) **there is a serious deficiency in the quality and reliability of the monitoring system;**

(e) the Commission has adopted a decision by means of an implementing act recognising that a Member State has failed to comply with its obligations under the Common Fisheries Policy. Such non compliance shall be liable to affect the expenditure contained in a certified statement of expenditure for which the interim payment is requested;

(f) **the conditions referred to in Article 17(5) and Article 20 (3) of Regulation (EU) No [...] laying down Common Provisions] are fulfilled.**

2. **The Commission may decide, by means of implementing act, to suspend all or part of interim payments after having given the Member State the opportunity to present its observations within a period of two months.** The Commission may lay down, by means of implementing acts adopted in accordance with the examination procedure referred to in Article 151(3), detailed rules on the part of the payments which may be suspended. **Those** amounts shall be proportionate to the nature and importance of the **deficiency, irregularity or** non-compliance by the Member State.

2a. **The Commission shall decide, by means of implementing act to end the suspension of all or part of interim payments where the Member State has taken the necessary measures to enable the suspension to be lifted. Where such measures are not taken by the Member State, the Commission may adopt, by means of implementing act, a decision to apply financial corrections by cancelling all or part of the Union contribution to the operational programme in accordance with Articles 128 and Article 129.**

#### Amendment 578

#### Proposal for a regulation

#### Article 103 a (new)

Text proposed by the Commission

Amendment

#### Article 103a

#### On-the-spot controls by the Commission

1. **Without prejudice to the controls carried out by Member States under national laws, regulations and administrative provisions or Article 287 of the Treaty, and any check organised under Article 322 of the Treaty, the Commission may organise on-the-spot controls in Member States with a view to verifying in particular:**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

- (a) *compliance of administrative practices with Union rules;*
- (b) *the existence of the requisite supporting documents and their correlation with the operations financed by the EMFF;*
- (c) *the terms on which the operations financed by the EMFF have been undertaken and controlled.*

2. *Persons delegated by the Commission to carry out on-the-spot controls or Commission agents acting within the scope of the powers conferred upon them shall have access to the books and all other documents, including documents and metadata drawn up or received and recorded on an electronic medium, relating to expenditure financed by the EMFF.*

4. *The Commission shall give sufficient prior notice of an on-the-spot control to the Member State concerned or to the Member State within whose territory the control is to take place. Agents from the Member State concerned may take part in such controls.*

5. *At the request of the Commission and with the agreement of the Member State concerned, additional controls or inquiries into the operations covered by this Regulation shall be undertaken by the competent bodies of that Member State. Commission agents or persons delegated by the Commission may take part in such controls.*

6. *In order to improve controls, the Commission may, with the agreement of the Member States concerned, request the assistance of the authorities of those Member States for certain controls or inquiries.*

7. *The Commission may, by means of implementing acts, adopted in accordance with the advisory procedure referred to in Article 151(2), lay down rules regarding the procedures to comply with when additional controls referred to in paragraphs 5 and 6 are carried out.*

#### Amendment 579

#### Proposal for a regulation

#### Article 104

Text proposed by the Commission

Amendment

1. *Member States shall make available to the Commission all information necessary for the smooth operation of the EMFF and shall take all appropriate measures to facilitate the controls which the Commission deems appropriate in connection with the management of Union financing, including on-the-spot controls.*

Wednesday 23 October 2013

## Text proposed by the Commission

On request by the Commission Member States shall communicate to the Commission their laws, regulations and administrative provisions which they have adopted for implementing Union acts relating to the Common Fisheries Policy, where those acts have a financial impact on the EMFF.

## Amendment

2. On request by the Commission Member States shall communicate to the Commission their laws, regulations and administrative provisions which they have adopted for implementing Union acts relating to the Common Fisheries Policy, where those acts have a financial impact on the EMFF.

3. **Member States shall make available to the Commission all information about irregularities and suspected fraud cases detected, and about the steps taken to recover undue payments in connection with those irregularities and frauds pursuant to Article 116.**

## Amendment 580

## Proposal for a regulation

## Article 107

## Text proposed by the Commission

**In addition to paragraph 2 of Article 137 of [Regulation (EU) No [...] laying down Common Provisions], where the Commission proposes a financial correction referred to in Article 106(2) the Member State shall be given the opportunity to demonstrate, through an examination of the documentation concerned, that the actual extent of the case of non compliance with CFP rules, and its link to the expenditure was less than the Commission's assessment.**

## Amendment

1. **Before taking a decision on a financial correction by means of implementing acts, the Commission shall open the procedure by informing the Member State of its provisional conclusions and requesting the Member State to submit its comments within two months.**

2. **Where the Commission proposes a financial correction on the basis of extrapolation or at a flat rate, the Member State shall be given the opportunity to demonstrate, through an examination of the documentation concerned, that the actual extent of irregularity or other case of non compliance, including non compliance with CFP rules, was less than the Commission's assessment. In agreement with the Commission, the Member State may limit the scope of this examination to an appropriate proportion or sample of the documentation concerned. Except in duly justified cases, the time allowed for this examination shall not exceed a further period of two months after the two-month period referred to in paragraph 1.**

3. **The Commission shall take account of any evidence supplied by the Member State within the time limits referred to in paragraphs 1 and 2.**

4. **Where the Member State does not accept the provisional conclusions of the Commission, the Member State shall be invited to a hearing by the Commission, in order to ensure that all relevant information and observations are available as a basis for conclusions by the Commission on the application of the financial correction.**

Wednesday 23 October 2013

Text proposed by the Commission

Amendment

5. In order to apply financial corrections the Commission shall take a decision, by means of implementing acts, within six months of the date of the hearing, or of receipt of additional information where the Member State agrees to submit such additional information following the hearing. The Commission shall take account of all information and observations submitted during the course of the procedure. If no hearing takes place, the six-month period shall begin to run two months after the date of the letter of invitation to the hearing sent by the Commission.

6. Where irregularities affecting annual accounts sent to the Commission are detected by the Commission or by the Court of Auditors, the resulting financial correction shall reduce support from the EMFF to the operational programme.

#### Amendment 557

##### Proposal for a regulation

##### Article 111 — paragraph 1

Text proposed by the Commission

1. Key information on the implementation of the programme, on each operation selected for funding, as well as on completed operations, needed for monitoring and evaluation, including the key characteristics of the beneficiary and the project, shall be recorded and maintained electronically.

Amendment

(Does not affect the English version)

#### Amendment 558

##### Proposal for a regulation

##### Article 113— paragraph 2

Text proposed by the Commission

2. The managing authority and the monitoring committee shall carry out monitoring of the operational programme by means of financial, output and target indicators.

Amendment

(Does not affect the English version)

Wednesday 23 October 2013

## Amendment 559

## Proposal for a regulation

## Article 114 — paragraph 1 — point a

*Text proposed by the Commission*

- (a) shall be consulted and issue an opinion, within four months of the decision approving the programme, on the selection criteria for the financed operations; the selection criteria shall be revised according to programming needs;

*Amendment**(Does not affect the English version)*

## Amendments 581, 560 and 561

## Proposal for a regulation

## Article 120 — paragraph 1

*Text proposed by the Commission*

1. The managing authority shall be responsible in accordance with Article 99(1)(b) for:

- (a) ensuring the establishment of a single website or a single website portal providing information on, and access to, the operational **programme** in each Member State;
- (b) informing potential beneficiaries about funding opportunities under the operational programme;
- (c) publicising to Union citizens the role and achievements of the EMFF through information and communication actions on the results and impact of Partnership Contracts, operational programmes and operations.

*Amendment*

1. The managing authority shall be responsible in accordance with Article 99(1)(b) **to (d)** for:

- (a) ensuring the establishment of a single website or a single website portal providing information on, and **easy** access to, the operational **programmes** in each Member State;
- (b) informing potential beneficiaries about funding opportunities under the operational programme **and the obligation to comply with the rules of the Common Fisheries Policy**;
- (c) publicising to Union citizens the role and achievements of the EMFF through information and communication actions on the results and impact of Partnership Contracts, operational programmes and operations;
- (d) **ensuring that a summary of measures towards ensuring the compliance with CFP rules including the cases of non-compliance by Member States or beneficiaries as well as the remedy actions such as financial corrections taken, is made publicly available.**

Wednesday 23 October 2013

**Amendment 562**  
**Proposal for a regulation**  
**Article 120 — paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**4a. With regard to access to environmental information, Directive 2003/4/EC and Regulations (EC) No 1049/2001 and (EC) No 1367/2006 shall apply.**

**Amendment 563**  
**Proposal for a regulation**  
**Annex I — table — line 1**

*Text proposed by the Commission*

Type of operations	Percentage points
Related to small scale coastal fisheries may benefit from an increase by	<b>25</b>

*Amendment*

Type of operations	Percentage points
Related to small scale coastal fisheries may benefit from an increase by	<b>30</b>

**Amendment 564**  
**Proposal for a regulation**  
**Annexe I — table — line 5**

*Text proposed by the Commission*

Type of operations	Percentage points
Implemented by producer organisation <b>or associations</b> of producer organisations may benefit from an increase by	<b>20</b>

*Amendment*

Type of operations	Percentage points
Implemented by producer organisation, <b>an association</b> of producer organisations, <b>a professional fishermen's organisation recognised by the Member State or an interbranch organisation</b> , may benefit from an increase by	<b>30</b>

Wednesday 23 October 2013

**Amendment 565**  
**Proposal for a regulation**  
**Annex I — table — line 5 a (new)**

*Amendment by Parliament*

Type of operations	Percentage points
<b><i>Compliance with the requirements of all the sustainability criteria that the Member States may apply could lead to an increase of</i></b>	<b>10</b>

**Amendment 566**  
**Proposal for a regulation**  
**Annex I — table — line 8**

*Text proposed by the Commission*

Type of operations	Percentage points
Operations performed by companies considered to be outside the definition of SMEs: a reduction of	<b>20</b>

*Amendment by Parliament*

Type of operations	Percentage points
Operations performed by companies considered to be outside the definition of SMEs: a reduction of	<b>15</b>

**Amendment 567**  
**Proposal for a regulation**  
**Annex I — table — line 8 a (new)**

*Amendment by Parliament*

Type of operations	Percentage points
<b><i>If they fulfil the requirements of the set of sustainability criteria that the Member States may implement, they may receive an additional</i></b>	<b>10</b>

Wednesday 23 October 2013

**Amendment 568****Proposal for a regulation****Annex III — table 1 — line 7 a (new)***Amendment by Parliament*

<b>7a. Legislation relating to working conditions</b>	<b>Respect by operators of Union law on working conditions.</b>	<b>The effective application and implementation of Union law on working conditions covering:</b>
		— <b>law relating to working hours and rest periods for fishermen;</b>
		— <b>health and safety law;</b>
		— <b>law relating to the initial qualifications and further training of fishermen.</b>

**Amendment 569****Proposal for a regulation****Annex III — table 2 — line 3***Text proposed by the Commission*

EMFF Priority: 6 Fostering the implementation of the CFP TO 6: protecting the environment and promoting resource efficiency	Proven administrative capacity to comply with the data requirements for fisheries management set out in Article 37 of the [Regulation on the CFP]	Proven administrative capacity to prepare and apply a multi-annual programme for data collection, to be reviewed by STECF and accepted by the Commission  Proven administrative capacity to prepare and implement an annual work plan for data collection, to be reviewed by STECF and accepted by the Commission  Sufficient capacity in human resources allocation to undertake bilateral or multilateral agreements with other MS if work to implement the data collection obligations is shared
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Wednesday 23 October 2013

## Amendment

<p>EMFF Priority:</p> <p>6 Fostering the implementation of the CFP</p> <p>TO 6: protecting the environment and promoting resource efficiency</p>	<p>Proven administrative capacity to comply with the data requirements for fisheries management set out in Article 37 of the [Regulation on the CFP]</p> <p><b>Assessment of the balance between fishing capacity and fishing opportunities:</b></p> <p><b>Specific analysis of the balance between fishing capacity and fishing opportunity has been carried out in order to ensure the effective implementation of fleet management measures</b></p>	<p>Proven administrative capacity to prepare and apply a multi-annual programme for data collection, to be reviewed by STECF and accepted by the Commission</p> <p>Proven administrative capacity to prepare and implement an annual work plan for data collection, to be reviewed by STECF and accepted by the Commission</p> <p>Sufficient capacity in human resources allocation to undertake bilateral or multilateral agreements with other MS if work to implement the data collection obligations is shared</p> <p><b>Proven administrative capacity to prepare and implement fleet capacity assessments;</b></p> <p><b>Adequate reporting on efforts to establish a balance between fishing capacity and fishing opportunities as requested by Article 34 and Article 37 of Regulation (EU) No .../..... [on the CFP].</b></p>
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## Amendment 570

## Proposal for a regulation

## Annex III — table 2 — line 4 a (new)

## Amendment by Parliament

EU priority for EMFF/CSF Thematic Objective (TO)	Ex ante conditionality	Criteria for fulfilment
<p>EMFF Priority:</p> <p>Fostering the implementation of the CFP</p> <p>TO 6: protecting the environment and promoting resource efficiency.</p>	<p><b>Annual assessment of the balance between fishing capacity and fishing opportunities: Specific analysis of the balance between fishing capacity and fishing opportunities has been carried out in order to ensure the effective implementation of fleet management measures that concern reduction of the capacity of the fleet and direct investments on vessels.</b></p>	<p>The specific actions include:</p> <ul style="list-style-type: none"> <li>— Proven administrative capacity to prepare and implement fleet capacity assessments;</li> <li>— Adequate reporting on efforts to establish a balance between fishing capacity and fishing opportunities, as required by Articles 34 and 37 [of the proposed Basic Regulation].</li> </ul>

Wednesday 23 October 2013

## Amendment 614

## Proposal for a regulation

## Annex IV — point 1 — paragraph 1 — indent 1

*Text proposed by the Commission*

— Beneficiary name **(only legal entities; no natural persons shall be named);**

*Amendment*

— Beneficiary name;

## Amendment 582

## Proposal for a regulation

## Annex IV — points 2 and 3

*Text proposed by the Commission*

## 2. INFORMATION AND PUBLICITY MEASURES FOR THE PUBLIC

### 2.1 Responsibilities of the Member State

1. The Member State shall ensure that the information and publicity measures aim at the widest possible media coverage using various forms and methods of communication at the appropriate level.

2. The Member State shall be responsible for organising at least the following information and publicity measures:

(a) a major information activity publicising the launch of the operational programme;

(b) at least twice during the programming period major information activity which promotes the funding opportunities and the strategies pursued and presents the achievements of the operational programme;

(c) displaying the flag of the European Union in front of, or at a place visible to the public, at the premises of each managing authority;

(d) publishing electronically the list of operations in accordance with section 1;

(e) giving examples of operations, by operational programme, on the single website or on the operational programme's website that is accessible through the single website portal; the examples should be in a widely spoken official language of the European Union other than the official language or languages of the Member State concerned;

*Amendment*

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(d) publishing electronically the list of operations in accordance with section 1;

(e) giving examples of operations, by operational programme, on the single website or on the operational programme's website that is accessible through the single website portal; the examples should be in a widely spoken official language of the European Union other than the official language or languages of the Member State concerned;

Wednesday 23 October 2013

## Text proposed by the Commission

## Amendment

- (f) a specific section of the single website shall be dedicated to give a short summary of innovation and eco-innovation operations;
- (g) updating information about the operational programme's implementation, including its main achievements, on the single website or on the operational programme's website that is accessible through the single website portal.
3. The managing authority shall involve in information and publicity measures, in accordance with national laws and practices, the following bodies:
- h)* the partners referred to in Article 5 of the [Regulation (EU) No [...] laying down Common Provisions];
- i)* information centres on Europe, as well as Commission representation offices in the Member States;
- j)* educational and research institutions.

These bodies shall widely disseminate the information described in Article 120(1)(a) and (b).

### 3. INFORMATION MEASURES FOR POTENTIAL BENEFICIARIES AND BENEFICIARIES

#### 3.1 Information measures for potential beneficiaries

1. The managing authority shall ensure that the operational programme's objectives and funding opportunities offered by the EMFF are disseminated widely to potential beneficiaries and all interested parties.
2. The managing authority shall ensure that potential beneficiaries are informed on at least the following:
- (a) the conditions of eligibility of expenditure to be met in order to qualify for support under an operational programme;
- (b) a description of the admissibility conditions for applications, procedures for examining applications for funding and of the time periods involved;
- (c) the criteria for selecting the operations to be supported;

- (f) a specific section of the single website shall be dedicated to give a short summary of innovation and eco-innovation operations;
- (g) updating information about the operational programme's implementation, including its main achievements, on the single website or on the operational programme's website that is accessible through the single website portal.

**(ga) A summary shall be published on an annual basis by 31 January, starting in 2016, on the cases of non-compliance committed by Member States and beneficiaries, as well as remedy actions including financial corrections carried out by Member States or by the Commission.**

3. The managing authority shall involve in information and publicity measures, in accordance with national laws and practices, the following bodies:

- a)* the partners referred to in Article 5 of the [Regulation (EU) No [...] laying down Common Provisions];
- b)* information centres on Europe, as well as Commission representation offices in the Member States;
- c)* educational and research institutions.

These bodies shall widely disseminate the information described in Article 120(1)(a) and (b).

### 3. INFORMATION MEASURES FOR POTENTIAL BENEFICIARIES AND BENEFICIARIES

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2. The managing authority shall ensure that potential beneficiaries are informed on at least the following:
- (a) the conditions of eligibility of expenditure to be met in order to qualify for support under an operational programme;
- (b) a description of the admissibility conditions for applications, procedures for examining applications for funding and of the time periods involved;
- (ba) the possible financial consequences in case of non-compliance with the rules of the Common Fisheries Policy**
- (c) the criteria for selecting the operations to be supported;

**Wednesday 23 October 2013***Text proposed by the Commission*

- (d) the contacts at national, regional or local level that are able to provide information on the operational programmes;
- (e) that applications should propose communication activities, proportional to the size of the operation, in order to inform the public about the operation's aims and the EU support to the operation.

**3.2. Information measures for beneficiaries**

The managing authority shall inform beneficiaries that acceptance of funding constitutes an acceptance of their inclusion in the list of operations published in accordance with Article 120 (2).

*Amendment*

- (d) the contacts at national, regional or local level that are able to provide information on the operational programmes;
- (e) that applications should propose communication activities, proportional to the size of the operation, in order to inform the public about the operation's aims and the EU support to the operation.

**3.2. Information measures for beneficiaries**

The managing authority shall inform beneficiaries that acceptance of funding constitutes an acceptance of their inclusion in the list of operations published in accordance with Article 120 (2).

Wednesday 23 October 2013

P7\_TA(2013)0442

**Drug precursors \*\*\*I**

**European Parliament legislative resolution of 23 October 2013 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors (COM(2012)0548 — C7-0319/2012 — 2012/0261(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/27)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0548),
  - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0319/2012),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic Social Committee of 16 January 2013 <sup>(1)</sup>,
  - having regard to the undertaking given by the Council representative by letter of 26 June 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rules 55 of its Rules of Procedure,
  - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs (A7-0153/2013),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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**P7\_TC1-COD(2012)0261**

**Position of the European Parliament adopted at first reading on 23 October 2013 with a view to the adoption of Regulation (EU) No .../2013 of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1258/2013.)*

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<sup>(1)</sup> OJ C 76, 14.3.2013, p. 54.

Thursday 24 October 2013

P7\_TA(2013)0450

## Draft amending budget No 6/2013

**European Parliament resolution of 24 October 2013 on the Council position on Draft amending budget No 6/2013 of the European Union for the financial year 2013, Section III — Commission (14870/2013 — C7-0378/2013 — 2013/2151(BUD))**

(2016/C 208/28)

*The European Parliament,*

- having regard to Article 314 of the Treaty on the Functioning of the European Union and Article 106a of the Euratom Treaty,
  - having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 <sup>(1)</sup> ('Financial Regulation'),
  - having regard to the general budget of the European Union for the financial year 2013, as definitively adopted on 12 December 2012 <sup>(2)</sup>,
  - having regard to Council Decision 2007/436/EC, Euratom of 7 June 2007 on the system of the European Communities' own resources <sup>(3)</sup>,
  - having regard to Draft amending budget No 6/2013, which the Commission submitted on 10 July 2013 (COM(2013) 0518) and amended on 18 September 2013 by amending letter (COM(2013)0655),
  - having regard to the position on Draft amending budget No 6/2013 which the Council adopted on 21 October 2013 and forwarded to Parliament on the same day (14870/2013 — C7-0378/2013),
  - having regard to Rule 75b and 75e of its Rules of Procedure,
  - having regard to the report of the Committee on Budgets (A7-0347/2013),
- A. whereas Draft amending budget No 6/2013, as amended on 18 September 2013 by the Commission by amending letter, concerns a revision of the forecast of Traditional Own Resources (TOR, i.e. customs duties and sugar sector levies), VAT and GNI bases, the budgeting of the relevant UK corrections, and a revision of the forecast of other revenue arising from fines, thereby resulting in a change in the level and distribution between Member States of their own resources contributions to the Union budget;
- B. whereas DAB No 6/2013 also covers the creation of the necessary budgetary structure to accommodate the creation of the Union trust funds foreseen in Article 187 of the Financial Regulation;
- C. whereas Council's position on DAB No 6/2013 does not modify the Commission's proposal, as amended by amending letter;
- D. whereas this DAB is crucial to avoid cash shortages that could lead to an implementation deficit in 2013, on the basis of the level of payment appropriations authorised in the Budget 2013 including Amending Budgets 1 to 5/2013 only;
1. Takes note of DAB No 6/2013, presented by the Commission on 10 July 2013, as amended by the amending letter of 18 September 2013, which provides for a revision of the forecast of Traditional Own Resources (TOR, i.e. customs duties and sugar sector levies), on the basis of Commission's best estimates and certain other developments, as well as the further revision of the forecast of other revenue, arising from a series of fines that have become definitive and can therefore be budgeted;

<sup>(1)</sup> OJ L 298, 26.10.2012, p. 1.

