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II

*(Information)*INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
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EUROPEAN COMMISSION

COMMISSION NOTICE

**Guidance on ensuring the respect for the Charter of Fundamental Rights of the European Union
when implementing the European Structural and Investment Funds ('ESI Funds')**

(2016/C 269/01)

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1. INTRODUCTION

The Charter of Fundamental Rights of the European Union (the Charter) became legally binding on the EU with the entry into force of the Treaty of Lisbon, in December 2009 and now has the same legal value as the EU Treaties. Respect for fundamental rights enshrined in the Charter is thus a legal obligation for the EU institutions, bodies, agencies and offices in all their actions, and for EU Member States when they are implementing EU law.

The purpose of this guide is to provide an explanation to Member-States of the importance of ensuring respect of the Charter of Fundamental Rights when implementing ESI funds and to provide a practical tool, the 'Fundamental Rights check-list', to help Member States screen ESIF implementing measures against the Charter.

The guide contains explanations on the content, legal status and applicability of the Charter in general as well as within the framework of the ESI Funds. It also explains its enforcement in the context of ESIF and the possible consequences of noncompliance with the Charter. This Guidance also contains recommendations to the relevant actors how to carry out the assessment of compliance of the actions with the Charter and identifies actions in the context of ESI Funds that are considered to be actions of implementation of EU law.

2. THE CONTENT AND LEGAL STATUS OF THE CHARTER OF FUNDAMENTAL RIGHTS

2.1. The content of the Charter

The Charter contains rights and principles in relation to six themes: Dignity, Freedoms, Equality, Solidarity, Citizens' Rights, and Justice as summarized in the table below.

Title I '**Dignity**' (Articles 1-5):

- human dignity, the right to life, the right to the integrity of the person, prohibition of torture and inhuman or degrading treatment or punishment, prohibition of slavery and forced labour;

Title II '**Freedoms**' (Articles 6-19):

- the right to liberty and security, respect for private and family life, protection of personal data, the right to marry and found a family, freedom of thought, conscience and religion, freedom of expression and information, freedom of assembly and association, freedom of the arts and sciences, the right to education, freedom to choose an occupation and the right to engage in work, freedom to conduct a business, the right to property, the right to asylum, protection in the event of removal, expulsion or extradition;

Title III '**Equality**' (Articles 20-26):

- equality before the law, non-discrimination, cultural, religious and linguistic diversity, equality between men and women, the rights of the child, the rights of the elderly, integration of persons with disabilities;

Title IV '**Solidarity**' (Articles 27-38):

- workers' right to information and consultation within the undertaking, the right of collective bargaining and action, the right of access to placement services, protection in the event of unjustified dismissal, fair and just working conditions, prohibition of child labour and protection of young people at work, family and professional life, social security and social assistance, health care, access to services of general economic interest, environmental protection, consumer protection;

Title V '**Citizens' rights**' (Articles 39-46):

- the right to vote and stand as a candidate at elections to the European Parliament and at municipal elections, the right to good administration, the right of access to documents, the right to refer to the European Ombudsman, the right to petition, freedom of movement and residence, diplomatic and consular protection;

Title VI '**Justice**' (Articles 47-50):

- the right to an effective remedy and a fair trial, presumption of innocence and the right of defence, principles of legality and proportionality of criminal offences and penalties, the right not to be tried or punished twice in criminal proceedings for the same criminal offence;

The text of the Charter can be found under this link:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT>.

The Explanations relating to the Charter of Fundamental Rights provide guidance on the meaning of the provisions of the Charter and can be found under this link:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2007.303.01.0017.01.ENG

In order to contribute to a greater awareness about fundamental rights, Fundamental Rights Agency (FRA) has developed a user friendly online tool Charterpedia, which compiles international, EU and national constitutional law in the area of fundamental rights linked to the topics, chapters and Articles of the Charter (¹).

(¹) https://infoportal.fra.europa.eu/InfoPortal/infobaseFrontEndCountryHome.do?btnCountryLinkHome_1

2.2. Legal status and applicability of the Charter

2.2.1. *Legal status of the Charter*

The Lisbon Treaty accorded the Charter the same legal value as the EU Treaties. It is legally binding and respect for fundamental rights enshrined in the Charter is a legal requirement.