<sup>(2)</sup> OJ L 66, 8.3.2013.

<sup>(3)</sup> OJ L 163, 23.6.2007, p. 17.

Thursday 24 October 2013

2. Notes that the drop in TOR forecast, by some EUR 3 955 million, and in the VAT based own resource, by EUR 384 million, is compensated by the above-mentioned fines for a cumulated amount of EUR 1 229 million;
  3. Notes that this mechanically results in an increase in the complementary GNI based contributions from Member States, by an amount of EUR 3 110 million, i.e. a net increase in 'national contributions' (including VAT) by EUR 2 736 million;
  4. While acknowledging the significant burden that this will represent for national budgets, underlines that this technical adjustment on the revenue side should not come at the expense of fully covering justified payment needs, that have already been identified by the Commission in Draft amending budgets 8 and 9/2013; recalls the Council of its position based on artificial under-budgeting of previous years and stresses, in this respect, that the accumulation of annual budgets for the period 2007-2013 reaches a level that is by EUR 60 billion inferior to the agreed MFF overall payment ceiling for period 2007-2013, while a cumulated surplus of EUR 12 billion for the period 2007-2013 has de facto been returned to Members States by reducing their cumulated GNI contributions by this amount;
  5. Requests the Commission to provide the European Parliament with all information it has on when and how these increased national contributions will be transferred from Member States' treasuries to the Union budget; requests the Commission to provide the Parliament with the net impact that these increased GNI contribution will have, if any, on the balance of Member States' budgets in 2013 or 2014;
  6. Approves the Council position on Draft amending budget No 6/2013;
  7. Underlines that the adoption of Draft amending budget 6/2013 does not address the lack of payment appropriations authorised in the 2013 budget which are necessary to pay outstanding bills; insists once more on the need for the Council to adopt as a matter of urgency Draft amending budget 8/2013; reiterates once more that it will not give its consent to the MFF 2014-2020 Regulation as long as Draft amending budget 8/2013 has not been adopted, as clearly stated in its resolution of 3 July 2013.
  8. Instructs its President to declare that Amending budget No 6/2013 has been definitively adopted and arrange for its publication in the Official Journal of the European Union;
  9. Instructs its President to forward this resolution to the Council, the Commission and the national parliaments.
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Thursday 24 October 2013

P7\_TA(2013)0451

### **General Union Environment Action Programme to 2020 \*\*\*I**

**European Parliament legislative resolution of 24 October 2013 on the proposal for a decision of the European Parliament and of the Council on a General Union Environment Action Programme to 2020: 'Living well, within the limits of our planet' (COM(2012)0710 — C7-0392/2012 — 2012/0337(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/29)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0710),
  - having regard to Article 294(2) and Article 192(3) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0392/2012),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 20 March 2013 <sup>(1)</sup>,
  - having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,
  - having regard to the undertaking given by the Council representative by letter of 26 June 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0166/2013),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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**P7\_TC1-COD(2012)0337**

**Position of the European Parliament adopted at first reading on 24 October 2013 with a view to the adoption of Decision No .../2013/EU of the European Parliament and of the Council on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 1386/2013/EU.)*

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<sup>(1)</sup> OJ C 161, 6.6.2013, p. 77.

<sup>(2)</sup> OJ C 218, 30.7.2013, p. 53.

Thursday 24 October 2013

FP7\_TA(2013)0452

**Dangers arising from exposure to ionising radiation \*\*\*I**

**European Parliament legislative resolution of 24 October 2013 on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (COM(2012)0242 — C7-0151/2012 — 2011/0254(COD))**

**(Ordinary legislative procedure: first reading)**

(2016/C 208/30)

*The European Parliament,*

- having regard to the Commission proposal to the Council (COM(2012)0242),
  - having regard to Articles 31 and 32 of the Euratom Treaty pursuant to which the Council consulted Parliament (C7-0151/2012),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Article 294(3) and Article 192(1) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 22 February 2012 <sup>(1)</sup>,
  - having regard to Rules 55 and 37 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Employment and Social Affairs (A7-0303/2013),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 293(2) of the Treaty on the Functioning of the European Union;
  3. Calls on the Commission to notify the Parliament how Parliament's position has been taken into due account;
  4. Instructs its President to forward its position to the Council and the Commission.

**P7\_TC1-COD(2011)0254**

**Position of the European Parliament adopted at first reading on 24 October 2013 with a view to the adoption of Directive 2013/.../EU of the European Parliament and of the Council laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Atomic Energy Community~~ **on the Functioning of the European Union**, and in particular ~~Articles 31 and 32~~ **Article 192(1)** thereof, [Am. 1]

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

After transmission of the draft legislative act to the national parliaments,

<sup>(1)</sup> OJ C 143, 22.5.2012, p. 113.

Thursday 24 October 2013

Having regard to the opinion of the European Economic and Social Committee,

Acting in accordance with the ordinary legislative procedure, <sup>(1)</sup> ,

Whereas:

- (1) Article ~~24(b)~~ **191** of the Treaty **on the Functioning of the European Union (TFEU)** provides for the establishment of uniform safety standards to protect the health of workers and the general public and Article 30 of the Treaty defines 'basic standards' for **the legal basis for preserving, protecting and improving the quality of the environment and protecting human health protection of workers and the general public, including** against the dangers arising from **exposure to ionising radiations radiation**. [Am. 2]

**(1a) Article 153 TFEU allows for the establishment of safety standards to protect the health of workers and of the general public. [Am. 3]**

**(1b) Article 168 TFEU allows for the establishment of basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. [Am. 4]**

- (2) In order to perform its task, the Community laid down basic standards for the first time in 1959 pursuant to Article 218 of the Treaty by means of the Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation <sup>(2)</sup>. The Directives have been revised several times, most recently in 1996 by Council Directive 96/29/Euratom <sup>(3)</sup> which repealed the earlier Directives.
- (3) Directive 96/29/Euratom establishes the basic safety standards. This Directive applies to normal and emergency situations and has been supplemented by more specific legislation.
- (4) Council Directive 97/43/Euratom <sup>(4)</sup>, Council Directive 89/618/Euratom <sup>(5)</sup>, Council Directive 90/641/Euratom <sup>(6)</sup> and Council Directive 2003/122/Euratom <sup>(7)</sup> cover different specific aspects complementary to Directive 96/29/Euratom.
- (5) Over time, definitions used in that legislation have evolved and been adjusted to the specific scope, however many requirements laid down therein fit in the original context at the time of adoption of that legislation but cannot be extended for use in Directive 96/29/Euratom.
- (6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of Euratom Treaty should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in Publication 103 (2007) <sup>(8)</sup>, and should be revised in the light of new scientific evidence and operational experience.

<sup>(1)</sup> Position of the European Parliament of 24 October 2013.

<sup>(2)</sup> OJ L 11, 20.2.1959, p. 221.

<sup>(3)</sup> Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L 159, 29.6.1996, p. 1).

<sup>(4)</sup> Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).

<sup>(5)</sup> Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (OJ L 357, 7.12.1989, p. 31).

<sup>(6)</sup> Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (OJ L 349, 13.12.1990, p. 21).

<sup>(7)</sup> Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (OJ L 346, 31.12.2003, p. 57).

<sup>(8)</sup> The 2007 Recommendations of the International Commission on Radiological Protection

Thursday 24 October 2013

- (7) This Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. **With regard to the application of the standards and requirements, however, it should also draw a distinction between existing exposure situations attributable to natural radiation and existing anthropic exposure situations.** Taking into account this new framework the Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures. [Am. 5]
- (8) A new methodology introduced by ICRP to calculate doses based on the latest knowledge on radiation risks should also be taken into account in this Directive.
- (9) The current annual dose limits for occupational and public exposure are maintained. However, there should be no further need for averaging over five years, except in special circumstances specified in national legislation.
- (10) New scientific information on tissue effects calls for the optimisation principle to be applied to organ doses as well, where appropriate, in order to keep doses as low as reasonably achievable. The directive should also follow new ICRP guidance on the organ dose limit for the lens of the eye in occupational exposure.
- (11) Industries processing naturally occurring radioactive material extracted from the earth's crust subject workers and, if material is released into the environment, the public to increased radiation exposure.
- (12) Protection against natural radiation sources, rather than being addressed separately in a specific title, should be fully integrated within the overall requirements. In particular, industries processing materials containing naturally occurring radionuclides should be managed within the same regulatory framework as other practices.
- (13) The new requirements on **natural** radioactivity in building materials should allow for the free circulation of building materials **while at the same time improving protection against radiological risks.** [Am. 6]
- (14) Recent epidemiological findings from residential studies demonstrate a lung cancer risk from exposure to indoor radon at levels of the order of 100 Bq m<sup>-3</sup>. The new concept of exposure situations allows the provisions of Commission Recommendation 90/143/Euratom on the protection of the public against indoor exposure to radon <sup>(1)</sup> to be incorporated in the binding requirements of the Basic Safety Standards while leaving enough flexibility for implementation.
- (15) The exposure of aircrew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and should be managed as a specially authorised exposure.
- (16) ~~The health protection of the general public allows for~~ The presence of radioactive substances in the environment **has consequences for the health of the general public.** In addition to direct environmental exposure pathways, consideration should be given to the protection of the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. As far as mankind is part of its environment, this policy benefits to long term health protection. **As organisms are susceptible to both internal and external radiation, more resources should be devoted to examining in detail the impact that ionising radiation has on both humankind and the environment.** [Am. 8]
- (17) In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, the Directive should emphasise the need for justification of medical exposure, including the exposure of asymptomatic individuals, and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices.
- (18) Accidental and unintended medical exposures are a source of continuing concern. Their prevention and follow-up, should they occur, need to be fully addressed. In this respect, the role of quality assurance programmes, including risk analysis in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.

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<sup>(1)</sup> OJ L 80, 27.3.1990, p. 26.

Thursday 24 October 2013

- (19) The so-called 'medico-legal' exposures introduced in Directive 97/43/Euratom have now been clearly identified as the deliberate exposure of individuals for other than medical purposes, or 'non-medical imaging exposures'. Such practices need to be placed under appropriate regulatory control and should be justified in a similar way as for medical exposures. However, a different approach is needed on the one hand for procedures implemented by medical staff using medical equipment and on the other hand for procedures implemented by non-medical staff using non-medical equipment. In general, the annual dose limits and corresponding constraints for public exposure should apply.
- (20) Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices. Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.
- (21) There is benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from regulated practices. After a comprehensive review, it has been concluded that the values recommended in IAEA document RS-G-1.7 <sup>(1)</sup> can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122 <sup>(2)</sup>.
- (22) Member States may grant specific exemption from authorisation for certain practices involving activities above the exemption values.
- (23) Specific clearance levels, above the default values for exemption and clearance, as well as corresponding Community guidance <sup>(3)</sup> remain important tools for the management of large volumes of materials arising from the dismantling of licensed facilities.
- (24) Member States should ensure that outside workers receive the same protection as exposed workers employed by undertakings performing practices with radiation sources. The specific arrangements for outside workers in Directive 90/641/Euratom should be extended to cover work in supervised areas as well.
- (25) With regard to the management of emergency exposure situations, the current approach based on intervention levels should be replaced by a more comprehensive system comprising threat analysis, an overall emergency management system, emergency response plans for identified threats, and pre-planned strategies for the management of each postulated event.
- (26) The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as consideration of other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.
- (27) The efficient management of a nuclear emergency with cross-border consequences calls for enhanced cooperation **and transparency** between Member States in emergency planning and response. [**Am. 9**]
- (28) The International Atomic Energy Agency together with the World Health Organisation, the Food and Agricultural Organisation, the International Labour Organisation, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development, and the Pan-American Health Organisation are revising the International Basic Safety Standards in the light of the ICRP's new Publication 103.

<sup>(1)</sup> IAEA 2004 Safety Standards Series RS-G-1.7 'Application of the Concepts of Exclusion, Exemption and Clearance'.

<sup>(2)</sup> Radiation Protection 122: Practical use of the Concepts of the Clearance and Exemption — Part I, Guidance on General Clearance Levels for Practices.

<sup>(3)</sup> Radiation Protection 89: Recommended radiological protection criteria for the recycling of metals from dismantling of nuclear installations, Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations, Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption.

Thursday 24 October 2013

- (29) The roles and responsibilities of the national services and experts involved in ensuring that the technical and practical aspects of radiation protection are managed with a high level of competence need to be clarified.
- (30) More precise requirements **and appropriate penalties** should be introduced for the issuing discharge authorisations and for the monitoring of discharges. Commission Recommendation 2004/2/Euratom <sup>(1)</sup> introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities. [Am. 10]
- (31) ~~No major changes need to be made to the most recent~~ Directive 2003/122/Euratom, ~~except to broaden some of~~ **should be broadened with regard to** the requirements **in order** to include any sealed radioactive source. However, there are still unresolved problems with orphan sources, **for example unexploded munitions** and there have been significant cases of contaminated metal being imported from third countries. Accordingly, a requirement should be introduced for the notification of incidents with orphan sources or the contamination of metal. With regard to international security, it is also important to harmonise the levels above which a source is regarded as a high-activity sealed source with those established by the IAEA. [Am. 11]
- (32) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (33) Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom should therefore be repealed,

HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER I

## SUBJECT MATTER AND SCOPE

## Article 1

## Subject matter

1. This Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of ~~their uniform implementation by~~ **guaranteeing a uniform threshold level of protection in the** Member States **without barring Member States from maintaining or establishing higher basic safety standards than set out in this Directive.** [Ams. 12 and 133]
2. This Directive applies to the protection of the environment as a pathway from radiation sources to the exposure of man, complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole.
3. This Directive sets out requirements for the control of the safety and security of radioactive sources and the provisions of ~~appropriate~~ **mandatory** information in an emergency exposure situation. [Am. 13]
4. This Directive sets out requirements for the prevention of exposure of workers and members of the public to ionising radiation arising from orphan sources and from inadequate control of high-activity sealed radioactive sources and for the harmonisation of controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control.
5. This Directive defines at Community level common objectives with regard to measures and procedures for informing the public for the purpose of improving the operational health protection provided in the event of an emergency.

<sup>(1)</sup> Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation (OJ L 2, 6.1.2004, p. 36).

Thursday 24 October 2013

## Article 2

### Scope

1. This Directive applies to any planned, existing, **accidental** or emergency exposure situation which involves a risk from exposure to ionising radiation ~~which cannot be disregarded from the radiation protection point of view~~ with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment. [Am. 14]
2. This Directive applies to all practices involving radiation sources, namely:
  - (a) the production, processing, handling, use, storage, holding, transport, shipment, import to, and export from the Community ~~and the disposal of radioactive material~~ **and temporary or final radioactive waste storage**; [Am. 15]
  - (b) the operation of electrical equipment emitting ionising radiation and the operation of any electrical equipment operating at a potential difference of more than 5 kV;
  - (c) practices which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:
    - (i) **practices exposing workers to cosmic radiation, including** the operation of aircraft and spacecraft **as well as frequent flying**; [Am. 16]
    - (ii) exposure to radon in workplaces;
    - (iii) the activities in industries processing materials with naturally occurring radionuclides, or activities related to such processing.
  - (d) any other practice specified by the Member State.
3. This Directive applies to the management of existing exposure situations, in particular the exposure of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past activity.
4. This Directive applies to the management of emergency exposure situations to the extent that these are deemed to warrant intervention to protect the health of the public or workers or to protect the environment; potential exposures as well as emergency preparedness and planning are part of planned exposure situations.

## Article 3

### Exclusion from the scope

This Directive shall not apply to radionuclides naturally contained in the human body, to cosmic radiation prevailing at ground level, and to aboveground exposure to radionuclides present in the undisturbed earth's crust.

## CHAPTER II

### DEFINITIONS

## Article 4

For the purpose of this Directive, the following definitions shall apply:

- (1) Medical exposure means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health or well-being, as well as exposure incurred by carers and comforters and by volunteers in biomedical research;
- (2) Ionising radiation means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3x10<sup>15</sup> Hertz or more) capable of producing ions directly or indirectly;

Thursday 24 October 2013

- (3) Emergency means a ~~non-routine~~ situation ~~or~~ **resulting from an accident, malfunction, malicious act or conflict or from any other non-routine** event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies; [Am. 17]
- (4) Emergency exposure situation means a situation of exposure due to any sudden event which requires urgent decisions to be taken in order to control this situation; the event may result from an accident (whether or not envisaged as a potential exposure) or from a malicious act;
- (5) Exposure means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);
- (6) Exposure situation means a situation giving rise to exposure, including the radiation sources and the activities or actions which may affect the exposure from these radiation sources;
- (7) Members of the public mean individuals, subject to public exposure;
- (8) Radiation source means an entity that may cause radiation exposure — such as by emitting ionising radiation or by releasing radioactive material — and can be treated as a single entity for protection and safety purposes;
- (9) Radioactive source means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;
- (10) Radioactive material means **any** material **in a liquid, gaseous or solid form** incorporating radioactive substances; [Am. 18]
- (11) Orphan source means a sealed source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation;
- (12) Building material means a construction product which is produced for incorporation in a permanent manner in a building;
- (13) Disposal means the emplacement of radioactive waste or spent fuel in an authorised facility without the intention of retrieval;
- (14) Existing exposure situation means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;
- (15) Natural radiation source means sources of ionising radiation of natural terrestrial or cosmic origin;
- (16) Planned exposure situation means an exposure situation that arises from the planned operation or introduction of a radiation source or from activities which alter exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures;
- (17) Potential exposure means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.
- (18) Radiation protection means the protection of people from harmful effects of exposure to ionising radiation, and the means for achieving this;
- (19) Practice means any activity that involves the operation or introduction of radiation sources or which alters exposure pathways and is managed as a planned exposure situation;
- (20) Radon means the isotope Rn-222 and its progeny, as appropriate (exposure to radon means exposure to radon progeny);
- (21) Storage means the holding of radioactive sources or radioactive waste in a facility that provides adequate containment, with the intention of retrieval;
- (22) Optimisation means a forward-looking iterative process to establish adequate protection measures taking into account the prevailing circumstances, the available options, and the nature of the exposure situation, with the aim of keeping the magnitude and likelihood of exposure and the number of people exposed as low as ~~reasonably achievable~~ **possible**; [Am. 19]

Thursday 24 October 2013

- (23) Public exposure means exposure of individuals, excluding any occupational or medical exposure;
- (24) Occupational exposure means exposure of workers, **including employees and self-employed people as well as trainees and volunteers**, incurred in the course of their work; [Am. 20]
- (25) Health detriment means an estimate of the risk of reduction in length and quality of life occurring in a population following exposure. ~~This includes~~ **The definition used in ICRP Publication 103 delimits detriment as** loss arising from tissue effects, cancer and severe genetic disorder **(equivalent to a terminal illness)**; [Am. 21]
- (26) Effective dose (E) means the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external irradiation. It is defined by the expression:

$$E = \sum_T w_T H_T = \sum_T w_T \sum_R w_R D_{T,R}$$

where

$D_{T,R}$  is the absorbed dose averaged over tissue or organ T, due to radiation R,

$w_R$  is the radiation weighting factor and

$w_T$  is the tissue weighting factor for tissue or organ T.

The appropriate  $w_T$  and  $w_R$  values are specified in Publication 103 of the International Commission on Radiological Protection. The unit for effective dose is the sievert;

- (27) Dose limit means the value of the effective dose or the equivalent dose in a specified period which may not be exceeded for an individual. The dose limit applies to the sum of exposures from all authorised practices;
- (28) Dose constraint means a constraint set as a prospective upper bound of an individual dose, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;
- (29) Equivalent dose ( $H_T$ ) means the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by:

$$H_{T,R} = w_R D_{T,R}$$

where

—  $D_{T,R}$  is the absorbed dose averaged over tissue or organ T, due to radiation R,

—  $w_R$  is the radiation weighting factor.

When the radiation field is composed of types and energies with different values of  $w_R$ , the total equivalent dose,  $H_T$ , is given by:

$$H_T = \sum_R w_R D_{T,R}$$

The appropriate  $w_R$  values are specified in Publication 103 of the International Commission on Radiological Protection. The unit for equivalent dose is the sievert.