According to Article 51(1) of the Charter, its provisions are addressed to the EU institutions, bodies, offices and agencies, subject to the principle of subsidiarity, and to Member States when they are implementing EU law. Accordingly, they must respect the rights and observe the principles enshrined in the Charter and promote their application in accordance with their respective powers when adopting and implementing rules. Article 6(1) of the Treaty on European Union and Article 51(2) of the Charter specify that the provisions of the Charter may not extend in any way the competences of the Union as defined in the Treaties.

The requirement to respect rights defined in the Charter is only binding on Member States when they act within the scope of EU law. As regards Member States, the Charter applies to all 'emanations of State'. It thus applies to central authorities, as well as to regional, local and other public authorities when implementing EU law.

In the context of the implementation of the ESI Funds, all the Member States' actions undertaken for the implementation of the applicable regulations fall within the scope of EU law. The Charter might apply to ESIF beneficiaries, whatever their legal form, which have been made responsible, pursuant to a measure adopted by a Member State, for providing a public service under the control of the State and which have for that purpose special powers beyond those which result from the normal rules applicable in relations between individuals.

Whereas the respect for fundamental rights enshrined in the Charter is a legal requirement, there is no legal obligation under the Charter to take active measures of promotion of the rights enshrined in the Charter, but Member States are encouraged to adopt these measures if they wish so.

2.2.2. *Applicability of the Charter*

According to its Article 51(1), the Charter is addressed to Member States only when they are implementing EU law.

In line with the Court of Justice's settled case-law interpreting these provisions, the concept of 'Member States implementing Union law' does not mean that Member States are automatically implementing Union law when they hand out support under the ESIF Funds, regardless what is the 'national measure' or 'national legislation' behind the act attacked by a complainant or applicant.

In order to determine whether a national measure involves the implementation of EU law, it is according to the Court of Justice 'necessary to determine, inter alia:

- whether that national legislation is intended to implement a provision of EU law;
- the nature of the legislation at issue
- whether the national legislation pursues objectives other than those covered by EU law, even if it is capable of indirectly affecting EU law;
- whether there are specific rules of EU law on the matter or rules which are capable of affecting it.'

The above reasoning would apply *mutatis mutandis* to any national measure implementing EU law, legislative or not.

The Court has further confirmed that, in cohesion policy as in other areas, the concept of 'implementing Union law' requires a certain degree of connection above and beyond the matters covered being closely related or one of those matters having an indirect impact on the other.

The consequences of this case law is that it will be necessary to examine whether or not in a practical case a national measure is intended to implement a provision of Union law.

Implementation of EU law in the context of implementation of ESIF is explained in section 3 below and Annex I.

3. IMPLEMENTATION OF ESIF AND THE CHARTER

In the context of the implementation of cohesion policy the provisions of the Charter of fundamental rights apply under the conditions indicated below.

The principle of non-discrimination has been reinforced in Regulation (EU) No 1303/2013 of the European Parliament and of the Council⁽¹⁾ (Hereinafter 'the CPR') through the introduction of an *ex ante* check of the existence of the arrangements to ensure its respect.

According to Article 7 of Regulation (EU) No 1303/2013, Member States and the Commission have to ensure the respect of the principles of equality between men and women and non-discrimination throughout the preparation and implementation of programmes.

Regarding the principle of non-discrimination on the basis of disability and the principle of integration of persons with disabilities, it should be noted that the EU is a party to the UNCRPD⁽²⁾. The legal consequences of ratification of the UNCRPD by the Union for the management of ESI funds are described below in Annex II.

Article 4(2) of Regulation (EU) No 1303/2013 requires the Commission and the Member States to ensure that support of the ESI Funds is consistent with relevant policies and horizontal principles as referred to, inter alia, in Article 7 of the Regulation (EU) No 1303/2013 and priorities of the Union.

The legal framework applicable to cohesion policy has been furthermore reinforced to ensure that Member States have a system in place for handling complaints, including complaints alleging a violation of the Charter of Fundamental Rights.