- (30) Outside worker means any exposed worker of category A who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in these areas, including trainees, apprentices and students;
- (31) Undertaking means a natural or legal person who has legal responsibility for carrying out a practice or who has legal responsibility for a radiation source (including cases where the owner or holder of a radiation source does not conduct related activities);
- (32) Risk constraint means a constraint set as a restriction on the individual risk from a radiation source (risk in the sense of probability of health detriment due to a potential exposure, which is a function of the probability of an unintended event causing a dose and the probability of detriment due to that dose);

Thursday 24 October 2013

- (33) Carers and comforters means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;
- (34) Reference level means, in an emergency exposure situation or in an existing exposure situation, the level of dose or risk above which it is judged inappropriate to allow exposures to occur, and below which optimisation of protection should continue to be implemented;
- (35) Exposed worker means a person, either self-employed or working under an employer, **including a trainee or volunteer**, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure; [Am. 22]
- (36) Sievert (Sv) means the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram:  $1 \text{ Sv} = 1 \text{ J kg}^{-1}$ ;
- (37) Intake means the activities of radionuclides entering the body from the external environment;
- (38) Apprentice means a person **aged 16 years or over (including trainees and students)** receiving training or instruction within an undertaking with a view to exercising a specific skill, **which involves operations which would, in the case of an employee, be considered as working with ionising radiation**. [Am. 23]
- (39) Committed effective dose ( $E(\tau)$ ) means the sum of the committed organ or tissue equivalent doses  $H_T(\tau)$  resulting from an intake, each multiplied by the appropriate tissue weighting factor  $w_T$ . It is defined by:

$$E(\tau) = \sum_T w_T H_T(\tau)$$

In specifying  $E(\tau)$ ,  $\tau$  is given in the number of years over which the integration is made. For the purpose of complying with dose limits specified in this Directive,  $\tau$  is a period of 50 years following intake for adults and up to age 70 for children. The unit for committed effective dose is the sievert;

- (40) Medical physics expert means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence to act is recognised by the competent authorities;
- (41) Occupational health service means a health professional or body having competence for the medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the competent authorities;
- (42) Radiation protection expert means an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities;
- (42a) Competent authority means any authority designated by a Member State. [Am. 24]**
- (43) High-activity sealed source means a sealed source in which the amount of radioactive material exceeds the values laid down in Annex II;
- (44) Emergency response plan means arrangements to plan for adequate response in the event of an emergency exposure situation related to a specific facility or activity on the basis of postulated events and related scenarios;
- (45) Emergency worker means any person having a defined role as a worker in an emergency and who might be exposed while taking action in response to the emergency;
- (46) Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, **whose status affords a guarantee of independence from the employer of the exposed workers and** whose capacity to act in this respect is recognised by the competent authorities; [Am. 25]

Thursday 24 October 2013

- (47) Emergency management system means legal or administrative framework establishing responsibilities for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation;
- (48) Medical radiological means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other planning and guiding radiology using ionising radiation;
- (49) Practical aspects of medical exposure procedures means the physical conduct of a medical exposure and any supporting aspects including handling and use of medical radiological equipment, and the assessment of technical and physical parameters, including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing as carried out by, among others, radiographers and technicians in nuclear medicine and radiotherapy;
- (50) Practitioner means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements.
- (51) Diagnostic reference levels means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;
- (52) Activation means the process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained;
- (53) Radioactive substance means any substance that contains one or more radionuclides, the activity concentration of which cannot be disregarded as far as radiation protection is concerned;
- (54) Non-medical imaging exposure means any deliberate exposure of humans for imaging purposes where the primary motivation for the exposure is not related to the health or well-being of the individual being exposed;
- (55) Notification means submission of a document to the competent authority to notify the intention to carry out a practice within the scope of this Directive.
- (56) Registration means permission granted in a document by the competent authority, or granted by national legislation, to carry out an activity in accordance with conditions laid down in national legislation;
- (57) Consumer product means a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;
- (58) Accelerator means an apparatus or installation in which particles are accelerated, emitting ionising radiation with energy higher than 1 mega-electron volt (MeV);
- (59) Disused sealed source means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted;
- (60) Inspection means an investigation by any competent authority to verify compliance with national provisions;
- (61) Radiation generator means a device capable of generating ionising radiation, such as X rays, neutrons, electrons or other charged particles, which may be used for scientific, industrial or medical purposes;
- (62) Radioactive waste means radioactive material for which no further use is foreseen.
- (63) Quality assurance means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;
- (64) Licence means permission granted by the competent authority, on application, to carry out a practice subject to conditions laid down in a specific licence document;
- (65) Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations **and of total activity**, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive. [Am. 26]

Thursday 24 October 2013

- (66) Supervised area means an area subject to supervision for the purpose of protection against ionising radiation;
- (67) Controlled area means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled;
- (68) Accidental exposure means an exposure of individuals, other than emergency workers, as a result of an accident;
- (69) Emergency occupational exposure means occupational exposure received in an emergency exposure situation by individuals taking action to mitigate the consequences of the emergency;
- (70) Health screening means a procedure using medical radiological installations for early diagnosis in population groups at risk;
- (71) **Highly** radon-prone area means a geographic area or administrative region defined on the basis of surveys indicating that the percentage of dwellings expected to exceed the national reference level is significantly higher than in other parts of the country; [Am. 27]
- (72) Medical radiological procedure means any procedure giving rise to medical exposure;
- (73) Referrer means a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements;
- (74) Individual detriment means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed ~~and, in the latter case, implies a probability rather than a certainty of appearance;~~ [Am. 28]
- (75) Interventional radiology means the use of X-ray imaging techniques, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionising radiation techniques, to introduce and guide devices in the body for diagnostic or treatment purposes;
- (76) Radiodiagnostic means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;
- (77) Radiotherapeutic means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;
- (78) Clinical responsibility means responsibility of a practitioner for individual medical exposures, notably: justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical exposure procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;
- (79) Clinical audit means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary;
- (80) Medical radiological installation means a facility containing medical radiological equipment;
- (81) Unintended exposure means medical exposure that is significantly different from the medical exposure intended for a given purpose;
- (82) Representative person means an individual receiving **or liable to receive** a dose that is representative of the more highly exposed individuals in the population. **Evaluations shall take account of scenarios that are worse than the existing conditions unless it is demonstrated that such scenarios are not liable to arise or that their emergence would be identified and would trigger re-evaluation of the dosimetric impact;** [Am. 30]
- (83) Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice and is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking, **and whose capacity to act is recognised by the competent authorities;** [Am. 31]

Thursday 24 October 2013

- (84) Remedial measures means the removal of a source or the reduction of its magnitude (in terms of activity or amount) for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation.
- (85) Protective measures means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation.
- (86) Authorisation means the granting by a competent authority of written permission for an undertaking to perform specified activities subject to regulatory control in the form of registration or a licence;
- (87) Sealed source means a radioactive source in which the radioactive material is permanently sealed in a capsule or closely bonded in a solid form;
- (88) Supplier means any natural or legal person who supplies or makes available a sealed source;
- (89) Source container means the containment of a sealed source, where this is not an integral part of the source but is meant for shielding the source during its use, transport, handling, etc.
- (90) Thoron means the isotope Rn-220;
- (91) Residual dose means the dose expected to be incurred from all exposure pathways after protective measures have been fully implemented, ~~or where a decision has been taken not to implement any protective measures;~~ [Am. 32]
- (92) Absorbed dose (D) means the energy absorbed per unit mass

$$D = \frac{d\bar{\epsilon}}{dm}$$

where

—  $d\bar{\epsilon}$  is the mean energy imparted by ionising radiation to the matter in a volume element,

—  $dm$  is the mass of the matter in this volume element.

In this Directive, absorbed dose denotes the dose averaged over a tissue or an organ. The unit for absorbed dose is the gray.

- (93) Gray (Gy) is the unit of absorbed dose. One gray is equal to one joule per kilogram:  $1\text{ Gy} = 1\text{ J kg}^{-1}$ ;
- (94) Activity (A) means the activity, A, of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of  $dN$  by  $dt$ , where  $dN$  is the expectation value of the number of spontaneous nuclear transitions from that energy state in the time interval  $dt$ :

$$A = \frac{dN}{dt}$$

The unit of activity is the becquerel;

- (95) Becquerel (Bq) means the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second:  $1\text{ Bq} = 1\text{ s}^{-1}$ ;
- (96) Committed equivalent dose ( $H(\tau)$ ) means the integral over time ( $\tau$ ) of the equivalent dose rate (in tissue or organ T) that will be received by an individual as a result of an intake. It is given by:

$$H_T(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}(t) dt$$

for an intake at time  $t_0$  where

$\dot{H}_T(\tau)$  is the relevant equivalent dose rate (in organ or tissue T) at time  $t$ ,

$\tau$  is the time over which the integration is performed.

Thursday 24 October 2013

In specifying  $H_T(\tau)$ ,  $\tau$  is given in years. When  $\tau$  is not given, a period of 50 years is assumed for adults and up to age 70 for children. The unit for committed equivalent dose is the sievert;

- (97) ~~Normal~~ Exposure **in normal situations** means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operational occurrences; [Am. 33]
- (98) Projected dose means the dose that would be expected to be incurred if no protective measures were to be taken;
- (99) Quality control means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;
- (100) Response strategy means a set of different protective measures to respond to postulated or actual events so as to manage an emergency exposure situation in accordance with the stated objectives. Within an emergency response plan, response strategies are established for each postulated event and scenario;

### CHAPTER III

#### SYSTEM OF RADIATION PROTECTION

#### Article 5

#### General principles

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on ~~the up-to-date, robust scientific evidence~~, following principles of justification, optimisation ~~and~~, dose limitation **and reparation of damages**: [Am. 34]

- (a) justification: decisions ~~introducing or altering a radiation source, an exposure pathway or actual exposures~~ **which increase individuals' exposure to ionising radiation** shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from them offsets the detriment that they may cause; [Am. 35]
- (b) optimisation: in all exposure situations, radiation protection shall be optimised with the aim of keeping the magnitude and likelihood of exposure and the number of individuals exposed as low as ~~reasonably achievable~~ **possible**, taking into account ~~economic and~~ societal factors, whereby optimisation of the protection of individuals undergoing medical exposure shall be commensurate with the medical purpose of the exposure as described in Article 55. This principle shall be applied in terms of effective dose as well as organ doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold, for deterministic effects; [Am. 36]
- (c) dose limitation: ~~in planned exposure situations,~~ **the sum of doses received by a member of the public from all regulated radiation sources and all existing anthropic exposure situations shall not exceed the dose limits laid down for public exposure.**

The sum of doses to an ~~individual~~ **exposed worker** from all regulated radiation sources may not exceed the dose limits laid down for occupational exposure ~~or public exposure~~.

Dose limits shall not apply to medical exposures. [Am. 37]

- (ca) **reparation for damages: before authorising the construction of a nuclear installation or renewing its operating licence, Member States shall establish a mechanism which guarantees reparation for all physical damage and personal injury likely to be caused by an emergency at the installation.** [Am. 38]

**Information regarding justification and dose limitation shall be made available to the general public.** [Am. 39]

Thursday 24 October 2013

## Section 1

### Tools for optimisation

#### Article 6

##### Dose constraints for occupational and public exposure

1. For occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking ~~under the general supervision of~~ **in consultation with workers' representatives. Their decision shall be supervised by** the competent authorities. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking **in consultation with workers' representatives.** [Am. 40]
2. For public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source **or as a result of an existing anthropic exposure situation.** The competent authorities shall set the **dose** constraint so as to ensure **the protection of health of the general public and** compliance with the dose limit for the sum of doses to the same individual from all authorised practices, **as well as from natural sources of radiation and residual contamination. The values chosen for the dose constraints shall be published, so that any member of the public can check that he or she has not received, as a result of aggregate planned and existing anthropic exposure situations, a dose in excess of the legal limit.** [Am. 41]
3. With regard to potential exposures, optimisation shall include adequate management of the safety and security of sources and facilities. Where appropriate risk constraints may be established.
4. Dose constraints shall be established in terms of individual effective or equivalent doses over a year or any other appropriate shorter time period.
5. Where dose constraints are introduced to restrict any protracted accumulated exposure, these shall be established in terms of annual effective doses or equivalent doses to an organ.

#### Article 7

##### Dose constraints for medical exposure

Dose constraints shall not apply for the medical exposure of patients.

For carers and comforters and for volunteers participating in medical and biomedical research (for whom no direct medical benefit is expected from the exposure), dose constraints shall be established in terms of the individual dose that is unlikely to be exceeded for the period of the examination, treatment or research project in question.

#### Article 8

##### Reference levels

1. Reference levels shall be established for emergency and existing exposure situations as a level of effective dose or organ dose above which it is judged inappropriate to allow exposures in emergency or existing exposure situations.
2. Optimised protective strategies shall be planned and implemented with the objective of reducing individual doses **to the lowest level** below the reference levels **which can reasonably be achieved.** The values chosen for reference levels shall depend upon the type of exposure situation, **the nature of the risk and the forms of intervention and protective and remedial measures available.** [Am. 42]
3. Optimisation of protection shall give priority to exposures above the reference level. The choices of reference levels shall take into account both radiological protection requirements and societal criteria.

Thursday 24 October 2013

**3a. Levels of intervention shall be laid down for the various countermeasures applicable in emergency exposure situations; they shall correspond to a level of effective dose or organ dose above which protective measures must be taken to limit the risk incurred by the persons exposed. [Am. 43]**

**4. ~~The choice of reference levels for the effective dose shall take into account the three bands of~~ The values corresponding to effective dose and equivalent organ dose set by the Member States for the reference and intervention levels set out in point 1 of Annex I shall be communicated to the Commission and published. Member States shall involve stakeholders in the process of setting these values. [Am. 44]**

## Section 2

### Dose limitation

#### Article 9

##### Age limit for exposed workers

Subject to Article 12(2), persons under 18 years of age may not be assigned to any work which would result in their being exposed workers.

#### Article 10

##### Dose limits for occupational exposure

1. The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv per year may be authorised in a single year, provided that the average dose over any five consecutive years does not exceed 20 mSv per year.

For emergency workers a higher effective dose may be authorised, in accordance with Article 52.

2. In addition to limits of effective dose laid down in paragraph 1, the following limits on equivalent dose shall apply:

- (a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a year or, where applicable, the same value as specified for the limit on effective dose;
- (b) the limit on the equivalent dose for the skin shall be 500 mSv in a year; this limit shall apply to the dose averaged over any area of 1 cm<sup>2</sup>, regardless of the area exposed;
- (c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a year.

#### Article 11

##### Protection of pregnant women

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the unborn child shall be ~~comparable with~~ **equivalent to** that provided for members of the public. The employment conditions for the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy. **[Am. 45]**

2. As soon as a breastfeeding woman informs the undertaking of her condition, she shall not be employed in work involving a significant risk of intake of radionuclides.

#### Article 12

##### Dose limits for apprentices and students

1. The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources shall be the same as the dose limits for occupational exposure laid down in Article 10.

2. The limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources shall be 6 mSv per year.

Thursday 24 October 2013

In addition to limits of effective dose laid down in the first subparagraph, the following limits on equivalent dose shall apply:

- (a) the limit on the equivalent dose for the lens of the eye shall be ~~20~~ **15** mSv in a year; [Am. 46]
  - (b) the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm<sup>2</sup>, regardless of the area exposed;
  - (c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in a year.
3. The dose limits for apprentices and students who are not subject to paragraphs 1 and 2 shall be the same as the dose limits for members of the public as specified in Article 13.

#### Article 13

##### Dose limits for public exposure

1. The limit on the effective dose for public exposure shall be 1 mSv in a year. ***That limit shall be based on the aggregate doses received as a result of internal and external exposure linked to all regulated practices and existing anthropic exposure situations.*** [Am. 49]
2. In addition to the dose limit referred to in the paragraph 1, the following limits on the equivalent dose shall apply:
- (a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;
  - (b) the limit on the equivalent dose for the skin shall be 50 mSv in a year, averaged over any 1 cm<sup>2</sup> area of skin, regardless of the area exposed.

#### Article 14

##### Estimation of the effective and equivalent dose

For the estimation of effective and equivalent doses, the following values and relationships shall be used:

- (a) for external radiation, the values and relationships laid down in Publication 103 of the International Commission on Radiological Protection shall be used to estimate the effective and equivalent doses;
- (b) for internal exposure from a radionuclide or from a mixture of radionuclides, the values and relationships laid down in Publication 103 of the International Commission on Radiological Protection and the ingestion and inhalation dose coefficients laid down in Publication 72 of the International Commission on Radiological Protection shall be used to estimate the committed effective doses.

### CHAPTER IV

#### REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

#### Article 15

##### General responsibilities for education, training and provision of information

1. Member States shall establish an adequate legislative and administrative framework for providing appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection. The training, retraining and information of relevant individuals shall be repeated at appropriate intervals and documented.
2. Member States shall establish ***continuous*** education, training and retraining to ~~allow~~ ***enable*** the recognition of radiation protection experts, medical physics experts, ***radiation protection officers***, occupational health services, and dosimetry services, ***and to support the exchange of best practices between the Member States. All forms of education, training and up-to-date information shall enhance preparedness and enable swifter preventive and/or response actions in the field.*** [Am. 51]

#### Article 16

##### Training of exposed workers, apprentices and students and information provided to them

1. Member States shall require the undertaking or the employer to inform, ***without exception***, exposed workers, apprentices and students who are subject to occupational exposure about: [Am. 52]
- (a) the health risks involved in their work;

Thursday 24 October 2013

**(aa) safe working procedures to minimise risks;** [Am. 53]

- (b) the general radiation protection procedures and precautions to be taken, in particular those connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;
- (c) the emergency response plans and procedures;
- (d) the importance of complying with the technical, medical and administrative requirements;

**(da) the conditions under which workers are entitled to health surveillance;** [Am. 54]

**Where appropriate, information on the risks connected with frequent flying shall also be provided.** [Am. 55]

2. Member States shall require the undertaking or the employer to inform women on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child and the risk of contaminating a nursing infant after intake of radionuclides.

3. Member States shall require that the undertaking or the employer provides appropriate radiation protection training and information programmes for their personnel.

4. In addition to the information and training in the field of radiation protection as provided for in paragraphs 1, 2 and 3, an undertaking responsible for high-activity sealed sources shall ensure that such training includes specific requirements for the safe management and security of high-activity sealed sources with a view to preparing the relevant workers adequately for any events affecting their own safety or the radiation protection of other individuals. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

#### Article 17

##### Information and training of workers potentially exposed to orphan sources

Member States shall ensure that the management of and workers in installations where orphan sources are most likely to be found or processed, in particular large metal scrap yards and major metal scrap recycling plants, and in significant nodal transit points, are:

- (a) informed of the possibility that they may be confronted with a source;
- (b) advised and trained in the visual detection of sources ~~and their containers~~ **and their containers as well as in how to report them;** [Am. 56]
- (c) informed of basic facts about ionising radiation and its effects;
- (d) informed about detection systems;
- (e) informed of and trained in the action to be taken on site in the event of the detection or suspected detection of a source.

#### Article 18

##### Information and training for emergency workers

1. Member States shall ensure that emergency workers and any other persons who might be involved in the organisation of emergency assistance in the event of an emergency are **promptly** given ~~adequate~~ **complete** and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies. [Am. 57]

2. As soon as an emergency occurs, the information referred to in paragraph 1 shall be supplemented appropriately, having regard to the specific circumstances.

Thursday 24 October 2013

3. Member States shall ensure that emergency workers receive regular training as provided for in the emergency management system set out in Article 97. Where appropriate, this training shall include practical exercises.

4. Member States shall ensure that, in addition to the emergency response training referred to in paragraph 3 of this Article, the organisation responsible for the protection of emergency workers as referred to in Article 30(1)(b) provides these workers with appropriate radiation protection training and information.

#### Article 19

##### Education, information and training in the field of medical exposure

1. Member States shall ensure that practitioners and the individuals involved in the practical aspects of medical exposure procedures have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.

For this purpose Member States shall ensure that appropriate curriculum are established and shall recognise the corresponding diplomas, certificates or formal qualifications.

2. Individuals undergoing relevant training programmes may participate in practical aspects of medical exposure procedures as set out in Article 56(4).

3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiation protection requirements.

4. Member States shall ensure that mechanisms are in place for the timely dissemination of information relevant to radiation protection for medical exposure regarding lessons learned from significant events.

5. Member States shall ensure the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

**5a. As regards Union citizens, the information requirements laid down in this Directive shall be met in one of the official languages of the Union in order that each citizen understands the information provided. [Am. 58]**

#### CHAPTER V

##### JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

#### Article 20

##### Justification of practices

1. Member States shall ensure that new types of practices resulting in exposure to ionising radiation are justified **and pre-tested** before being approved, **and are regularly checked during implementation**. [Am. 59]

**Member States shall ensure that all stakeholders, in particular the persons likely to be affected by the health impact of the practice, whether in normal operating circumstances or in an emergency, are involved in the decision-making process. That involvement shall be arranged sufficiently far ahead of the deadline for a decision so that alternative solutions can be properly studied. [Am. 60]**

2. Member States shall list the approved types of practices in legislation or administrative acts.

3. Existing types of practices shall be reviewed as to their justification whenever new and important evidence about their efficacy or potential consequences is acquired **and/or where negative results have been registered. The Commission and the Member States shall lay down procedures for the revision of the justifications for existing practices at Union and national level. The arrangements shall in particular ensure that groups or individuals exposed to the dangers of ionising radiation as a result of these practices, and in particular members of the public and workers, can put forward proposals and take part in the decision-making process. [Am. 61]**

Thursday 24 October 2013

## Article 21

## Justification of practices with apparatus or products emitting ionising radiation

1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionising radiation to provide the competent authorities **in the country in which the undertaking has its registered office** with relevant information as set out in Annex III, Section A, in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified. [Am. 62]
  2. The competent authority shall share the information received in accordance with paragraph 1 with the competent authorities of the other Member States **in order to allow inform them to take their own of its decision on the justification of concerning** the intended use of the apparatus or product. **The competent authorities shall make that information available to all the other Member States.** [Am. 63]
  3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of ~~six~~ **four** months. [Am. 64]
- 3a. In accordance with Article 22, this type of apparatus and products shall be intended for use in controlled environments.** [Am. 65]

## Article 22

## Prohibition of practices

Member States shall prohibit **and penalise** the ~~deliberate~~ addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics **and, more generally, in consumer goods**, and shall prohibit the import or export of such products. Without prejudice to Directive 1999/2/EC of the European Parliament and of the Council <sup>(1)</sup>, practices involving the activation of material resulting in an increase in activity in the associated products shall be deemed not to be justified. [Am. 66]

## Article 23

## Practices involving the deliberate exposure of humans for non-medical purposes

1. Member States shall ensure the identification, by means of surveys or by any other appropriate means, of practices involving non-medical imaging exposure, as set out in Annex IV. **They shall assess each year the individual and collective doses associated with each of the practices listed, their impact and their development over time.** [Am. 67]
2. Member States shall **monitor and** ensure that special attention is given to the justification of practices involving non-medical imaging exposure, in particular: [Am. 68]
  - (a) all types of practices involving non-medical imaging exposure, as listed in Annex IV, shall be justified in advance before being generally accepted;
  - (b) each particular application of a generally accepted type of practice shall be justified in advance;
  - (c) all individual non-medical imaging exposure procedures as listed in Annex IV, section A implemented by medical staff using medical radiological equipment shall be justified in advance taking into account the specific objectives of the procedure and the characteristics of the individual involved;
  - (d) the general and particular justification of practices involving non-medical imaging exposure, as specified in points (a) and (b), shall be subject to periodic review by the competent authority.
3. Where a Member State has determined that a particular practice involving non-medical imaging exposure is justified it shall ensure that:
  - (a) each practice is subject to authorisation;

<sup>(1)</sup> OJ L 66, 13.3.1999, p. 16.

Thursday 24 October 2013

- (b) requirements for the practice, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant agencies and professional bodies as appropriate;
- (c) dose constraints are established for each practice. Such shall be well below the dose limit for members of the public, including, whenever practicable, for procedures implemented by medical staff using medical equipment as set out in Annex IV, Section A; for other practices set out in Annex IV, section B, the dose constraint shall satisfy the requirements of Article 6(2);
- (d) relevant requirements set out in Chapter VII, including those for equipment, optimisation, responsibilities and special protection during pregnancy, are met for procedures implemented by medical staff using medical radiological equipment;
- (e) the informed consent of the individual to be exposed is sought, allowing for cases where the law enforcement bodies may proceed without consent according to national legislation;
- (f) where the exposure is routinely carried out for security purposes the screened individuals are provided with a choice of an alternative technique which does not involve exposure to ionising radiation.

**3a. Member States shall be responsible for researching, developing and implementing alternative technologies.**  
[Am. 69]

#### Article 24

##### Identification of practices involving naturally occurring radioactive material

Member States shall ensure the identification **and publication** of practices involving naturally occurring radioactive material and leading to exposure of workers or members of the public ~~which cannot be disregarded from a radiation protection point of view~~. Such identification shall be carried out by means of surveys or by any other appropriate means taking into account, **in particular**, industrial sectors listed in Annex V. [Am. 70]

#### Article 25

##### Notification

1. Member States shall require all practices, including practices identified in accordance with Article 24, to be notified, except for justified practices involving the following:

- (a) materials containing radioactive substances where the quantities of the activity involved do not exceed in total the exemption values set out in Annex VI or higher values that, for specific applications, are authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or
- (b) materials containing radioactive substances, provided that the concentrations of activity per unit mass do not exceed the exemption values set out in Table A of Annex VI, or higher values that, for specific applications, are authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or
- (c) any cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kV, or any other apparatus or product which is of a type approved by the competent authorities of the Member State, provided that:
  - (i) it does not cause, in normal operating conditions, a dose rate exceeding 1  $\mu\text{Sv} \cdot \text{h}^{-1}$  at a distance of 0,1 m from any accessible surface of the apparatus; and
  - (ii) if it contains radioactive substances, these substances are embedded in a capsule or fixed to a solid holder; and
  - (iii) conditions for disposal have been specified by the competent authorities.

2. Member States may exempt further types of practices from the notification requirement subject to compliance with the general exemption criteria established in point 3 of Annex VI, or in such cases where an assessment of the optimisation of protection shows that exemption is the best option.

Thursday 24 October 2013

**2a. Member States shall specify the information which the undertaking is required to provide in order to enable the competent authority to assess the levels of exposure of members of the public and workers and the radiological risks, in normal and emergency situations. On that basis, and drawing, where appropriate, on the findings of additional investigations, the competent authority shall determine which administrative arrangements are applicable and what regulatory control resources are required. [Am. 71]**

3. Practices that involve naturally occurring radioactive material, identified in accordance with Article 24, and produce or process residues which are known to be recycled into identified building materials are subject to notification if the activity concentration index as defined in Annex VII in the resulting building materials is liable to exceed 1. The undertaking shall also in this case inform the user of the residue about the activity concentration of the residue.

4. In situations identified by Member States where there is concern that a practice identified in accordance with Article 24 may lead to the presence of naturally occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the competent authority may require that the practice be subject to notification irrespective of paragraph 1(b) of this Article.

5. For types of practices subject to notification, Member States shall specify the information to be provided by the undertaking so as to allow the competent authority to establish appropriate means of regulatory control.

6. For the purpose of exemption in accordance with paragraph 1(c), Member States shall exchange information on the type approvals that have been granted and on the underlying documentation and assessment. Competent authorities shall take into account such information received, as well as applicable European and international standards, in making their own decisions with regard to the exemption of corresponding practices.

#### Article 26

##### Regulatory control

1. Member States shall require any notified practice to be subject to regulatory control ~~commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations~~ **by the competent authority. [Am. 72]**

~~2. Notified practices may be exempted from authorisation. [Am. 73]~~

3. In the case of moderate amounts of material as specified by Member States, the activity concentration values laid down in Annex VI, Table B, column 2, may be used for the purpose of exemption.

4. Notified practices which are not exempted shall be subject to authorisation through registration or licensing.

#### Article 27

##### Authorisation

1. In cases where **a quantifiable dose limit can be established for a practice**, a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections. **Licensing should be requested where the authorisation is applied to the overall activities of an undertaking. [Am. 74]**

2. Member States shall require licensing **for undertakings performing the following activities, or, where appropriate in accordance with paragraph 1, registration** for the following practices: **[Am. 75]**

(a) the operation and decommissioning of any facility of the nuclear fuel cycle and the exploitation and closure of uranium mining;

~~(b) the deliberate addition of radioactive substances in the production and manufacture of consumer products or other products, including medicinal products, and the import or export of such products; [Am. 76]~~

(c) the manufacture, use or taking possession of a high-activity sealed source;

(d) the operation, decommissioning and closure of any facility for the processing, storage or disposal of radioactive waste;

Thursday 24 October 2013

- (e) practices in which workers are liable to receive an annual effective dose of more than 6 mSv in normal operation and under normal working conditions;
  - (f) practices discharging significant amounts of airborne or liquid effluent into the environment.
3. Member States shall require either registration or licensing of the following practices:
- (a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;
  - (b) the use of radiation generators or radioactive sources for industrial radiography, the processing of products or research, and the use of accelerators, except electron microscopes;
  - (c) the use of radiation generators or radioactive sources for medical exposures;
  - (d) the manufacture and operation of electrical equipment emitting ionising radiation and operating at a potential difference of more than 30 kV, as well as the import or export of such equipment;
  - (e) practices in which workers are liable to receive an annual effective dose of more than 1 mSv in normal operation and under normal working conditions;
  - (f) industries involving naturally occurring radioactive material identified by Member States as required in Article 24, and liable to lead to an effective dose to a member of the public equal to or exceeding 0,3 mSv per year.
4. Member States may require registration or licensing for types of practices other than those listed in paragraphs 2 and 3.

#### Article 28

##### Authorisation procedure

1. For authorisation purposes, Member States shall require the provision of information commensurate with the nature of the practice and the risks involved.
2. The information required for the purpose of granting a license cover at least the following:
- (a) responsibilities and organisational arrangements for protection and safety;
  - (aa) measures taken pursuant to this Directive; [Am. 78]**
  - (b) staff competences, including information and training;
  - (c) design features of the installation and radiation sources;
  - (d) anticipated occupational and public exposures in normal operation;
  - (e) safety assessment of the activities and the installation in order to:
    - (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
    - (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
    - (iii) assess the quality and extent of protection and safety provisions, including engineering features as well as administrative procedures;
    - (iv) define the operational limits and conditions of operation;
  - (f) emergency procedures and communication links;
  - (g) maintenance, testing, inspection and servicing so as to ensure that the radiation source and the installation continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime;
  - (h) management of radioactive waste and arrangements for the disposal of such waste in accordance with applicable regulatory requirements;
  - (i) management of disused sealed sources;

Thursday 24 October 2013

(j) quality assurance.

3. A licence shall include specific conditions so as to ensure that the elements of the licence are legally enforceable or to impose appropriate restrictions on the operational limits or conditions of operation. The conditions shall also require the formal, documented implementation of the principle of optimisation.

4. Where applicable, a licence shall include a discharge authorisation issued in accordance with the requirements laid down in Chapter VIII for authorisation of the release of liquid or airborne radioactive effluent into the environment.

5. Member States shall require the undertaking to promptly notify the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure or as defined by the authorities for medical exposure. **Random controls by the authorities shall be put in place.**

**Medical devices which emit ionising radiation shall be dealt with in accordance with Council Directive 93/42/EEC<sup>(1)</sup>. The arrangements for the exchange of information provided for under that Directive shall be exhausted and other competent authorities shall be informed. [Am. 79]**

#### Article 29

##### Release from regulatory control

1. The disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.

2. The materials for disposal, recycling or reuse may be released from the requirements of this Directive provided that the concentrations of activity per unit mass:

(a) do not exceed the values set out in Annex VI, Table A, part 1; or

(b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels, in addition to the general clearance levels referred to in point (a), shall be established by the national competent authority following the general exemption criteria set out in Annex VI, point 3 and taking into account technical guidance provided by the Community.

3. For the clearance of materials containing naturally occurring radionuclides, the values for the concentrations of activity per unit mass shall be those laid down in Annex VI, Table A, part 2. Nevertheless the following requirements shall apply:

(a) for practices subject to licensing as specified in Article 27(3)(f), the dose criteria for clearance of naturally occurring radionuclides shall be complied with;

(b) for other licensed practices, in particular those forming part of the nuclear fuel cycle, the clearance levels shall comply with the dose criteria for clearance of materials containing artificial radionuclides;

(c) for authorised practices subject to notification as specified under Article 25(3), the corresponding requirements for the placing on the market of building materials shall be complied with.

4. The deliberate dilution of radioactive residues, other than the mixing of materials that takes place in normal operation when radioactivity is not a consideration, shall not be permitted. The competent authority may authorise in specific situations the mixing of radioactive residues containing naturally occurring radioactive material with other materials to promote the reuse and recycling of these materials and to reduce public exposure.

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<sup>(1)</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 50).

Thursday 24 October 2013

CHAPTER VI  
PROTECTION OF WORKERS, APPRENTICES AND STUDENTS

Article 30  
Responsibilities

1. The requirements for occupational exposure laid down in this Chapter and in Articles 9, 10, 11 and 12, shall apply to the protection of workers in any exposure situation where their exposure at work or as the result of work is the legal responsibility of an undertaking or another legal person, including for instance:

- (a) the employer of outside workers;
- (b) the organisation responsible for the protection of emergency workers;
- (c) the organisation responsible for the remediation of contaminated land, buildings and other constructions;
- (d) the employer who has legal responsibility for the exposure of workers to radon at work, in the situation specified in Article 53(4).

2. The responsibility of an undertaking for occupational exposure shall extend to apprentices and students who in the course of their studies are obliged to work with radiation sources and to individuals who are self-employed or work on a voluntary basis or for a charity organisation.

3. The undertaking shall be responsible for assessing and implementing arrangements for the radiation protection of exposed workers.

Article 31  
Operational protection of workers

The operational protection of exposed workers shall be based on:

- (a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers;
- (b) implementation of the optimisation of radiation protection in all working conditions;
- (c) classification of workers into different categories;
- (d) implementation of control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;
- (e) medical surveillance.

Article 32  
Consultations with radiation protection expert

Member States shall require the undertaking to consult a radiation protection expert on the examination and testing of protective devices and measuring instruments, in particular for:

- (a) prior critical examination of plans for installations from the point of view of radiation protection;
- (b) the acceptance into service of new or modified radiation sources from the point of view of radiation protection;
- (c) regular checking of the effectiveness of protective devices and techniques;
- (d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

Thursday 24 October 2013

## Article 33

## Arrangements in workplaces

1. For the purposes of radiation protection, arrangements shall be made as regards all workplaces where there is a possibility of exposure to ionising radiation in excess of an effective dose of 1 mSv per year or an equivalent dose of 15 mSv per year for the lens of the eye or 50 mSv per year for the skin and extremities. Such arrangements shall be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.
2. For practices involving naturally occurring radioactive material where the effective dose to workers is liable to exceed 6 mSv per year, the requirements set out in this Chapter shall apply. Where the effective dose to workers is less than or equal to 6 mSv per year the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process or the work arrangements.
3. For undertakings operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, the relevant requirements set out in this Chapter shall apply. Where the effective dose to the crew is less than or equal to 6 mSv per year and liable to be above 1 mSv per year, the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for doses to change over time or as a result of changes in the work arrangements. The undertakings shall take appropriate measures, in particular:
  - (a) to assess the exposure of the crew **or workers** concerned; [Am. 80]
  - (b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew;
  - (c) to inform the workers concerned of the health risks their work involves and their individual dose.

## Article 34

## Classification of workplaces

1. Workplaces shall be classified into different areas, where appropriate, on the basis of an assessment of the expected annual doses and the probability and magnitude of potential exposures.
2. A distinction shall be made between controlled areas and supervised areas. The competent authorities shall establish guidance on the classification of controlled and supervised areas with regard to particular circumstances.
3. The undertaking shall keep under review the working conditions in controlled and supervised areas.

## Article 35

## Requirements for controlled areas

1. The minimum requirements for a controlled area shall be the following:
  - (a) the controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including for the access and exit of individuals and goods and for monitoring contamination within the controlled area and in the adjacent area;
  - (b) taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the working environment shall be organised in accordance with Article 37;
  - (c) signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;
  - (d) working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The undertaking shall be responsible for implementation of these requirements following consultations with the radiation protection expert.

Thursday 24 October 2013

## Article 36

### Requirements for supervised areas

1. The requirements for a supervised area shall be the following:
  - (a) taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the working environment shall be organised in accordance with Article 37;
  - (b) signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;
  - (c) working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The undertaking shall be responsible for implementation of these requirements following consultations with the radiation protection expert.

## Article 37

### Radiological surveillance of the working environment

1. The radiological surveillance of the working environment referred to in Articles 35(1)(b) and 36(1)(a) shall comprise, where appropriate:
  - (a) the measurement of external dose rates, indicating the nature and quality of the radiation in question;
  - (b) the measurement of the air activity concentration and the surface density of contaminating radionuclides, indicating their nature and their physical and chemical states;
  - (c) the measurement of radon concentrations in the workplace.
2. The results of these measurements shall be recorded and shall be used, if necessary, for estimating individual exposure, as provided for in Article 39.

## Article 38

### Categorisation of exposed workers

1. For the purposes of monitoring and surveillance, a distinction shall be made between two categories of exposed workers:
  - (a) category A: exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than ~~150~~ 50 mSv per year for skin and extremities; **[Am. 81]**
  - (b) category B: exposed workers who are not classified as category A workers.
2. The distinction between two categories of exposed workers referred to in paragraph 1 shall be made prior to employment for work involving exposure and shall be subject to regular review on the basis of working conditions and medical surveillance.
3. For emergency workers, the distinction between two categories of exposed workers referred to in paragraph 1 of this Article, where appropriate, shall have no effect on the requirements for monitoring set out in Articles 37, 39 — 43 as long as the workers are not involved in an actual emergency exposure situation.

## Article 39

### Individual monitoring

1. Category A workers shall be systematically monitored based on individual measurements performed by a dosimetry service. In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities an adequate system for monitoring shall be set up. The competent authority shall give special attention to the identification of such workers.

Thursday 24 October 2013

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States ~~may~~ **should** require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers. [Am. 82]

3. In cases where individual measurements are impossible or inadequate, the individual monitoring shall be based on an estimate arrived at either from individual measurements made on other exposed workers or from the results of the surveillance of the working environment provided for in Article 37.

#### Article 40

##### Monitoring in the case of accidental exposure

In the case of accidental exposure, the undertaking in collaboration with the dosimetry service shall assess the relevant doses and their distribution in the body.

#### Article 41

##### Recording and reporting of results

1. A record containing the results of individual monitoring shall be made for each exposed worker for whom such monitoring is performed.

2. For the purposes of paragraph 1, the following information on exposed workers shall be retained:

- (a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 39, 40, 51, and 52;
- (b) in the case of exposures as referred to in Articles 40 and 52, the reports relating to the circumstances and the action taken;
- (c) the results of workplace monitoring used to assess individual doses where necessary.

3. ***Therecord referred to in paragraph 1 shall be submitted to the data system for individual radiological monitoring established by the Member State in accordance with Annex VIII.*** The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure. [Am. 83]

4. Exposure as referred to in Articles 40, 51, and 52 shall be recorded separately in the record referred to in paragraph 1.

5. Where the results of monitoring are used for the management of planned exposure situations, appropriate arrangements shall be made for not including in the records exposures attributed to an existing exposure situation namely background external radiation or radon ingress from soil in the case of industries processing naturally occurring radioactive material.

#### Article 42

##### Access to the results

1. The Member States shall require that the results of the individual monitoring set out in Articles 39, 40 and 52 be:

- (a) made available to the competent authorities, to the undertaking, and to the employer of outside workers;
- (b) made available to the worker concerned in accordance with Article 43(1);
- (c) submitted to the occupational health services in order for them to interpret the implications of the results for human health, as provided for in Article 44;
- (d) submitted to the data system for individual radiological monitoring established by the Member State in accordance with paragraph 2.

Thursday 24 October 2013

2. Member States shall determine the arrangements under which the results of individual monitoring are conveyed.
3. The data system for individual radiological monitoring shall communicate at least the data listed in Annex VIII, Section A.
4. In the case of an accidental or emergency exposure, the results of individual monitoring shall be communicated without delay.

#### Article 43

##### Workers' access to the results

1. Member States shall require workers to have access at their request ***in a timely manner*** to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of workplace measurements. [Am. 84]
2. Member States shall facilitate the exchange among competent authorities, occupational health services, radiation protection experts, or dosimetry services within the Union of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 44 and to control the further exposure of workers.

#### Article 44

##### Medical surveillance of exposed workers

1. The medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.
2. The medical surveillance of category A workers shall be the responsibility of occupational health services.

This medical surveillance shall allow for the state of health of workers under surveillance to be ascertained as regards their fitness for the tasks assigned to them. To this end, the occupational health services shall have access to any relevant information they require, including the environmental conditions in the working premises.

3. Medical surveillance shall include:
  - (a) A medical examination prior to employment or classification as a category A worker to determine the worker's fitness for a post as a category A worker for which the worker is being considered.
  - (b) Periodic reviews of health.

The state of health of all category A workers shall be reviewed at least once a year, in order to determine whether they remain fit to perform their duties. The nature of these reviews, which can be performed as many times as the occupational health services consider necessary, shall depend on the type of work and on the individual worker's state of health.

**3a. Examination of the workers will take place during working hours and without costs to them. [Am. 85]**

4. The occupational health services may indicate the need for medical surveillance to continue after cessation of work for as long as they consider it necessary to safeguard the health of the person concerned.

Thursday 24 October 2013

## Article 45

## Medical classification

The following medical classification shall be established with respect to fitness for work as a category A worker:

- (a) fit;
- (b) fit, subject to certain conditions;
- (c) unfit.

## Article 46

## Prohibition to employ or classify unfit workers

No worker may be employed or classified for any period in a specific post as a category A worker if medical surveillance establishes that the worker is unfit for that specific post.

## Article 47

## Medical records

1. A medical record shall be opened for each category A worker and kept up to date so long as the worker remains a worker in that category. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionising radiation.
2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by Article 41.

## Article 48

## Special medical surveillance

1. In addition to the medical surveillance of exposed workers provided for in Article 44, provision shall be made for any further action considered necessary by the occupational health services for the health protection of exposed individuals, such as further examinations, decontamination measures or urgent remedial treatment.
2. Special medical surveillance shall be performed in each case where an annual effective dose of 50 mSv in a year or any of the other dose limits laid down in Article 10(2) has been exceeded.
3. Subsequent exposure conditions shall be subject to the agreement of the occupational health services.

## Article 49

## Appeals

1. Member States shall lay down the procedure for appeal against the findings and decisions made pursuant to Articles 45, 46 and 48.
2. ***Consultation and participation of workers and/or their representatives shall be regulated by Article 11 of Council Directive 89/391/EEC <sup>(1)</sup>. [Am. 86]***

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<sup>(1)</sup> Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 193, 29.6.1989, p. 1).

Thursday 24 October 2013

Article 50

Protection of outside workers

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection **and medical care** to that for workers employed on a permanent basis by the undertaking. [Am. 87]
2. The undertaking shall be responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers.
3. In particular, the undertaking shall:
  - (a) check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;
  - (b) ensure that, in addition to the basic training in radiation protection referred to in Article 16, the outside worker has received specific training in connection with the characteristics of both the controlled area and the activities;
  - (c) ensure that the outside worker has been issued with the necessary personal protective equipment;
  - (d) ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;
  - (e) ensure compliance with the system of protection as defined in Chapter III;
  - (f) ensure or take all appropriate steps to ensure that after every activity the radiological data referred to in Annex VIII, Section B, point 2. from individual exposure monitoring of each outside worker are recorded.
4. Employers of outside workers shall, either directly or through contractual agreements with the undertaking, ensure that the radiation protection of their workers is in accordance with the relevant provisions of this Directive, in particular by:
  - (a) ensuring compliance with the system of protection as defined in Chapter III;
  - (b) providing the information and training in the field of radiation protection referred to in Article 16;
  - (c) guaranteeing that their workers are subject to the assessment of exposure and medical surveillance under the conditions laid down in Articles 37, 39 to 48;
  - (d) ensuring that the radiological data from the individual exposure monitoring of each of their workers within the meaning of Annex VIII, Section B, point 1, are kept up to date in the data system for individual radiological monitoring referred to in Article 42(1)(d).
5. All outside workers shall be obliged to make their own contribution as far as practicable towards the protection to be afforded to them by the radiological monitoring system referred to in paragraph 1.