In the context of ESI Funds, EU law provision triggering the application of the Charter can be found in the following EU regulations and directives:

1. The CPR;
2. Fund-specific Regulations;
3. Commission delegated and implementing regulations adopted on the basis of the CPR or the Fund specific Regulations;
4. Other EU regulations and directives, which are applicable to Member States' actions implementing the ESI Funds. It would go beyond the purpose of this guidance to identify the national measures of implementation of all other EU regulations and directives, applicable to Member States' actions when implementing ESI Funds. However, national authorities have the obligations to respect the Charter in this context as well.

In the area of the ESI Funds Member States are implementing EU law when establishing the ESI Funds intervention strategy and drawing up the programming documents (1), when setting up the management, monitoring and control system (2), when implementing programmes (3) under the set of regulations mentioned above under point 1 to 3. Therefore in the following phases Member States should ensure compliance with the Charter⁽³⁾:

3.1. Establishing the ESI Funds intervention strategy and drawing up the programming documents (preparation of strategic policy frameworks, Partnership Agreements, programs etc.)

Member States are considered to act in the scope of EU law when adopting acts or drawing up documents resulting from an obligation included in the CPR, or any of its delegated or implementing acts. This includes, by way of example, the drawing up of the Partnership Agreement or operational programmes (OPs).

When Member States draw up such documents, they need to ensure, with the help of the 'Fundamental Rights Checklist' that the content of the document is in compliance with the provisions of the Charter. The content of the document should respect the rights protected by the Charter and observe the principles therein.

In this context, the most relevant rights and principles are equality before the law, non-discrimination, equality between women and men, integration of persons with disabilities, the right to property, and environmental protection.

⁽¹⁾ Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (OJ L 347, 20.12.2013, p. 320).

⁽²⁾ Convention on the Rights of Persons with Disabilities (adopted by the General Assembly by its resolution 61/106 of 13 December 2006. It came into force on 3 May 2008 upon its 20th ratification) - <https://www.un.org/development/desa/disabilities/conference-of-states-parties-to-the-convention-on-the-rights-of-persons-with-disabilities-2.html>

⁽³⁾ The examples of Member States' actions that are considered to be implementation of EU law are given in the context of the legal framework for the programming period 2014-2020. However since 2009 the provisions of the Charter must be applied, inter alia, in the context of implementation of ESIF under the conditions reminded in this guidance document.

3.2. Setting up the management, monitoring and control systems

Member States are considered to act in the scope of EU law when they set up structures and procedures required under the CPR for the management, monitoring and control of the ESI funds or if not explicitly required, when they put in place such structures for the sake of implementing the CPR, fund specific rules or their delegated or implementing acts. This covers the designation of the authorities and intermediate bodies, the working arrangements between them, the set-up of the monitoring committee and the adoption of manuals of procedures.

When doing so, Member States authorities should ensure that the rights and principles of the Charter are respected. In this context, the most relevant provisions are in particular Articles 7, 8 and 41 and 47 of the Charter.

Article 47 recognises the right to an effective remedy and to a fair trial, including the right to be heard. Article 7 is about the respect for private and family life. Article 8 concerns the protection of personal data while Article 41 concerns the obligation of the administration to give reasons for its decisions.

The right to an effective remedy and to a fair trial (due process) needs to be ensured throughout all procedures which are put in place to give effect to the provisions of the CPR, fund specific rules or its delegated or implementing acts.

For example, subject of the CJEU Case C-562/12 *Liivimaa Lihaveis MTÜ v Eesti-Läti programmi 2007-2013, Seirekomitee* has been the following set-up under the Estonia-Latvia cross-border cooperation programme: The Seirekomitee, a body composed by representatives of both Member States, took the final decisions on the qualitative assessment of project applications under that programme. That committee had also adopted a programme manual, which stipulated that its decisions could not be subject to appeal before a national court. Although the adoption of a programme manual was neither explicitly referred to in the applicable legislation for the programming period 2007-2013 nor in any EU implementing provisions, the CJEU concluded that the manual had clearly been adopted with the intention to implement EU legislation and that it was binding on any person wishing to obtain aid under the said programme. Therefore the Charter, including its Article 47, was held to be applicable in this case. The CJEU held that excluding in a programme manual the judicial review before a national court of a grant refusal decision is not compliant with Article 47.