Thursday 24 October 2013

## Article 51

## Specially authorised exposures

1. In exceptional circumstances evaluated case by case, excluding emergencies, the competent authorities may, where a specific operation so requires, authorise individual occupational exposures of identified volunteer workers exceeding the dose limits set out in Article 10, provided that such exposures are limited in time, confined to certain working areas and within the maximum exposure levels defined for the particular case by the competent authorities. The following conditions shall be taken into account:

- (a) only category A workers as defined in Article 38 may be subject to such exposures;
- (b) apprentices, students, pregnant women, and, if there is a risk of intake of radionuclides, breastfeeding women shall be excluded from such exposures;
- (c) the undertaking shall carefully justify such exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the occupational health services or the radiation protection expert;
- (d) information about the risks involved and the precautions to be taken during the operation shall be provided to the relevant workers in advance;
- (e) all doses relating to such exposures shall be separately recorded in the medical record referred to in Article 47 and the individual record referred to in Article 41.

2. The exceeding of dose limits as a result of specially authorised exposures shall not necessarily constitute a reason for excluding workers from their usual occupation or relocating them, without their agreement.

3. The exposure of space crew above the dose limits shall be managed as a specially authorised exposure.

## Article 52

## Emergency occupational exposure

1. Emergency response organisations shall ensure that no emergency worker undertakes actions resulting in doses in excess of 50 mSv, except in specific cases identified in the national emergency plan. In such cases, appropriate reference levels above 50 mSv shall be defined. In exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level above 100 mSv may be set.

2. Emergency response organisations shall ensure that emergency workers who are liable to undertake actions whereby 50 mSv may be exceeded are volunteers who have been clearly and comprehensively informed in advance of the associated health risks and the available protection measures.

3. In the event of an emergency exposure, Member States shall require radiological monitoring and medical surveillance of emergency workers. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

## Article 53

## Radon in workplaces

1. Within the action plan referred to in Article 103, Member States shall establish national reference levels for indoor radon concentrations. Such reference levels shall not exceed an annual average of 1 000 Bq m<sup>-3</sup> for workplaces.

2. Under the national action plan, Member States shall ensure that radon measurements are carried out in workplaces located on the ground floor or at basement level within radon-prone areas and in specific types of workplaces as identified in the action plan.

Thursday 24 October 2013

3. Member States shall require undertakings in which the national reference level for existing workplaces is exceeded to take appropriate action in order to reduce radon concentrations or exposures, in accordance with the principle of optimisation set out in Chapter III.

4. Where workplaces or specific rooms within a building continue to exceed the reference level despite the action taken in accordance with paragraph 3, the Member States shall manage this situation as a planned exposure situation and apply the relevant requirements for occupational exposure as specified in Article 30.1(d).

## CHAPTER VII

### PROTECTION OF PATIENTS AND OTHER INDIVIDUALS SUBJECTED TO MEDICAL EXPOSURE

#### Article 54

##### Justification

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health or well-being of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

Account shall also be taken of the individual detriment from the exposure of the medical radiological staff and other individuals.

In particular the following requirements shall be applied:

- (a) all new types of practices involving medical exposure shall be justified in advance before being generally adopted;
- (b) existing types of practices involving medical exposure shall be reviewed whenever new, important evidence about their efficacy or consequences is acquired;
- (c) all individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type may be justified in special circumstances, to be evaluated on a case-by-case basis and documented.

The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

#### **1a. *Staff shall be trained regularly and compliance with the applicable rules shall be monitored.* [Am. 88]**

2. Medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities.

3. Specific justification for medical radiological procedures to be performed as part of a health screening programme shall be carried out by the health authority in conjunction with appropriate professional bodies.

4. The exposure of carers and comforters shall show a sufficient net benefit, taking into account the direct health benefits to a patient, the benefits to the carer/comforter and the detriment that the exposure might cause.

Thursday 24 October 2013

5. Any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, shall be part of a health screening programme, or shall require specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant professional bodies and competent authorities. Special attention shall be given to the provision of information to the patients, as required by Article 56(3).

6. If an exposure cannot be justified in accordance with paragraphs 1 to 5, it shall be prohibited.

#### Article 55

#### Optimisation

1. All doses due to medical exposure for radiodiagnostic and interventional radiology purposes shall be kept as low as reasonably achievable consistent with obtaining the required imaging information, taking into account economic and social factors.

For all medical exposure of individuals for radiotherapeutic purposes, exposures of target volumes shall be individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

3. Member States shall ensure that for each biomedical and medical research project:

(a) the individuals concerned participate voluntarily;

(b) these individuals are ~~informed~~ **given full information** about the risks of exposure; [Am. 89]

(c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

(d) in the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer.

4. The optimisation shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, **including appropriate staff training**, and the assessment and evaluation of patient and staff doses or administered activities, taking into account economic and social factors. [Am. 90]

5. Member States shall ensure that:

(a) dose constraints are established for the exposure of carers and comforters;

(b) appropriate guidance is established for the exposure of carers and comforters, **as well as for the proper use of the equipment**. [Am. 91]

6. Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as appropriate, provides the patient or legal guardian with written instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable and providing information on the risks of ionising radiation.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

#### Article 56

#### Responsibilities

1. The referrer and the practitioner shall be involved in the justification process as specified by Member States.

Thursday 24 October 2013

2. Member States shall ensure that any medical exposure takes place under the clinical responsibility of a practitioner.
3. The practitioner shall ensure that the patient or legal guardian is provided with ~~adequate~~ **concise and easily understandable** information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent. Similar information as well as relevant guidance in accordance with Article 55(5)(b) shall be given to carers and comforters. **[Am. 92]**
4. Practical aspects of medical exposure procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

#### Article 57

##### Procedures

1. Written protocols for every type of standard medical radiological procedure shall be established for each equipment.
2. Member States shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers.
3. In medical radiological practices, a medical physics expert shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:
  - (a) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;
  - (b) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, a medical physics expert shall be involved;
  - (c) for other simple radiodiagnostic procedures, a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.
4. Clinical audits shall be carried out in accordance with national procedures.
5. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective action is taken where appropriate.

#### Article 58

##### Training

Member States shall ensure that training and recognition requirements, as laid down in Articles 15, 19 and 81, are met for the practitioner, the medical physics expert and the individuals referred to in Article 56(4).

#### Article 59

##### Equipment

1. Member States shall take such steps as they consider necessary with a view to avoiding unnecessary proliferation of medical radiological equipment.
2. Member States shall ensure that:
  - (a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection **and is disposed of in accordance with the appropriate legislation in force**; **[Am. 93]**
  - (b) an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authorities;
  - (c) appropriate quality assurance programmes and dose or administered activity assessments are implemented by the undertaking; and

Thursday 24 October 2013

- (d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure. **In performing such testing, Member States shall comply with the Commission guidelines (in particular, Radiation Protection No. 162 — Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy) and European and international standards currently applicable to medical radiological equipment (IEC60601 on Electrical equipment in medical practice, IAEA Standards, ICRP Guidelines).** [Am. 94]
3. Competent authorities shall take steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective features of medical radiological equipment. They shall also adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including, if appropriate, taking the equipment out of service.
4. The use of fluoroscopy equipment without a device to control the dose rate, or without an image intensifier or equivalent device, shall be prohibited.
5. Any equipment used for interventional radiology and computed tomography shall have a device or a feature informing the practitioner of the quantity of radiation produced by the equipment during the medical radiological procedure. Any other medical radiodiagnostic equipment brought into use after this Directive has entered into force shall have such a device or a feature or equivalent means of determining the quantity of radiation produced. The radiation dose shall form part of the report on the examination.

#### Article 60

##### Special practices

1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment are used for medical exposure
- (a) of children;
- (b) as part of a health screening programme;
- (c) involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

Special attention shall be given to quality assurance programmes and the assessment of dose or administered activity, as mentioned in Article 59(2)(c), for these practices.

2. Member States shall ensure that practitioners and those individuals referred to in Article 56(4) who perform the exposures referred to in paragraph 1 of this Article obtain appropriate training in these medical radiological practices as required by Article 19.

#### Article 61

##### Special protection during pregnancy and breastfeeding

1. In the case of a woman of childbearing age, the referrer and the practitioner shall inquire as specified by Member States whether she is pregnant or breastfeeding, if relevant.

If pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure both of the expectant mother and the unborn child.

2. In the case of breastfeeding women, in nuclear medicine, depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure both of the mother and the child.
3. Without prejudice to paragraphs 1 and 2, Member States shall take measures to increase the awareness of women to whom this Article applies, such as public notices in appropriate places.

Thursday 24 October 2013

## Article 62

### Accidental and unintended exposures

Member States shall ensure that:

- (a) all reasonable steps are taken to minimise the probability and magnitude of accidental or unintended exposures of patients from all medical radiological procedures, taking into account economic and social factors;
- (b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;
- (c) for all medical exposures the undertaking implements a system for the registration and analysis of events involving or potentially involving accidental or unintended exposures;
- (d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events. ***In the case of medical devices, the undertaking or the user shall immediately forward all relevant information to the competent authorities*** ~~shall share this information with the competent authorities~~ for post-market surveillance established in Council Directive 93/42/EEC concerning medical devices. ***Where necessary those authorities shall notify other competent authorities;*** [Am. 95]
- (e) arrangements are made to inform the referrer, the practitioner and the patient about an unintended or accidental exposure.

## Article 63

### Estimates of population doses

Member States shall ensure that the distribution of individual dose estimates from medical exposure is determined and shall take into account the age distribution and the gender of the exposed population.

## CHAPTER VIII

### PROTECTION OF MEMBERS OF THE PUBLIC

## Section 1

### Protection of members of the public in normal circumstances

## Article 64

### Principles of protection of members of the public

Member States shall create the conditions necessary to ensure the best possible protection of members of the public under the prevailing circumstances, based on the principles set out in Chapter III on the system of radiation protection and applying the requirements laid down in this Chapter.

## Article 65

### Operational protection of members of the public

1. The operational protection of members of the public in normal circumstances from practices subject to licensing shall include all arrangements and surveys for detecting and eliminating factors which, in the course of any operation involving exposure to ionising radiation, are liable to create a risk of exposure for members of the public which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:

- (a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;

Thursday 24 October 2013

- (b) acceptance into service of new installations involving an exposure risk, subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;
- (c) examination and approval of plans for the discharge of radioactive effluents.

These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the exposure risk involved.

2. The competent authority shall establish **and publish** authorised limits for discharging radioactive effluents. These discharge authorisations shall [Am. 96]

- (a) take into account **the doses received by members of the public due to existing anthropogenic situations and other planned activities and** the results of the optimisation of public exposure; [Am. 97]
- (b) reflect good practice in the operation of similar facilities;
- (c) allow a margin for operational flexibility of a facility.

#### Article 66

##### Estimation of doses to members of the public

1. Member States shall, on the basis of the exposure risk involved, establish a system for the estimation of doses to members of the public from planned exposure situations.
2. The competent authorities shall identify practices where a realistic assessment of doses to members of the public shall be carried out. For other practices Member States may require only a screening assessment with generic data.
3. For the realistic assessment of doses to members of the public, the competent authority shall:
  - (a) ensure that dose estimates for practices as referred to in Article 65 are made as realistic as possible for representative persons;
  - (b) decide on the frequency of assessments and take all necessary steps to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;
  - (c) ensure, taking into account the radiological risks, that the estimates of doses to members of the public include:
    - (i) assessment of the doses due to external radiation, indicating, where appropriate, the quality of the radiation in question;
    - (ii) assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity and concentrations of these radionuclides;
    - (iii) assessment of the doses that the representative person is liable to receive and specification of the characteristics of the representative person;
  - (d) require records to be kept and be made available to all stakeholders relating to measurements of external exposure, estimates of intakes of radionuclides and radioactive contamination, and the results of the assessment of the doses received by the representative person.

#### Article 67

##### Monitoring of radioactive discharges

1. Member States shall require the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately the radioactive airborne or liquid discharges into the environment and to report the results of this monitoring to the competent authority.

Thursday 24 October 2013

2. Member States shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor discharges in normal operation in accordance with the standardised information selected for monitoring and reporting to the European Commission as laid down in Commission Recommendation 2004/2/Euratom <sup>(1)</sup>.

#### Article 68

##### Tasks for the undertakings

1. Member States shall require the undertaking to carry out the following tasks:

- (a) achieving and maintaining ~~an optimal~~ **the highest** level of protection **of public health and the environment**; [Am. 98]
- (b) checking the effectiveness and maintenance of technical devices;
- (c) acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring and assessing, as appropriate, exposure of members of the public and radioactive contamination of the environment;
- (d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

2. Radiation protection experts and, as appropriate, radiation protection officers shall be involved in the performance of the tasks referred to in paragraph 1.

#### Article 69

##### Environmental monitoring programme

Member States shall ensure that an appropriate environmental monitoring programme is in place for estimating the exposure of members of the public.

#### Section 2

##### Emergency exposure situations

#### Article 70

##### Emergency response

1. Member States shall require the undertaking responsible for a **licensed** practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences. [Am. 99]

2. Member States shall ensure that, in the event of an emergency on its own territory, the undertaking makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.

**2a. Member States should inform each other immediately about any radiation emergency that has occurred on their territory.** [Am. 100]

3. Member States shall ensure that provision is made for protective measures with regard to:

- (a) the radiation source, to reduce or stop the direct radiation and emission of radionuclides, or to prevent exposure or contamination resulting from orphan sources;
- (b) the environment, to reduce the transfer of radioactive substances to individuals;
- (c) individuals, to reduce exposure **and to be fully informed, as quickly as possible, of the risks and possible side effects of the emergency that has occurred.** [Am. 101]

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<sup>(1)</sup> OJ L 2, 6.1.2004, p. 36.

Thursday 24 October 2013

4. In the event of an emergency on or outside its territory, the Member State or the emergency response authority shall require:
  - (a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Annex IX, Section B;
  - (b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.
5. The Member State or the emergency response authority shall, if the situation so requires, ensure that provision is made to organise the medical treatment of victims.

#### Article 71

##### Information to members of the public likely to be affected in the event of an emergency

1. Member States shall ensure that members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency. ***This shall apply, at the very least, for people living within 50km of an installation at risk.*** [Am. 102]
2. The information supplied shall include at least the elements set out in Annex X, Section A.
3. The information shall be communicated to the members of the public referred to in paragraph 1 without any request being made.
4. Member States shall update the information and circulate it at regular intervals and whenever significant changes take place. This information shall be permanently available to the public.

#### Article 72

##### Information to the members of the public actually affected in the event of an emergency

1. Member States shall ensure that, when an emergency occurs, the members of the public actually affected are informed without delay of the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.
2. The information provided shall cover those points contained in Annex X, Section B which are relevant to the type of emergency.

#### Article 72a

##### ***Informing the general public***

***As soon as news of an emergency situation is received, Member States shall ensure that the general public is informed as quickly as possible.***

***All information necessary for an assessment of the situation and its development — in particular weather data and forecasts, air movements and ground deposits, ambient dose rates and contamination levels of critical foodstuffs — shall be made public. The relevant authorities shall make public forecasts of the effective dose and equivalent dose for the vital organs, planned and completed interventions, and the expected and actual residual doses.*** [Am. 103]

#### Section 3

##### Existing exposure situations

#### Article 73

##### Contaminated areas

1. Strategies for managing contaminated areas shall include, where applicable, the following:
  - (a) delineation of the affected regions and identification of the affected members of the public;

Thursday 24 October 2013

- (b) consideration of the need for and extent of protective measures applied to the affected regions and members of the public;
- (c) consideration of the need to prevent or control access to the affected regions, or to impose restrictions on living conditions in these regions;
- (d) assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure;
- (e) objectives and long-term goals pursued by the strategy and corresponding reference levels.

2. For areas with long-lasting residual contamination in which the Member State has decided to allow habitation and the resumption of social and economic activities, Member States shall ensure, in consultation with stakeholders, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:

- (a) establishment of reference levels consistent with day-to-day life;
- (b) establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring.

#### Article 74

##### Radon in dwellings and buildings with public access

1. Within the action plan referred to in Article 103, Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed (as an annual average):

- (a) 200 Bq m<sup>-3</sup> for new dwellings and new buildings with public access;
- (b) 300 Bq m<sup>-3</sup> for existing dwellings;
- (c) 300 Bq m<sup>-3</sup> for existing buildings with public access. In specific cases where the occupancy time is low, a reference level of up to 1 000 Bq m<sup>-3</sup> can be set.

2. Under the national action plan, Member States shall

- (a) identify existing dwellings exceeding the reference level and to encourage radon-reducing measures in existing dwellings where the reference levels are exceeded;
- (b) ensure that radon measurements are carried out in buildings with public access within radon-prone areas.

3. Member States shall establish specific building codes to prevent radon ingress from the soil and, as specified in the national action plan, from building materials, and require compliance with such building codes, in particular in radon-prone areas, so as to avoid radon concentrations exceeding the reference level for new buildings.

4. Member States shall provide local and national information on prevailing radon concentrations, on the associated health risks and on the technical means available for reducing existing radon concentrations.

#### Article 75

##### Building materials

1. The requirements laid down in this Article shall apply to the following:

- (a) building materials which are identified and listed by the relevant competent authority as being of concern from the radiation protection point of view, taking into account the indicative list of materials set out in Annex XI with regard to their emitted gamma radiation; or

Thursday 24 October 2013

- (b) building materials which the authority has assessed to be of concern in the national action plan for radon, as specified in Article 103.
2. For identified types of building materials, the industries placing such materials on the market
- (a) shall determine the concentrations of the radionuclides specified in Annex VII;
- (b) shall provide information to the competent authority on the results of measurements and the corresponding activity concentration index, as defined in Annex VII.
3. The competent authority shall ensure that identified types of building materials are classified, as laid down in Annex VII, on the basis of their intended use and activity concentration index.
4. Identified types of building materials which are not liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of prevailing outdoor external exposure, shall be exempt from requirements at national level, without prejudice to Article 103. Such building materials shall nevertheless be further monitored to ensure that the activity concentration continues to comply with this reference level. Building materials of category A as specified in Annex VII shall be exempt from any restrictions with regard to their placing on the market in the Union.
5. For identified types of building materials which are liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of the prevailing outdoor external exposure, the competent authority shall decide on appropriate measures, ranging from registration and general application of relevant building codes to specific restrictions on the envisaged use of such materials.
6. Information on identified types of building materials, relevant to the implementation of building codes, including their radionuclide concentrations, activity concentration index and corresponding classification, shall be made available prior to their placing on the market.

## CHAPTER IX

## PROTECTION OF THE ENVIRONMENT

## Article 76

## Environmental criteria

Member States shall include, in their legal framework for radiation protection and in particular within the overall system of human health protection, provision for the radiation protection of non-human species in the environment. This legal framework shall introduce environmental criteria aiming to protect populations of vulnerable or representative non-human species in the light of their significance as part of the ecosystem. Where appropriate, types of practices shall be identified for which regulatory control is warranted in order to implement the requirements of this legal framework. **To this end, Member States shall strengthen research in this area and update the legal framework to take account of any new findings accordingly.** [Am. 104]

## Article 77

## Authorised limits on discharges

Member States' competent authorities, when establishing authorised limits on discharges of radioactive effluents, in accordance with Article 65(2), shall also ensure adequate protection of non-human species. For this purpose, a generic screening assessment may be conducted to provide assurance that the environmental criteria are met.

## Article 78

## Accidental releases

Member States shall require undertakings to take appropriate technical measures to avoid significant environmental damage in the event of an accidental release or to mitigate the extent of such damage. **National authorities shall provide for random periodic checks of sites or installations, as well as of the practices used by the undertakings, in order to ensure that such measures are being taken or are in place.** [Am. 105]

Thursday 24 October 2013

## Article 79

### Environmental monitoring

When establishing environmental monitoring programmes, or requiring such programmes to be carried out, Member States' competent authorities shall include representative non-human species, ~~if necessary~~, and also environmental media which constitute a pathway of exposure for members of the public. ***In order to enhance the transparency and effectiveness of measures taken, Member States' national authorities shall regularly exchange data and information on environmental radioactivity monitoring, including the immediate dissemination of new data.*** [Am. 106]

## CHAPTER X

### REQUIREMENTS FOR REGULATORY CONTROL

## Section 1

### Institutional infrastructure

## Article 80

### Competent authority

1. Member States shall designate the competent authority or authorities to carry out ~~tasks~~ ***the regulatory control*** provided for in this Directive. ***The competent authority or authorities shall be functionally independent from any institution promoting or operating nuclear power.*** [Am. 107]

***1a. Each Member State shall ensure that public participation is enforced according to national legislation by the competent authority of the Member State when dose limits are set or amended.*** [Am. 108]

***1b. The public participation procedures shall include reasonable time-frames for the different phases, allowing sufficient time for informing the public and for the public to prepare and participate effectively during the decision making process.*** [Am. 109]

***1c. The competent authority shall ensure that in the decision for dose limits due account is taken of the outcome of public participation.*** [Am. 110]

2. Member States shall forward to the Commission the name and address of the competent authority or authorities and their respective areas of competence to ensure rapid communication with such authorities.

3. Where a Member State has more than one competent authority for the control of high-activity sealed sources and orphan sources, it shall designate one point of contact for communication with the competent authorities of other Member States.

4. Member States shall forward to the Commission any changes to the information referred to in paragraphs 2 and 3.

5. The Commission shall communicate the information referred to in paragraphs 2, 3 and 4 to all competent authorities and shall publish it periodically in the *Official Journal of the European Union*, at intervals of no more than two years.

## Article 81

### Recognition of services and experts

1. Member States shall make the necessary arrangements for the recognition of:

(a) occupational health services;

(b) dosimetry services;

(c) radiation protection experts ***and radiation protection officers;*** [Am. 111]

Thursday 24 October 2013

(d) medical physics experts.

Member States shall lay down provisions to ensure the continuity of expertise *and independence* of these services and experts. [Am. 112]

2. Member States shall specify the recognition requirements and communicate them to the Commission together with the name and address of the competent authorities in charge of recognition. Member States shall communicate any changes to this information.

3. Member States shall specify other services or experts requiring particular radiation protection qualifications and, where appropriate, the process for the recognition of such qualifications.

4. The Commission shall make the information received in accordance with paragraph 2 available to the Member States.

#### Article 82

##### Occupational health services

Occupational health services shall perform medical surveillance of exposed workers with regard to their exposure to ionising radiation and their fitness for the tasks assigned to them.

#### Article 83

##### Dosimetry services

Dosimetry services shall determine the internal and external dose to exposed workers subject to individual monitoring in order to record the dose in cooperation with the undertaking and the occupational health service. Dosimetry services shall include the calibration, reading and interpretation of individual monitoring devices, and the measurement of radioactivity in the human body and in biological samples.

#### Article 84

##### Radiation protection expert

1. The radiation protection expert shall, on the basis of professional judgment, measurements and assessments, give competent advice to the undertaking on matters relating to occupational exposure and public exposure.

2. The advice of the radiation protection expert shall cover, but not be limited to, the following:

- (a) plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
- (b) the categorisation of controlled and supervised areas;
- (c) the classification of workers;
- (d) the content of workplace and individual monitoring programmes;
- (e) the appropriate radiation monitoring instrumentation to be used;
- (f) the appropriate methods of personal dosimetry;
- (g) the optimisation and establishment of appropriate dose constraints,
- (h) quality assurance;
- (i) the environmental monitoring programme;
- (j) radioactive waste disposal requirements;
- (k) the arrangements for prevention of accidents and incidents;
- (l) preparedness and response in emergency exposure situations;
- (m) training and retraining programmes for exposed workers.

Thursday 24 October 2013

3. Where appropriate, the task of the radiation protection expert may be carried out by a group of specialists who together have the necessary expertise.

#### Article 85

##### Medical physics expert

1. Within the health care environment, the medical physics expert shall, as appropriate, act or give specialist advice on matters relating to radiation physics as applied to medical exposure.
2. Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient, give advice on medical radiological equipment, and contribute in particular to the following:
  - (a) optimisation of the radiation protection of patients and other individuals subjected to medical exposure, including the application and use of diagnostic reference levels;
  - (b) the definition and performance of quality assurance of the medical radiological equipment;
  - (c) the preparation of technical specifications for medical radiological equipment and installation design;
  - (d) the surveillance of the medical radiological installations with regard to radiation protection;
  - (e) the selection of equipment required to perform radiation protection measurements;
  - (f) the training of practitioners and other staff in relevant aspects of radiation protection;

**(fa) establishing documented procedures for providing information to and training for exposed workers.** [Am. 113]

Where appropriate, the task of the medical physics expert may be carried out by a medical physics service.

#### Article 86

##### Radiation protection officer

1. Member States shall decide in which practices the designation of a radiation protection officer is necessary to perform radiation protection tasks within an undertaking. Member States shall require undertakings to provide the radiation protection officers with the means necessary for them to carry out their duties. The radiation protection officer shall report directly to the undertaking.
2. Depending on the nature of the practice, the tasks of the radiation protection officer may include the following:
  - (a) ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
  - (b) supervise implementation of the programme for workplace monitoring;
  - (c) maintaining adequate records of radioactive sources;
  - (d) carrying out periodic assessments of the condition of the relevant safety and warning systems;
  - (e) supervise implementation of the personal monitoring programme;
  - (f) supervise implementation of the health surveillance programme;
  - (g) providing new employees with an introduction to local rules and procedures;
  - (h) giving advice and comments on work plans;
  - (i) authorising work plans;
  - (j) providing reports to the local management;

Thursday 24 October 2013

- (k) participating in the arrangements for prevention, preparedness and response for emergency exposure situations;
- (l) liaising with the radiation protection expert;

**(la) establishing documented procedures for providing information to and training of exposed workers.** [Am. 114]

The task of the radiation protection officer may be carried out by a radiation protection unit established within an undertaking.

## Section 2

### Control of sealed sources

#### Article 87

##### General requirements

1. Member States shall make arrangements for keeping adequate control of sealed sources with regard to their location, use and disuse.
2. Member States shall require the undertaking to keep records of all such sources under its responsibility, their location and their transfer.
3. Member States shall set up a system to enable them to be adequately informed of individual transfers of sealed sources, where necessary, and in any event of transfers of high-activity sealed sources.
4. Member States shall require each undertaking holding a sealed source to notify the competent authority promptly of any loss, theft or unauthorised use of a sealed source.

#### Article 88

##### Requirements for control of high-activity sealed sources

Member States shall ensure that, before issuing authorisation for practices involving a high-activity sealed source:

- (a) adequate arrangements have been made for the safe management and security of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;
- (b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

#### Article 89

##### Specific requirements for licensing of high-activity sealed sources

In addition to the general licensing requirements set out in Chapter V, Member States shall ensure that the licence for the manufacture, use or taking possession of a high-activity sealed source includes:

- (a) minimum performance criteria for the source, source container and additional equipment;
- (b) work procedures to be followed;
- (c) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

Thursday 24 October 2013

#### Article 90

##### Record keeping by the undertakings

Member States shall require that the records for high-activity sealed sources include the information set out in Annex XII and that the undertaking provides the competent authorities with a copy of all or part of these records upon request and at least as set out in Annex XIII. The undertaking's records shall be available for inspection by the competent authority.

#### Article 91

##### Record keeping by the competent authorities

**1.** The competent authorities shall keep records of undertakings authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources they hold. These records shall include the radionuclide involved, the activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market or at the time the undertaking acquired the source, and the type of source. The competent authorities shall keep the records up to date, taking transfers of the sources and other factors into account.

**2..** *Member States shall ensure that licence-holders mark containers and document the practices with high-activity sealed sources in a form not subject to weathering. The documentation shall comprise both the chemical, toxic and radiological composition of the inventory and an indication of whether it is solid, liquid or gaseous. [Am. 115]*

#### Article 92

##### Security of high-activity sealed sources

1. The undertaking carrying out activities involving high activity sealed sources shall comply with requirements set out in Annex XIV.
2. The manufacturer, the supplier, and each undertaking shall ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Annex XV.

#### Section 3

##### Orphan sources

#### Article 93

##### Detection of orphan sources

1. Member States shall require any person encountering an orphan source to promptly notify the emergency organisation or the competent authority and to refrain from any further action on the source until these bodies have given appropriate instructions.
2. Member States shall make arrangements for the establishment of systems to detect orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate, such as customs posts.
3. Member States shall ensure that specialised technical advice and assistance is promptly made available to persons who work in the places referred to in paragraph 2 and who are not normally involved in operations subject to radiation protection requirements. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

#### Article 94

##### Metal contamination

Member States shall require that a metal scrap recycling installation promptly notifies the competent authority of any melting of an orphan source and shall require that the contaminated metal not be further processed without authorisation by the competent authority.

Thursday 24 October 2013

## Article 95

## Recovery, management and disposal of orphan sources

1. Member States shall ensure that the competent authorities are prepared, or have made provision, including assignment of responsibilities, to recover orphan sources and to deal with emergencies due to orphan sources and have drawn up appropriate response plans and measures.
2. Member States shall ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past practices.

The campaigns may include the financial participation of Member States in the costs of recovering, managing and disposing of the sources and may also include surveys of historical records of authorities, such as customs, and of undertakings, such as research institutes, material testing institutes or hospitals.

## Article 96

## Financial security for orphan sources

Member States shall ensure that, on the basis of arrangements to be decided by Member States, a financial security system or other equivalent means is established to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of Article 95.

## Section 4

## Emergency exposure situations

## Article 97

## Emergency management system

1. Member States shall ensure that account is taken of the fact that emergencies may occur on their territory and that they may be affected by emergencies occurring outside their territory. Member States shall establish an emergency management system and adequate administrative provisions to maintain such a system.
2. The emergency management system shall be designed to be commensurate with the results of a threat assessment and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events, including malevolent acts and the discovery of orphan sources.
3. The emergency management system shall provide for the establishment of emergency response plans with the objective of avoiding deterministic effects in any individual from the affected members of the public and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Chapter III. The emergency management system shall include the elements listed in Annex IX, Section A.

## Article 98

## Emergency preparedness

1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by the threat assessment.
2. Member States shall ensure that emergency response plans are tested, reviewed and revised at regular intervals.
3. The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 97.
4. The emergency response plans shall include the elements defined in Annex IX, Section B.

Thursday 24 October 2013

## Article 99

### International cooperation

1. Member States shall cooperate with other Member States and third countries in addressing possible emergencies on their own territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in these Member States or third countries.
2. Member States shall, in the event of an emergency occurring on their territory or likely to have radiological consequences on its territory, establish contact to obtain the cooperation of any other Member State or third country which may be involved.
3. Member States shall promptly exchange information and cooperate with other relevant Member States or third countries and with relevant international organisations regarding the loss, removal, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.

## Section 5

### Existing exposure situations

## Article 100

### Programmes on existing exposure situations

1. Member States shall ensure that programmes are established to identify and evaluate existing exposure situations and to determine which occupational and public exposures are of concern from a radiation protection point of view.
2. The requirements for existing exposure situations shall apply to:
  - (a) exposure due to contamination of areas by residual radioactive material from:
    - (i) past activities that were never subject to regulatory control or were not regulated in accordance with the requirements laid down by this Directive;
    - (ii) an emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;
    - (iii) residues from past activities for which the undertaking is no longer legally accountable;
  - (b) exposure to natural radiation sources, including:
    - (i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;
    - (ii) indoor external exposure from building materials;
  - (c) exposure to commodities incorporating
    - (i) radionuclides from contaminated areas specified in point (a), or
    - (ii) naturally occurring radionuclides, in particular in foodstuffs, drinking water and building materials;
  - (d) other existing exposure situations which cannot be disregarded from a radiation protection point of view.
3. Member States may decide, having regard to the general principle of justification, that an existing exposure situation warrants no consideration of protective measures.
4. Existing exposure situations which are the legal responsibility of an undertaking and which are of concern from a radiation protection point of view shall be subject to the relevant requirements for planned exposure situations.

Thursday 24 October 2013

## Article 101

## Establishment of strategies

1. Member States shall arrange for the establishment of strategies to ensure that existing exposure situations are managed appropriately and that the resources made available for their management are commensurate with the risks and with the effectiveness of protective measures.
2. The competent authority charged with establishing a strategy for managing an existing exposure situation shall ensure that the strategy contains:
  - ~~(a)~~ the objectives pursued by the strategy, **in particular in terms of residual dose.** [Am. 116]
  - ~~(b)~~ appropriate reference levels, taking into account the bands of reference levels laid down in Annex I. [Am. 117]

## Article 102

## Implementation of strategies

1. Member States shall assign responsibilities to a competent authority for the implementation of strategies for the management of existing exposures, and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial and protective measures, and shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposures.
2. The form, scale and duration of all protective measures considered for implementation of a strategy shall be optimised.
3. The distribution of residual doses that has resulted from the implementation of a strategy shall be assessed. Further efforts shall be considered with the aim of reducing any exposures that are still above the reference level.
4. Throughout the implementation of a strategy, the competent authority shall regularly:
  - (a) evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;
  - (b) provide information to exposed individuals on the potential health risks and on the available means for reducing their own exposure;
  - (c) provide guidance for the management of exposures at individual or local level;
  - (d) with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, provide information to undertakings on appropriate means for monitoring concentrations and exposures and for taking protective measures in the context of overall health and safety requirements.

## Article 103

## Radon action plan

1. Member States shall establish an action plan to manage long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues set out in Annex XVI.
2. Member States shall forward the action plan and information on any identified radon-prone areas to the Commission. Member States shall update the action plan and information on radon-prone areas on a regular basis.

## Section 6

## System of enforcement

## Article 104

## Inspections

1. Member States shall establish a system or systems of inspection to enforce the provisions adopted pursuant to this Directive and to initiate surveillance and corrective action wherever necessary.

Thursday 24 October 2013

2. The competent authority shall establish a systematic inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with the provisions adopted pursuant to this Directive.
3. Member States shall ensure that the findings from each inspection are recorded and the reports communicated to the undertaking concerned.
4. Member States shall make the inspection programme and the main findings from its implementation available to the public.
5. The competent authority shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of sources and, where appropriate, international organisations, of protection and safety information concerning lessons learned from inspections and from reported incidents and accidents and related findings.

#### Article 105

##### Enforcement

Member States shall ensure that the competent authority has the power to require the undertaking to take action to remedy deficiencies and prevent their recurrence or to withdraw, where appropriate, authorisation when the results of a regulatory inspection or another regulatory assessment indicate that the undertaking is not in compliance with the provisions adopted pursuant to this Directive.

#### Article 106

##### Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 107 at the latest and shall notify it without delay of any subsequent amendment affecting them.

#### CHAPTER XI

##### FINAL PROVISIONS

#### Article 107

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [00.00.0000] at the latest. The provisions laid down in Chapter IX with regard to the protection of the environment shall be transposed by [00.00.0000] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive. ***The Commission shall report on those communications to the European Parliament.*** [Am. 118]

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

***Should a Member State plan to adopt standards stricter than those laid down by this Directive, it shall inform the Commission and the other Member States accordingly.*** [Am. 119]

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive. ***A summary of those communications shall be drawn up by the Commission, which shall forward it to the European Parliament.*** [Am. 120]

#### Article 108

##### Repeal

Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom, 2003/122/Euratom shall be repealed with effect from....

Thursday 24 October 2013

## Article 109

## Entry into force

The Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

## Article 110

## Addressees

This Directive is addressed to the Member States.

Done at ...,

*For the European Parliament*

*The President*

*For the Council*

*The President*

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ANNEX I

~~Bands of reference levels for public exposure~~

~~1. The optimisation of public exposures in emergency and existing exposure situations shall be based on a reference level to be established within the following bands, expressed in mSv effective dose (acute or annual):~~

- ~~(a) greater than 20 and less or equal to 100~~
- ~~(b) greater than 1 and less or equal to 20~~
- ~~(c) 1 or less.~~

~~The choice of the reference level shall fulfil the conditions set out in points 2-5.~~

~~2. Without prejudice to reference levels set for organ doses, reference levels expressed in effective doses shall be set in the range of 1 to 20 mSv per year for existing exposure situations and 20 to 100 mSv for emergency exposure situations.~~

~~3. In specific situations, a reference level below ranges referred to in point 1 may be considered, in particular:~~

- ~~(a) a reference level below 20 mSv may be set in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost;~~
- ~~(b) a reference level below 1 mSv per year may be set, where appropriate, in an existing exposure situation for specific source related exposures or pathways of exposure.~~

~~4. For the transition from an emergency exposure situation to an existing exposure situation, appropriate reference levels shall be set, in particular upon the termination of long-term countermeasures such as relocation.~~

~~5. The reference levels set shall take account of the features of prevailing situations as well as societal criteria, which may include the following:~~

- ~~(a) for exposures below 1 mSv or 1 mSv per year, general information on the level of exposure, without specific consideration of individual exposures;~~
  - ~~(b) in the range up to 20 mSv or 20 mSv per year, specific information to enable individuals to manage their own exposure, if possible;~~
  - ~~(c) in the range up to 100 mSv or 100 mSv per year, assessment of individual doses and specific information on radiation risks and on available actions to reduce exposures. [Am. 121]~~
-

Thursday 24 October 2013

## ANNEX II

## Activity values defining high-activity sealed sources

For radionuclides not listed in the table below, the relevant activity level is identical to the D-value defined in the IAEA publication 'Dangerous quantities of radioactive material (D-values)', (EPR-D-VALUES 2006).

Radionuclide	Activity level (TBq)
Am-241	$6 \times 10^{-2}$
Am-241/Be	$6 \times 10^{-2}$
Cf-252	$2 \times 10^{-2}$
Cm-244	$5 \times 10^{-2}$
Co-60	$3 \times 10^{-2}$
Cs-137	$1 \times 10^{-1}$
Gd-153	$1 \times 10^0$
Ir-192	$8 \times 10^{-2}$
Pm-147	$4 \times 10^1$
Pu-238	$6 \times 10^{-2}$
Pu-239/Be <sup>(1)</sup>	$6 \times 10^{-2}$
Ra-226	$4 \times 10^{-2}$
Se-75	$2 \times 10^{-1}$
Sr-90 (Y-90)	$1 \times 10^0$
Tm-170	$2 \times 10^1$
Yb-169	$3 \times 10^{-1}$

<sup>(1)</sup> The activity given is that of the alpha-emitting radionuclide

Thursday 24 October 2013

## ANNEX III

Placing on the market of apparatus or products *emitting ionising radiation* [Am. 122]

- A. Any undertaking intending to place on the market apparatus or products shall provide the competent authorities with all relevant information, including the following:
- (1) technical characteristics of the apparatus or product;
  - (2) in the case of apparatus containing radioactive substances, information on the means of fixation of the source in a holder and on shielding;
  - (3) dose rates at relevant distances for the use of the apparatus or product, including dose rates at a distance of 0,1 m from any accessible surface;
  - (4) intended use of the apparatus or product and information on the relative performance of the new apparatus or product compared to existing ones;
  - (5) expected doses to regular users of the apparatus or product;
- (5a) *the radiological risks associated with malfunctioning and accidents likely to affect the apparatus or product.* [Am. 123]**
- B. The competent authorities shall assess the information, listed in Section A and in particular shall assess:
- (1) whether the performance of the apparatus or product justifies its intended use;
  - (2) whether the design is adequate in order to reduce exposures in normal use and the likelihood and consequences of misuse or accidental exposures;
  - (3) in the case of a consumer product, whether the product is adequately designed to meet the exemption criteria and does not necessitate specific precautions for disposal when no longer in use;
  - (4) in the case of apparatus or products for use in practices exempted from authorisation, whether conditions for disposal are adequate;
  - (5) whether the apparatus or product is appropriately labelled and suitable documentation is provided to the ~~customer~~ **user** with instructions for proper use and disposal. [Am. 124]
- Ba. ***The competent authorities shall give prior and full information to potential users of apparatuses and products and shall ensure that they are involved in the decision-making process.* [Am. 125]**

## ANNEX IV

## Practices involving non-medical imaging exposure

For the purposes of Article 23, the following list of practices involving non-medical imaging exposure shall be taken into account:

- A. Procedures implemented by medical staff using medical radiological equipment:
1. Radiological health assessment for employment purposes;
  2. Radiological health assessment for immigration purposes;
  3. Radiological health assessment for insurance purposes;
  4. Radiological health assessment for other purposes not intended to benefit the health and well-being of the exposed individual;

Thursday 24 October 2013

5. Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing, etc.;
  6. Radiological age assessment;
  7. Use of ionising radiation for the identification of concealed objects within the human body.
- B. Procedures implemented by non-medical staff using non-medical equipment:
1. Use of ionising radiation for detection of concealed objects on or attached to the human body;
  2. Use of ionising radiation for detection of concealed humans as part of cargo screening;
  3. Other practices involving the use of ionising radiation for legal or security purposes.

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ANNEX V

List of industrial practices involving naturally occurring radioactive material

For the purposes of Article 24, the following list of industrial practices involving naturally occurring radioactive material, including relevant secondary processes, shall be taken into account:

- (1) extraction of rare earths from monazite;
  - (2) production of thorium compounds and manufacture of thorium-containing products;
  - (3) processing of niobium/tantalum ore;
  - (4) oil and gas production;
  - (5) geothermal energy production;
  - (6) TiO<sub>2</sub> pigment production;
  - (7) thermal phosphorus production;
  - (8) zircon and zirconium industry;
  - (9) production of phosphate fertilisers;
  - (10) cement production, maintenance of clinker ovens;
  - (11) coal-fired power plants, maintenance of boilers;
  - (12) phosphoric acid production;
  - (13) primary iron production;
  - (14) tin/lead/copper smelting;
  - (15) ground water filtration facilities;
  - (16) mining of ores other than uranium ore.
-

Thursday 24 October 2013

## ANNEX VI

## Exemption and clearance criteria

## 1. Exemption

Practices may be exempted from requirements of this Directive either directly, on the basis of compliance with numerical exemption criteria (activity values (Bq) or concentration values (Bq g<sup>-1</sup>)) laid down in Section 2, or through a regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria set out in Section 3, to exempt the practice from further requirements.

## 2. Exemption and clearance values

The total activity values (Bq) for exemption apply to the total activity involved in a practice and are laid down in column 3 of Table B for artificial radionuclides and for some naturally occurring radionuclides used in consumer products. For other practices involving naturally occurring radionuclides, such values are in general not applicable.

The exempt activity concentration values (Bq g<sup>-1</sup>) for the materials involved in the practice are laid down in Table A, Part 1 for artificial radionuclides and in Table A, Part 2 for naturally occurring radionuclides. The values in Table A1, Part 1 are given for individual radionuclides, where applicable including short-lived radionuclides in equilibrium with the parent nuclide as indicated. The values in Table A, Part 2 apply to all radionuclides in the decay chain of U-238 or Th-232, but for segments of the decay chain which are not in equilibrium with the parent radionuclide higher values may be applied.

The concentration values in Table A, Part 1 or in Table A, Part 2 also apply to the clearance of solid materials for re-use, recycling, conventional disposal or incineration. Higher values may be defined for specific materials or specific pathways, taking Community guidance into account, including where appropriate additional requirements in terms of surface activity or monitoring requirements.

For mixtures of artificial radionuclides, the weighted sum of nuclide-specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be less than unity. Where appropriate this condition can be verified on the basis of best estimates of the composition of the radionuclide mix. The values in Table A, Part 2 apply individually to each parent nuclide. Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of values significantly higher, by up to two orders of magnitude, taking Community guidance into account.

The values in Table A, Part 2 may not be used to exempt the incorporation into building materials of residues from industries processing naturally occurring radioactive material. Such recycling of residues from identified industries shall be managed as an authorised practice or be exempted on the basis of the general exemption criteria laid down in Section 3. For this purpose, compliance of the sum of radionuclide concentrations with the appropriate value of the radionuclide index I for building materials as defined in Annex VII shall be verified.