Concerning the organization of the partnership, the most relevant Charter's rights and principle include: non-discrimination, linguistic diversity, equality between women and men, integration of persons with disabilities, while in relation to formulation of rules of membership for example, it would be necessary to pay attention particularly to rights and principles of non-discrimination, linguistic diversity, equality between women and men.

As regards the functions and obligations of the monitoring committee within the framework of setting up of the management, monitoring and control system, the most relevant Charter's rights and principle would include protection of personal data, non-discrimination, linguistic diversity, equality between women and men, integration of persons with disabilities, equality before the law and the right to an effective remedy and to a fair trial.

3.3. Implementing programmes and carrying out concrete actions outlined in a project description for works carried out when implementing ESI funds

The implementation of the programmes requires actions to be taken by the managing authority or intermediate bodies⁽¹⁾. Such actions, like for example, launching calls for proposals, selecting operations, signing of grant agreements, follow up of the implementation, checking payment claims from beneficiaries, carrying out on the spot verifications, supervising the work of intermediate bodies, sending payment claims, preparing and submitting reports are actions of implementation of EU law.

Certifying authorities' responsibilities under Article 126 CPR also imply taking measures of implementation of EU law. Audit authorities as well when are drawing up an audit strategy, carrying out audit, drafting audit opinion and control reports

Furthermore, as explained in *Chapter 2.2, Legal status of the Charter*, the Charter might apply to certain beneficiaries, when the conditions mentioned in the Chapter 2.2 are fulfilled (Member State adopts a measure which makes these beneficiaries, whatever their legal form is, responsible for providing a public service under the control of the State. For that specific purpose they have special powers beyond those which result from the normal rules applicable in relations between individuals)⁽²⁾.

⁽¹⁾ For example Local Action Groups (LAGs) referred to in Articles 34(1) and 125 CPR acting as intermediate bodies.

⁽²⁾ The check list provided in Chapter 4 of this Guidance can be used to assess whether a certain action of these beneficiaries represent action of implementation of EU law.

When carrying out their tasks national authorities should ensure that the rights and principles of the Charter are respected and in this context, the most relevant Charter's rights and principles are the right to an effective remedy and to a fair trial, to the protection of personal data, to equality before the law and equality between women and men, to non-discrimination and the rights of the child, the integration of persons with disabilities and a high level of environmental protection, linguistic diversity, safe working conditions, freedom of expression and information, freedom of assembly and association, right to education, freedom to conduct a business, right to property, protection in the event of removal, expulsion or extradition, respect for private and family life.

3.4. **Applicability of the Charter in the context of Cohesion policy: why is Charter relevant for the state authorities managing ESI Funds?**

A breach of a fundamental right enshrined in the Charter is subject to judicial review by the courts of the Member States and by the Court of Justice of European Union (CJEU).

Provisions of EU law and national law based on EU law must be interpreted in coherence with Charter obligations, so as to give effect to the rights guaranteed under it. Where a national court has doubts as to the applicability of the Charter or the correct interpretation of its provisions, it can — and, in the case of a national court of last instance, must — refer to the CJEU for a preliminary ruling. The CJEU's answer enables the national court to decide the case. National courts regularly use this procedure. It helps the development of Charter-related case law and strengthens the role of national courts in upholding it.

The Commission, as the guardian of the Treaties, has the power to try to put an end to a violation of the Charter. It can open infringement proceedings against Member States for non-compliance with the Charter.

As the Charter applies to Member States only when they are implementing Union law, the Commission cannot launch an infringement procedure for non-compliance of a national law with the Charter if that national law in question does not implement EU law. Where the Charter does not apply, fundamental rights continue to be guaranteed at national level under the constitutions or constitutional traditions of Member States and international conventions they have ratified, the respect of which is guaranteed by national courts.

In addition, in the context of ESI Funds, Article 6 of Regulation (EU) No 1303/2013 requires operations supported by ESIF to comply with applicable Union law and the national law relating to its application. If a Member State does not respect the Charter properly when taking actions or measures of implementation of EU law, this could constitute an irregularity by an economic operator (Article 2(36) of the CPR). The Commission will therefore, where appropriate, make use of the means it has at its disposal to ensure that EU Funds are used in compliance with the Charter, in those cases where it is applicable, including interruptions of payment deadlines, suspensions of payments and financial corrections as well as infringement proceedings under Article 258 TFEU.