The values laid down in Table B, column 3, apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time. However, the regulatory authority may apply these values to smaller entities or packages, for instance to exempt the transport or storage of exempted consumer products, if the general exemption criteria in Section 3 are satisfied.

## 3. General exemption and clearance criteria

The general criteria for the exemption of notified practices or the clearance of **radioactive** materials from authorised practices are as follows: [Am. 126]

- (a) the radiological risks to individuals caused by the practice are sufficiently low as to be of no regulatory concern; and
- (b) the type of practice has been determined to be justified; and

Thursday 24 October 2013

(c) the practice is inherently safe.

Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Tables A, Part 1 or B, and in general all practices involving naturally occurring radionuclides are deemed to fulfil criterion (c).

Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Table A, Part 1 or Table B automatically comply with criterion (a) without further consideration. This is also the case for the values in Table A, Part 2, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance drinking water.

For notified practices not complying with these values, an assessment shall be made of the resulting exposure of individuals. For compliance with the general criterion (a), it shall be demonstrated that the following dose criteria are met in all feasible circumstances:

For artificial radionuclides **and natural radionuclides used for their fissile, fertile or radioactive properties**: [Am. 127]

The effective dose expected to be incurred by an individual due to the exempted practice is of the order of 10 µSv or less in a year.

For naturally occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 300 µSv or less in a year for members of the public and less than 1 mSv for workers.

The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues.

TABLE A:

Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material.

TABLE A Part 1: Artificial radionuclides

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
H-3	100
Be-7	10
C-14	1
F-18	10
Na-22	0,1
Na-24	1
Si-31	1 000
P-32	1 000
P-33	1 000
S-35	100
Cl-36	1
Cl-38	10
K-42	100
K-43	10
Ca-45	100
Ca-47	10
Sc-46	0,1
Sc-47	100
Sc-48	1

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
V-48	1
Cr-51	100
Mn-51	10
Mn-52	1
Mn-52m	10
Mn-53	100
Mn-54	0,1
Mn-56	10
Fe-52 <sup>a</sup>	10
Fe-55	1 000
Fe-59	1
Co-55	10
Co-56	0,1
Co-57	1
Co-58	1
Co-58m	10 000
Co-60	0,1
Co-60m	1 000
Co-61	100
Co-62m	10
Ni-59	100
Ni-63	100
Ni-65	10
Cu-64	100
Zn-65	0,1
Zn-69	1 000
Zn-69m <sup>a</sup>	10
Ga-72	10
Ge-71	10 000
As-73	1 000
As-74	10
As-76	10
As-77	1 000
Se-75	1
Br-82	1
Rb-86	100
Sr-85	1
Sr-85m	100
Sr-87m	100
Sr-89	1 000
Sr-90a	1
Sr-91a	10
Sr-92	10
Y-90	1 000
Y-91	100
Y-91m	100
Y-92	100
Y-93	100
Zr-93	10

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
Zr-95 <sup>a</sup>	1
Zr-97 <sup>a</sup>	10
Nb-93m	10
Nb-94	0,1
Nb-95	1
Nb-97 <sup>a</sup>	10
Nb-98	10
Mo-90	10
Mo-93	10
Mo-99a	10
Mo-101 <sup>a</sup>	10
Tc-96	1
Tc-96m	1 000
Tc-97	10
Tc-97m	100
Tc-99	1
Tc-99m	100
Ru-97	10
Ru-103 <sup>a</sup>	1
Ru-105 <sup>a</sup>	10
Ru-106 <sup>a</sup>	0,1
Rh-103m	10 000
Rh-105	100
Pd-103 <sup>a</sup>	1 000
Pd-109 <sup>a</sup>	100
Ag-105	1
Ag-110m <sup>a</sup>	0,1
Ag-111	100
Cd-109 <sup>a</sup>	1
Cd-115 <sup>a</sup>	10
Cd-115m <sup>a</sup>	100
In-111	10
In-113m	100
In-114m <sup>a</sup>	10
In-115m	100
Sn-113 <sup>a</sup>	1
Sn-125	10
Sb-122	10
Sb-124	1
Sb-125 <sup>a</sup>	0,1
Te-123m	1
Te-125m	1 000
Te-127	1 000
Te-127m <sup>a</sup>	10
Te-129	100
Te-129m <sup>a</sup>	10
Te-131	100
Te-131m <sup>a</sup>	10
Te-132 <sup>a</sup>	1

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
Te-133	10
Te-133m	10
Te-134	10
I-123	100
I-125	100
I-126	10
I-129	0,01
I-130	10
I-131	10
I-132	10
I-133	10
I-134	10
I-135	10
Cs-129	10
Cs-131	1 000
Cs-132	10
Cs-134	0,1
Cs-134m	1 000
Cs-135	100
Cs-136	1
Cs-137 <sup>a</sup>	0,1
Cs-138	10
Ba-131	10
Ba-140	1
La-140	1
Ce-139	1
Ce-141	100
Ce-143	10
Ce-144	10
Pr-142	100
Pr-143	1 000
Nd-147	100
Nd-149	100
Pm-147	1 000
Pm-149	1 000
Sm-151	1 000
Sm-153	100
Eu-152	0,1
Eu-152m	100
Eu-154	0,1
Eu-155	1
Gd-153	10
Gd-159	100
Tb-160	1
Dy-165	1 000
Dy-166	100
Ho-166	100
Er-169	1 000
Er-171	100

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
Tm-170	100
Tm-171	1 000
Yb-175	100
Lu-177	100
Hf-181	1
Ta-182	0,1
W-181	10
W-185	1 000
W-187	10
Re-186	1 000
Re-188	100
Os-185	1
Os-191	100
Os-191m	1 000
Os-193	100
Ir-190	1
Ir-192	1
Ir-194	100
Pt-191	10
Pt-193m	1 000
Pt-197	1 000
Pt-197m	100
Au-198	10
Au-199	100
Hg-197	100
Hg-197m	100
Hg-203	10
Tl-200	10
Tl-201	100
Tl-202	10
Tl-204	1
Pb-203	10
Bi-206	1
Bi-207	0,1
Po-203	10
Po-205	10
Po-207	10
At-211	1 000
Ra-225	10
Ra-227	100
Th-226	1 000
Th-229	0,1
Pa-230	10
Pa-233	10
U-230	10
U-231 <sup>a</sup>	100
U-232 <sup>a</sup>	0,1
U-233	1
U-236	10

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
U-237	100
U-239	100
U-240 <sup>a</sup>	100
Np-237 <sup>a</sup>	1
Np-239	100
Np-240	10
Pu-234	100
Pu-235	100
Pu-236	1
Pu-237	100
Pu-238	0,1
Pu-239	0,1
Pu-240	0,1
Pu-241	10
Pu-242	0,1
Pu-243	1 000
Pu-244a	0,1
Am-241	0,1
Am-242	1 000
Am-242m <sup>a</sup>	0,1
Am-243 <sup>a</sup>	0,1
Cm-242	10
Cm-243	1
Cm-244	1
Cm-245	0,1
Cm-246	0,1
Cm-247 <sup>a</sup>	0,1
Cm-248	0,1
Bk-249	100
Cf-246	1 000
Cf-248	1
Cf-249	0,1
Cf-250	1
Cf-251	0,1
Cf-252	1
Cf-253	100
Cf-254	1
Es-253	100
Es-254 <sup>a</sup>	0,1
Es-254m <sup>a</sup>	10
Fm-254	10 000

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )
Fm-255	100

a Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following table:

Parent radionuclide	Progeny
Fe-52	Mn-52m
Zn-69m	Zn-69
Sr-90	Y-90
Sr-91	Y-91m
Zr-95	Nb-95
Zr-97	Nb-97m, Nb-97
Nb-97	Nb-97m
Mo-99	Tc-99m
Mo-101	Tc-101
Ru-103	Rh-103m
Ru-105	Rh-105m
Ru-106	Rh-106
Pd-103	Rh-103m
Pd-109	Ag-109m
Ag-110m	Ag-110
Cd-109	Ag-109m
Cd-115	In-115m
Cd-115m	In-115m
In-114m	In-114
Sn-113	In-113m
Parent radionuclide	Progeny
Sb-125	Te-125m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
Cs-137	Ba-137m
Ce-144	Pr-144, Pr-144m
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
U-240	Np-240m, Np-240
Np-237	Pa-233
Pu-244	U-240, Np-240m, Np-240
Am-242m	Np-238
Am-243	Np-239
Cm-247	Pu-243
Es-254	Bk-250
Es-254m	Fm-254

For radionuclides not listed in Table A, Part 1 the competent authority shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A, Part 1.

TABLE A Part 2: naturally occurring radionuclides

Values for exemption or clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny:

Natural radionuclides from the U-238 series	1 Bq g <sup>-1</sup>
Natural radionuclides from the Th-232 series	1 Bq g <sup>-1</sup>
K-40	10 Bq g <sup>-1</sup>

Thursday 24 October 2013

TABLE B:

Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2).

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
H-3	$1 \times 10^6$	$1 \times 10^9$
Be-7	$1 \times 10^3$	$1 \times 10^7$
C-14	$1 \times 10^4$	$1 \times 10^7$
O-15	$1 \times 10^2$	$1 \times 10^9$
F-18	$1 \times 10^1$	$1 \times 10^6$
Na-22	$1 \times 10^1$	$1 \times 10^6$
Na-24	$1 \times 10^1$	$1 \times 10^5$
Si-31	$1 \times 10^3$	$1 \times 10^6$
P-32	$1 \times 10^3$	$1 \times 10^5$
P-33	$1 \times 10^5$	$1 \times 10^8$
S-35	$1 \times 10^5$	$1 \times 10^8$
Cl-36	$1 \times 10^4$	$1 \times 10^6$
Cl-38	$1 \times 10^1$	$1 \times 10^5$
Ar-37	$1 \times 10^6$	$1 \times 10^8$
Ar-41	$1 \times 10^2$	$1 \times 10^9$
K-40 ( <sup>1</sup> )	$1 \times 10^2$	$1 \times 10^6$
K-42	$1 \times 10^2$	$1 \times 10^6$
K-43	$1 \times 10^1$	$1 \times 10^6$
Ca-45	$1 \times 10^4$	$1 \times 10^7$
Ca-47	$1 \times 10^1$	$1 \times 10^6$
Sc-46	$1 \times 10^1$	$1 \times 10^6$
Sc-47	$1 \times 10^2$	$1 \times 10^6$
Sc-48	$1 \times 10^1$	$1 \times 10^5$
V-48	$1 \times 10^1$	$1 \times 10^5$
Cr-51	$1 \times 10^3$	$1 \times 10^7$
Mn-51	$1 \times 10^1$	$1 \times 10^5$
Mn-52	$1 \times 10^1$	$1 \times 10^5$
Mn-52m	$1 \times 10^1$	$1 \times 10^5$
Mn-53	$1 \times 10^4$	$1 \times 10^9$
Mn-54	$1 \times 10^1$	$1 \times 10^6$
Mn-56	$1 \times 10^1$	$1 \times 10^5$
Fe-52	$1 \times 10^1$	$1 \times 10^6$
Fe-55	$1 \times 10^4$	$1 \times 10^6$
Fe-59	$1 \times 10^1$	$1 \times 10^6$
Co-55	$1 \times 10^1$	$1 \times 10^6$
Co-56	$1 \times 10^1$	$1 \times 10^5$
Co-57	$1 \times 10^2$	$1 \times 10^6$
Co-58	$1 \times 10^1$	$1 \times 10^6$
Co-58m	$1 \times 10^4$	$1 \times 10^7$
Co-60	$1 \times 10^1$	$1 \times 10^5$

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
Co-60m	$1 \times 10^3$	$1 \times 10^6$
Co-61	$1 \times 10^2$	$1 \times 10^6$
Co-62m	$1 \times 10^1$	$1 \times 10^5$
Ni-59	$1 \times 10^4$	$1 \times 10^8$
Ni-63	$1 \times 10^5$	$1 \times 10^8$
Ni-65	$1 \times 10^1$	$1 \times 10^6$
Cu-64	$1 \times 10^2$	$1 \times 10^6$
Zn-65	$1 \times 10^1$	$1 \times 10^6$
Zn-69	$1 \times 10^4$	$1 \times 10^6$
Zn-69m	$1 \times 10^2$	$1 \times 10^6$
Ga-72	$1 \times 10^1$	$1 \times 10^5$
Ge-71	$1 \times 10^4$	$1 \times 10^8$
As-73	$1 \times 10^3$	$1 \times 10^7$
As-74	$1 \times 10^1$	$1 \times 10^6$
As-76	$1 \times 10^2$	$1 \times 10^5$
As-77	$1 \times 10^3$	$1 \times 10^6$
Se-75	$1 \times 10^2$	$1 \times 10^6$
Br-82	$1 \times 10^1$	$1 \times 10^6$
Kr-74	$1 \times 10^2$	$1 \times 10^9$
Kr-76	$1 \times 10^2$	$1 \times 10^9$
Kr-77	$1 \times 10^2$	$1 \times 10^9$
Kr-79	$1 \times 10^3$	$1 \times 10^5$
Kr-81	$1 \times 10^4$	$1 \times 10^7$
Kr-83m	$1 \times 10^5$	$1 \times 10^{12}$
Kr-85	$1 \times 10^5$	$1 \times 10^4$
Kr-85m	$1 \times 10^3$	$1 \times 10^{10}$
Kr-87	$1 \times 10^2$	$1 \times 10^9$
Kr-88	$1 \times 10^2$	$1 \times 10^9$
Rb-86	$1 \times 10^2$	$1 \times 10^5$
Sr-85	$1 \times 10^2$	$1 \times 10^6$
Sr-85m	$1 \times 10^2$	$1 \times 10^7$
Sr-87m	$1 \times 10^2$	$1 \times 10^6$
Sr-89	$1 \times 10^3$	$1 \times 10^6$
Sr-90b	$1 \times 10^2$	$1 \times 10^4$
Sr-91	$1 \times 10^1$	$1 \times 10^5$
Sr-92	$1 \times 10^1$	$1 \times 10^6$
Y-90	$1 \times 10^3$	$1 \times 10^5$
Y-91	$1 \times 10^3$	$1 \times 10^6$
Y-91m	$1 \times 10^2$	$1 \times 10^6$
Y-92	$1 \times 10^2$	$1 \times 10^5$
Y-93	$1 \times 10^2$	$1 \times 10^5$
Zr-93b	$1 \times 10^3$	$1 \times 10^7$
Zr-95	$1 \times 10^1$	$1 \times 10^6$
Zr-97b	$1 \times 10^1$	$1 \times 10^5$
Nb-93m	$1 \times 10^4$	$1 \times 10^7$
Nb-94	$1 \times 10^1$	$1 \times 10^6$
Nb-95	$1 \times 10^1$	$1 \times 10^6$
Nb-97	$1 \times 10^1$	$1 \times 10^6$
Nb-98	$1 \times 10^1$	$1 \times 10^5$

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
Mo-90	$1 \times 10^1$	$1 \times 10^6$
Mo-93	$1 \times 10^3$	$1 \times 10^8$
Mo-99	$1 \times 10^2$	$1 \times 10^6$
Mo-101	$1 \times 10^1$	$1 \times 10^6$
Tc-96	$1 \times 10^1$	$1 \times 10^6$
Tc-96m	$1 \times 10^3$	$1 \times 10^7$
Tc-97	$1 \times 10^3$	$1 \times 10^8$
Tc-97m	$1 \times 10^3$	$1 \times 10^7$
Tc-99	$1 \times 10^4$	$1 \times 10^7$
Tc-99m	$1 \times 10^2$	$1 \times 10^7$
Ru-97	$1 \times 10^2$	$1 \times 10^7$
Ru-103	$1 \times 10^2$	$1 \times 10^6$
Ru-105	$1 \times 10^1$	$1 \times 10^6$
Ru-106b	$1 \times 10^2$	$1 \times 10^5$
Rh-103m	$1 \times 10^4$	$1 \times 10^8$
Rh-105	$1 \times 10^2$	$1 \times 10^7$
Pd-103	$1 \times 10^3$	$1 \times 10^8$
Pd-109	$1 \times 10^3$	$1 \times 10^6$
Ag-105	$1 \times 10^2$	$1 \times 10^6$
Ag-108m	$1 \times 10^1$	$1 \times 10^6$
Ag-110m	$1 \times 10^1$	$1 \times 10^6$
Ag-111	$1 \times 10^3$	$1 \times 10^6$
Cd-109	$1 \times 10^4$	$1 \times 10^6$
Cd-115	$1 \times 10^2$	$1 \times 10^6$
Cd-115m	$1 \times 10^3$	$1 \times 10^6$
In-111	$1 \times 10^2$	$1 \times 10^6$
In-113m	$1 \times 10^2$	$1 \times 10^6$
In-114m	$1 \times 10^2$	$1 \times 10^6$
In-115m	$1 \times 10^2$	$1 \times 10^6$
Sn-113	$1 \times 10^3$	$1 \times 10^7$
Sn-125	$1 \times 10^2$	$1 \times 10^5$
Sb-122	$1 \times 10^2$	$1 \times 10^4$
Sb-124	$1 \times 10^1$	$1 \times 10^6$
Sb-125	$1 \times 10^2$	$1 \times 10^6$
Te-123m	$1 \times 10^2$	$1 \times 10^7$
Te-125m	$1 \times 10^3$	$1 \times 10^7$
Te-127	$1 \times 10^3$	$1 \times 10^6$
Te-127m	$1 \times 10^3$	$1 \times 10^7$
Te-129	$1 \times 10^2$	$1 \times 10^6$
Te-129m	$1 \times 10^3$	$1 \times 10^6$
Te-131	$1 \times 10^2$	$1 \times 10^5$
Te-131m	$1 \times 10^1$	$1 \times 10^6$
Te-132	$1 \times 10^2$	$1 \times 10^7$
Te-133	$1 \times 10^1$	$1 \times 10^5$
Te-133m	$1 \times 10^1$	$1 \times 10^5$
Te-134	$1 \times 10^1$	$1 \times 10^6$
I-123	$1 \times 10^2$	$1 \times 10^7$
I-125	$1 \times 10^3$	$1 \times 10^6$
I-126	$1 \times 10^2$	$1 \times 10^6$

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
I-129	$1 \times 10^2$	$1 \times 10^5$
I-130	$1 \times 10^1$	$1 \times 10^6$
I-131	$1 \times 10^2$	$1 \times 10^6$
I-132	$1 \times 10^1$	$1 \times 10^5$
I-133	$1 \times 10^1$	$1 \times 10^6$
I-134	$1 \times 10^1$	$1 \times 10^5$
I-135	$1 \times 10^1$	$1 \times 10^6$
Xe-131m	$1 \times 10^4$	$1 \times 10^4$
Xe-133	$1 \times 10^3$	$1 \times 10^4$
Xe-135	$1 \times 10^3$	$1 \times 10^{10}$
Cs-129	$1 \times 10^2$	$1 \times 10^5$
Cs-131	$1 \times 10^3$	$1 \times 10^6$
Cs-132	$1 \times 10^1$	$1 \times 10^5$
Cs-134m	$1 \times 10^3$	$1 \times 10^5$
Cs-134	$1 \times 10^1$	$1 \times 10^4$
Cs-135	$1 \times 10^4$	$1 \times 10^7$
Cs-136	$1 \times 10^1$	$1 \times 10^5$
Cs-137 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^4$
Cs-138	$1 \times 10^1$	$1 \times 10^4$
Ba-131	$1 \times 10^2$	$1 \times 10^6$
Ba-140 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^5$
La-140	$1 \times 10^1$	$1 \times 10^5$
Ce-139	$1 \times 10^2$	$1 \times 10^6$
Ce-141	$1 \times 10^2$	$1 \times 10^7$
Ce-143	$1 \times 10^2$	$1 \times 10^6$
Ce-144 <sup>b</sup>	$1 \times 10^2$	$1 \times 10^5$
Pr-142	$1 \times 10^2$	$1 \times 10^5$
Pr-143	$1 \times 10^4$	$1 \times 10^6$
Nd-147	$1 \times 10^2$	$1 \times 10^6$
Nd-149	$1 \times 10^2$	$1 \times 10^6$
Pm-147	$1 \times 10^4$	$1 \times 10^7$
Pm-149	$1 \times 10^3$	$1 \times 10^6$
Sm-151	$1 \times 10^4$	$1 \times 10^8$
Sm-153	$1 \times 10^2$	$1 \times 10^6$
Eu-152	$1 \times 10^1$	$1 \times 10^6$
Eu-152m	$1 \times 10^2$	$1 \times 10^6$
Eu-154	$1 \times 10^1$	$1 \times 10^6$
Eu-155	$1 \times 10^2$	$1 \times 10^7$
Gd-153	$1 \times 10^2$	$1 \times 10^7$
Gd-159	$1 \times 10^3$	$1 \times 10^6$
Tb-160	$1 \times 10^1$	$1 \times 10^6$
Dy-165	$1 \times 10^3$	$1 \times 10^6$
Dy-166	$1 \times 10^3$	$1 \times 10^6$
Ho-166	$1 \times 10^3$	$1 \times 10^5$
Er-169	$1 \times 10^4$	$1 \times 10^7$
Er-171	$1 \times 10^2$	$1 \times 10^6$
Tm-170	$1 \times 10^3$	$1 \times 10^6$
Tm-171	$1 \times 10^4$	$1 \times 10^8$
Yb-175	$1 \times 10^3$	$1 \times 10^7$

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
Lu-177	$1 \times 10^3$	$1 \times 10^7$
Hf-181	$1 \times 10^1$	$1 \times 10^6$
Ta-182	$1 \times 10^1$	$1 \times 10^4$
W-181	$1 \times 10^3$	$1 \times 10^7$
W-185	$1 \times 10^4$	$1 \times 10^7$
W-187	$1 \times 10^2$	$1 \times 10^6$
Re-186	$1 \times 10^3$	$1 \times 10^6$
Re-188	$1 \times 10^2$	$1 \times 10^5$
Os-185	$1 \times 10^1$	$1 \times 10^6$
Os-191	$1 \times 10^2$	$1 \times 10^7$
Os-191m	$1 \times 10^3$	$1 \times 10^7$
Os-193	$1 \times 10^2$	$1 \times 10^6$
Ir-190	$1 \times 10^1$	$1 \times 10^6$
Ir-192	$1 \times 10^1$	$1 \times 10^4$
Ir-194	$1 \times 10^2$	$1 \times 10^5$
Pt-191	$1 \times 10^2$	$1 \times 10^6$
Pt-193m	$1 \times 10^3$	$1 \times 10^7$
Pt-197	$1 \times 10^3$	$1 \times 10^6$
Pt-197m	$1 \times 10^2$	$1 \times 10^6$
Au-198	$1 \times 10^2$	$1 \times 10^6$
Au-199	$1 \times 10^2$	$1 \times 10^6$
Hg-197	$1 \times 10^2$	$1 \times 10^7$
Hg-197m	$1 \times 10^2$	$1 \times 10^6$
Hg-203	$1 \times 10^2$	$1 \times 10^5$
Tl-200	$1 \times 10^1$	$1 \times 10^6$
Tl-201	$1 \times 10^2$	$1 \times 10^6$
Tl-202	$1 \times 10^2$	$1 \times 10^6$
Tl-204	$1 \times 10^4$	$1 \times 10^4$
Pb-203	$1 \times 10^2$	$1 \times 10^6$
Pb-210 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^4$
Pb-212 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^5$
Bi-206	$1 \times 10^1$	$1 \times 10^5$
Bi-207	$1 \times 10^1$	$1 \times 10^6$
Bi-210	$1 \times 10^3$	$1 \times 10^6$
Bi-212 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^5$
Po-203	$1 \times 10^1$	$1 \times 10^6$
Po-205	$1 \times 10^1$	$1 \times 10^6$
Po-207	$1 \times 10^1$	$1 \times 10^6$
Po-210	$1 \times 10^1$	$1 \times 10^4$
At-211	$1 \times 10^3$	$1 \times 10^7$
Rn-220 <sup>b</sup>	$1 \times 10^4$	$1 \times 10^7$
Rn-222 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^8$
Ra-223 <sup>b</sup>	$1 \times 10^2$	$1 \times 10^5$
Ra-224 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^5$
Ra-225	$1 \times 10^2$	$1 \times 10^5$
Ra-226 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^4$
Ra-227	$1 \times 10^2$	$1 \times 10^6$
Ra-228 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^5$
Ac-228	$1 \times 10^1$	$1 \times 10^6$

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
Th-226 <sup>b</sup>	$1 \times 10^3$	$1 \times 10^7$
Th-227	$1 \times 10^1$	$1 \times 10^4$
Th-228 <sup>b</sup>	$1 \times 10^0$	$1 \times 10^4$
Th-229 <sup>b</sup>	$1 \times 10^0$	$1 \times 10^3$
Th-230	$1 \times 10^0$	$1 \times 10^4$
Th-231	$1 \times 10^3$	$1 \times 10^7$
Th-234 <sup>b</sup>	$1 \times 10^3$	$1 \times 10^5$
Pa-230	$1 \times 10^1$	$1 \times 10^6$
Pa-231	$1 \times 10^0$	$1 \times 10^3$
Pa-233	$1 \times 10^2$	$1 \times 10^7$
U-230	$1 \times 10^1$	$1 \times 10^5$
U-231	$1 \times 10^2$	$1 \times 10^7$
U-232 <sup>b</sup>	$1 \times 10^0$	$1 \times 10^3$
U-233	$1 \times 10^1$	$1 \times 10^4$
U-234	$1 \times 10^1$	$1 \times 10^4$
U-235 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^4$
U-236	$1 \times 10^1$	$1 \times 10^4$
U-237	$1 \times 10^2$	$1 \times 10^6$
U-238 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^4$
U-239	$1 \times 10^2$	$1 \times 10^6$
U-240	$1 \times 10^3$	$1 \times 10^7$
U-240 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^6$
Np-237 <sup>b</sup>	$1 \times 10^0$	$1 \times 10^3$
Np-239	$1 \times 10^2$	$1 \times 10^7$
Np-240	$1 \times 10^1$	$1 \times 10^6$
Pu-234	$1 \times 10^2$	$1 \times 10^7$
Pu-235	$1 \times 10^2$	$1 \times 10^7$
Pu-236	$1 \times 10^1$	$1 \times 10^4$
Pu-237	$1 \times 10^3$	$1 \times 10^7$
Pu-238	$1 \times 10^0$	$1 \times 10^4$
Pu-239	$1 \times 10^0$	$1 \times 10^4$
Pu-240	$1 \times 10^0$	$1 \times 10^3$
Pu-241	$1 \times 10^2$	$1 \times 10^5$
Pu-242	$1 \times 10^0$	$1 \times 10^4$
Pu-243	$1 \times 10^3$	$1 \times 10^7$
Pu-244	$1 \times 10^0$	$1 \times 10^4$
Am-241	$1 \times 10^0$	$1 \times 10^4$
Am-242	$1 \times 10^3$	$1 \times 10^6$
Am-242m <sup>b</sup>	$1 \times 10^0$	$1 \times 10^4$
Am-243 <sup>b</sup>	$1 \times 10^0$	$1 \times 10^3$
Cm-242	$1 \times 10^2$	$1 \times 10^5$
Cm-243	$1 \times 10^0$	$1 \times 10^4$
Cm-244	$1 \times 10^1$	$1 \times 10^4$
Cm-245	$1 \times 10^0$	$1 \times 10^3$
Cm-246	$1 \times 10^0$	$1 \times 10^3$
Cm-247	$1 \times 10^0$	$1 \times 10^4$
Cm-248	$1 \times 10^0$	$1 \times 10^3$
Bk-249	$1 \times 10^3$	$1 \times 10^6$
Cf-246	$1 \times 10^3$	$1 \times 10^6$

Thursday 24 October 2013

Radionuclide	Activity concentration (Bq g <sup>-1</sup> )	Activity (Bq)
Cf-248	$1 \times 10^1$	$1 \times 10^4$
Cf-249	$1 \times 10^0$	$1 \times 10^3$
Cf-250	$1 \times 10^1$	$1 \times 10^4$
Cf-251	$1 \times 10^0$	$1 \times 10^3$
Cf-252	$1 \times 10^1$	$1 \times 10^4$
Cf-253	$1 \times 10^2$	$1 \times 10^5$
Cf-254	$1 \times 10^0$	$1 \times 10^3$
Es-253	$1 \times 10^2$	$1 \times 10^5$
Es-254	$1 \times 10^1$	$1 \times 10^4$
Es-254m	$1 \times 10^2$	$1 \times 10^6$
Fm-254	$1 \times 10^4$	$1 \times 10^7$
Fm-255	$1 \times 10^3$	$1 \times 10^6$

(<sup>1</sup>) Potassium salts in quantities less than 1 000 kg are exempted.

b Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ba-140	La-140
Ce-144	Pr-144
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

Thursday 24 October 2013

## ANNEX VII

## Definition and use of the activity concentration index for the gamma radiation emitted by building materials

For the purposes of Article 75(2), for identified types of building materials, the activity concentrations of primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40 shall be determined.

The activity concentration index I is given by the following formula:

$$I = C_{\text{Ra226}}/300 \text{ Bq/kg} + C_{\text{Th232}}/200 \text{ Bq/kg} + C_{\text{K40}}/3000 \text{ Bq/kg}$$

where  $C_{\text{Ra226}}$ ,  $C_{\text{Th232}}$  and  $C_{\text{K40}}$  are the activity concentrations in Bq/kg of the corresponding radionuclides in the building material.

The index relates directly to the gamma radiation dose, in excess of typical outdoor exposure, in a building constructed from a specified building material. It applies to the building material, not to its constituents. For application of the index to such constituents, in particular residues from industries processing naturally occurring radioactive material recycled into building materials an appropriate partitioning factor needs to be applied. The activity concentration index shall be used as a screening tool for identifying materials that may be exempted or subject to restrictions. For this purpose the activity concentration index I may be used for the classification of the materials into four classes, leading to two categories of building materials (A and B):

Use	Category (corresponding default dose)	
	A ( $\leq 1$ mSv)	B ( $> 1$ mSv)
(1) materials used in bulk amounts	A1 $I \leq 1$	B1 $I > 1$
(2) superficial and other materials with restricted use.	A2 $I \leq 6$	B2 $I > 6$

The division of materials into (1) or (2) according to their use shall be based on national building codes.

Where appropriate, actual doses for comparison with the reference level shall be assessed using more elaborate models which may also take into account the background outdoor external exposure from local prevailing activity concentrations in the undisturbed earth's crust.

## ANNEX VIII

## Data system for individual radiological monitoring

## General Provisions

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers ~~may~~ **should** be supplemented by the issuance of individual radiological monitoring documents for every outside worker. **[Am. 128]**

1. Any data system of the Member States for individual radiological monitoring of exposed workers shall comprise the following sections:

(a) particulars concerning the worker's identity;

Thursday 24 October 2013

- (b) particulars concerning the medical surveillance of the worker;
  - (c) particulars concerning the undertaking of the worker and, in the case of an outside worker, the employer of the worker;
  - (d) the results of the individual monitoring of the exposed worker.
2. The competent authorities of the Member States shall take the measures necessary to prevent any forgery or misuse of, or illegal tampering with, the data system for individual radiological monitoring.

A: Data to be included in the data system for individual radiological monitoring

3. Data on the worker's identity shall include the worker's
- (a) surname;
  - (b) first name;
  - (c) sex;
  - (d) date of birth;
  - (e) nationality; and
  - (f) unique identification number.
4. Data on the medical surveillance of the worker shall include
- (a) the medical classification of the worker in accordance with Article 45 (fit; fit, subject to certain conditions; unfit);
  - (b) information on any restrictions on working with radiation;
  - (c) the date of the last periodic health review;
  - (d) the responsible occupational health service; and
  - (e) the period of validity of the result.
5. Data on the undertaking shall include the name, address and unique identification number of the undertaking.
6. Data on the employment of the worker shall include:
- (a) the name, address and unique identification number of the employer;
  - (b) the starting date of employment; and
  - (c) the categorisation of the worker in accordance with Article 38.
7. The results of the individual monitoring of the exposed worker shall include:
- (a) the official dose record for the last 5 calendar years (year; effective dose in mSv; in the event of non-uniform exposure, dose-equivalent in the different parts of the body in mSv; and in the event of internal contamination, the committed dose in mSv); and
  - (b) the official dose record for the current year (period; effective dose in mSv; in the event of non-uniform exposure, dose-equivalent in the different parts of the body in mSv; and in the event of internal contamination, the committed dose in mSv).

B: Data on outside workers to be supplied via the data system for individual radiological monitoring

1. Before the start of any activity, the employer of the outside worker shall supply the following data to the undertaking via the data system for individual radiological monitoring:
- (a) data on the employer of the outside worker in accordance with Section A, point 6;

Thursday 24 October 2013

- (b) data on the medical surveillance of the outside worker in accordance with Section A, point 4;
  - (c) the results of the outside worker's individual exposure monitoring in accordance with Section A, point 7.
2. The following data shall be recorded or have been recorded by the undertaking in the data system for individual radiological monitoring after the end of any activity:
- (a) the period covered by the activity;
  - (b) an estimate of any effective dose received by the outside worker (operational dose for the period covered by the activity);
  - (c) in the event of non-uniform exposure, an estimate of the dose-equivalent in the different parts of the body;
  - (d) in the event of internal contamination, an estimate of the intake or the committed dose.
- C. Provisions concerning the individual radiological monitoring document
- 1. Member States may decide to issue an individual radiological monitoring document for every outside worker.
  - 2. The document shall be non-transferable.
  - 3. Member States shall take the measures necessary to prevent a worker from being issued with more than one valid individual monitoring document at the same time.
  - 4. In addition to the information required in Part A and Part B, the document shall include the name and address of the issuing body and the issuing date.

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## ANNEX IX

### A. Elements to be included in an emergency management system

- 1. Threat assessment;
- 2. Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements, including establishment and coordination of emergency response organisations with overall responsibilities in managing emergency exposure situations and, where appropriate, creation of special teams for protective measures;
- 3. Establishment of emergency response plans at national level, at local level and within installations;
- 4. Reliable communications and efficient and effective arrangements for cooperation and coordination at the installation and local, national and international levels;
- 5. Health protection of emergency workers;
- 6. Education and training of emergency workers and all other persons with duties or responsibilities in emergency response, including regular exercises;
- 7. Arrangements for individual monitoring of emergency workers and the recording of doses;
- 8. Public information arrangements;
- 9. Involvement of stakeholders;
- 10. Transition from emergency response to recovery and remediation.

### B. Elements to be included in an emergency response plan

For emergency preparedness:

- 1. Reference levels, taking into account the criteria laid down in Annex I;

Thursday 24 October 2013

2. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;
3. Predefined generic criteria for particular protective measures, expressed in terms of projected and received doses;
4. Default triggers or operational criteria such as observables and indicators of on-scene conditions;
5. Arrangements for prompt coordination with the emergency response organisation in a neighbouring Member State or non-Member State, for facilities in the vicinity of a national border;
6. Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve throughout the response.

For emergency response:

The response to an emergency exposure situation shall be undertaken through the timely implementation of preparedness arrangements, including but not limited to:

1. Promptly implementing protective measures, if possible, before any exposure occurs;
2. Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation;
3. Comparing the expected residual doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;
4. Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

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#### ANNEX X

A. Prior information to the members of the public likely to be affected by an emergency:

1. Basic facts about radioactivity and its effects on human beings and on the environment;
2. The various types of emergency covered and their consequences for the public and the environment;
3. Emergency measures envisaged to alert, protect and assist the public in the event of an emergency;
4. Appropriate information on action to be taken by the public in the event of an emergency.

**4a. Information on the nature and scale of harm liable to be caused by various emergency situations. [Am. 129]**

**4b. Information on the terms for damages for personal injury and material loss following an emergency. [Am. 130]**

**4c. Information on how to store and use stable iodine tablets provided by the competent authorities. [Am. 131]**

B. Information to be provided to the affected members of the public in the event of an emergency

1. On the basis of the emergency response plan previously drawn up in the Member States, the members of the public actually affected in the event of an emergency shall rapidly and regularly receive:
  - (a) information on the type of emergency which has occurred and, ~~where possible,~~ its characteristics (e.g. its origin, extent and probable development); **[Am. 132]**

Thursday 24 October 2013

- (b) advice on protection, which, depending on the type of emergency, may:
    - (i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements;
    - (ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public;
  - (c) announcements recommending cooperation with instructions or requests by the competent authorities.
2. If the emergency is preceded by a pre-alarm phase, the members of the public likely to be affected shall already receive information and advice during that phase, such as:
- (a) an invitation to the members of the public concerned to tune in to relevant communication channels;
  - (b) preparatory advice to establishments with particular collective responsibilities;
  - (c) recommendations to occupational groups particularly affected.
3. This information and advice shall be supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

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ANNEX XI

Indicative list of types of building materials considered for control measures with regard to their emitted gamma radiation

1. Natural materials

- (a) Alum-shale.
- (b) Building materials or additives of natural igneous origin, such as:
  - granite,
  - gneiss;
  - porphyries;
  - syenite;
  - basalt;
  - tuff;
  - pozzolana;
  - lava.

2. Materials incorporating residues from industries processing naturally occurring radioactive material, such as:

- fly ash;
  - phosphogypsum;
  - phosphorus slag;
  - tin slag;
  - copper slag;
  - red mud (residue from aluminium production);
  - residues from steel production.
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Thursday 24 October 2013

## ANNEX XII

Information to be provided in the records for high activity sealed sources HASS)

<b>1. HASS identification number</b>	<b>2. Identification of the authorised undertaking</b>			<b>3. Location of HASS (Use or storage) if not the same as in 2.</b>		
<i>Manufacturer device number</i>	Name: Address: Country:			Name: Address: Country:		
<i>Field of use:</i>	Manufacturer <input type="checkbox"/>	Supplier <input type="checkbox"/>	User <input type="checkbox"/>	Fixed use <input type="checkbox"/>	Storage <input type="checkbox"/>	Mobile use <input type="checkbox"/>
<b>4. Registration</b>	<b>5. Authorisation</b>			<b>6. Operational controls of HASS</b>		
Date of start of registration:	Number:			Date:		
Date of transfer of registration to historic file:	Date of issue:			Date:		
	Date of expiry:			Date:		
<b>7. HASS characteristic</b>	<b>8. Receipt of HASS</b>					
<i>Year of manufacture:</i>						
Radionuclide:	Date of receipt:			Date:		
Activity at the date of manufacturing:	Receipt from			Date:		
				Date:		
Activity reference date:	Name:			Date:		
Manufacturer/Supplier*:	Address:			Date:		
	Country:			Date:		
	Manufacturer <input type="checkbox"/>	Supplier <input type="checkbox"/>	Another user <input type="checkbox"/>	Date:		
	<b>9. Transfer of HASS</b>			<b>10. Further information</b>		
Physical and chemical characteristics	Date of transfer:			Loss <input type="checkbox"/>		
Source type identification:	Transfer to			Theft <input type="checkbox"/>		
Capsule identification:				Finding: Yes <input type="checkbox"/> No <input type="checkbox"/>		
ISO classification:	Name:			Date:		
ANSI classification:	Address:			Place:		
IAEA source category:	Country:			Other information:		
	Authorisation number:					
Neutron source: Yes <input type="checkbox"/> No <input type="checkbox"/>	Date of issue:					
Neutron source target:	Date of expiry:					
Neutron flux:	Manufacturer <input type="checkbox"/>	Supplier <input type="checkbox"/>	Another user <input type="checkbox"/>			
	Facility for long term storage and disposal <input type="checkbox"/>					

\* Where the manufacturer of the source is established outside the Community, the name and address of the importer-supplier may be provided instead.

Thursday 24 October 2013

#### ANNEX XIII

##### Provision of data on high-activity sealed sources

The undertaking shall provide the competent authority with an electronic or written copy of the records for high-activity sealed sources, referred to in Article 90 and covering the information set out in Annex XII, as follows:

1. without undue delay, at the time of the establishment of such records, which shall be as soon as possible after the source is acquired;
2. at intervals, to be determined by Member States, of not more than 12 months after the acquisition of the source;
3. if the situation indicated on the information sheet has changed;
4. without undue delay upon the closure of the records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal and storage facility to which the source is transferred shall be included;
5. without undue delay upon the closure of such records when the undertaking no longer holds any sources.

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#### ANNEX XIV

##### Requirements for undertakings responsible for a high-activity sealed source

Each undertaking responsible for a high-activity sealed source shall:

- (a) ensure that suitable tests, such as leak tests based on international standards, are undertaken regularly in order to check and maintain the integrity of each source;
  - (b) regularly verify at specific intervals, which may be determined by Member States, that each source and, where relevant, the equipment containing the source are still present and in apparently good condition at their place of use or storage;
  - (c) ensure that each fixed and mobile source is subject to adequate documented measures, such as written protocols and procedures, aimed at preventing unauthorised access to or loss or theft of the source or its damage by fire;
  - (d) promptly notify the competent authority of any loss, theft or unauthorised use of a source, arrange for a check on the integrity of each source after any event, including fire, that may have damaged the source, and, if appropriate, inform the competent authority thereof and of the measures taken;
  - (e) return each disused source to the supplier or place it in a facility for long term storage and disposal or transfer it to another authorised undertaking unless otherwise agreed by the competent authority, without undue delay after termination of the use;
  - (f) ascertain that, before a transfer is made, the recipient holds appropriate authorisation.
  - (g) Promptly notify the competent authority of any accident or incident resulting in unintentional exposure of a worker or a member of the public.
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Thursday 24 October 2013

## ANNEX XV

## Identification and marking of high-activity sealed sources

1. The manufacturer or supplier shall ensure that:

- (a) Each high-activity sealed source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable.

The number shall also be engraved or stamped on the source container. If this is not feasible, or in the case of reusable transport containers, the source container shall, at least, bear information on the nature of the source.

- (b) The source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard.

2. The manufacturer shall provide a photograph of each manufactured source design type and a photograph of the typical source container.

3. The undertaking shall ensure that each high-activity sealed source is accompanied by written information indicating that the source is identified and marked in compliance with point 1 and that the markings and labels referred to in point 1 remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

## ANNEX XVI

## Indicative list of items to be covered in the national action plan to manage long term risks from radon exposures

1. Strategy for conducting surveys of indoor radon concentrations, for the management of measurement data (national radon database) and for the establishment of other parameters (soil and rock types, soil gas concentration, permeability and radium-226 content of rock or soil).
2. Available data and criteria used for the delineation of radon-prone areas or for the identification of radon-prone buildings.
3. Identification of types of buildings with public access and workplaces, e.g. schools, underground workplaces or spas, where measurements are needed, based on a risk assessment including occupancy hours.
4. The basis for the establishment of reference levels for existing dwellings, workplaces, buildings with public access and for new buildings.
5. Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.
6. Strategy for reducing radon exposure in dwellings, particularly in radon-prone areas.
7. Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials with significant radon exhalation.
8. Schedules for audits and reviews of the action plan.
9. Strategy for communication to increase public awareness and inform local decision makers of the risks of radon in relation to smoking.
10. Where appropriate, guidance on methods and tools for measurements and remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.

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**Thursday 24 October 2013**

11. Where appropriate, provision of financial support for radon surveys and for remedial measures, in particular for private dwellings with very high radon concentrations.
  12. Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non-smokers).
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