The duty of national authorities to ensure the respect and the protection of fundamental rights is particularly relevant with regards to the complaints that the Member States can receive concerning a possible violation of the Charter. Related to the question of monitoring of application and implementation of the Charter in the Member States is the obligation for Member States arising from Article 74(3) of the CPR, to have in place effective arrangements for the examination of complaints concerning the ESI Funds submitted by legal or natural persons. Complaints concerning the ESI Funds can also be addressed directly to the Commission.

4. **HOW TO ASSESS COMPLIANCE WITH THE CHARTER — FUNDAMENTAL RIGHTS CHECKLIST**

National authorities responsible for the implementation of the ESI Funds are invited to carefully assess whether the actions and measures (planned or already adopted by them) do fall within the scope of EU law and to check if they may have any impact on the fundamental rights enshrined in the Charter.

As a practical tool to help them carrying out this assessment, the following checklist is proposed without being of compulsory use.

I. **CHECK — if the foreseen national action or measure is the measure of implementation of EU law and therefore falls within the scope of the application of the Charter**

NB: this check is not necessary for actions and documents identified in this guidance as implementing EU law.

a) Check if there is an obligation in EU law other than the Charter applicable to the national action or measure.

b) If there is such an obligation in EU law, check if the national action or measure is intended to implement it.

II. CHECK — if there is a possible breach of the fundamental rights

1. What fundamental rights are affected? (*Screening the foreseen action or measure against the fundamental rights in the Charter as well as 'key impact questions' in annex III provides a first indication as to which fundamental rights will be concerned*)
2. Are the rights in question absolute rights? (*Examples being, the ban on torture and the prohibition of slavery or servitude*).

If it is concluded that the examined action or measure limits an absolute right, it should be discarded already at this stage since absolute rights may not be limited and a further analysis under points 3-6 is not needed.

3. What is the impact of the foreseen action or measure under consideration on fundamental rights? *This step aims at identifying, for all different stakeholders concerned any positive impacts (promotion of fundamental rights) or negative impacts (limitation of fundamental rights)*
4. Do the foreseen action or measure have both a beneficial and a negative impact, depending on the fundamental rights concerned (*for example, a negative impact on freedom of expression and beneficial one on intellectual property*)

Should the analysis reveal that the foreseen action or measure would have no material impact on fundamental rights or only positive impacts on fundamental rights there is no need for further analysis under points 5 and 6. If you identify negative impacts, consider the following:

5. Would the limitation of/negative impact on fundamental rights be provided for by law, in a clear and predictable manner?
6. Would any such limitation/negative impact:
 - Genuinely meet an objective of general interest of the Union or to protect the rights and freedoms of others (*This step should identify which objective of general interest or to protect the rights and freedoms of others*)?
 - Be necessary to achieve the desired aim? (*This step should examine if the measure is appropriate and effective for attaining the objective pursued without going beyond what is necessary to achieve it? Why is no equally effective but less intrusive measure available?*);
 - Be proportionate to the desired aim?
 - Preserve the essence of the fundamental rights concerned?

If all these questions can be answered in the affirmative, then the limitation of the affected fundamental right can be considered to be legitimate.

To illustrate the use of this checklist, see below a concrete example of how it is used based on the facts of case C-401/11 *Blanka Soukupová v Ministerstvo zemědělství* and the assessment of the Court of Justice in its judgment of 11 April 2013.

The Member State in question had set up an early retirement support scheme for farmers co-financed from the European Agricultural Guidance and Guarantee Fund (EAGGF). The notion of 'retirement age' to be able to take part in the scheme was defined in national law. National legislation determined a retirement age which varied depending on the sex of the applicant and, for women, on the number of children raised.

When applying the checklist to this case at hand, the following questions need to be analysed:

1. What fundamental rights are affected?

The early retirement support scheme affects the principle of equal treatment and non-discrimination enshrined in Articles 20, 21(1) and 23 of the Charter.

2. Are the rights in question absolute rights?

No, the rights enshrined in Articles 20, 21(1) and 23 of the Charter are not absolute rights.

3. What is the impact of the foreseen action or measure under consideration on fundamental rights? This step aims at identifying, for all different stakeholders concerned any positive impacts (promotion of fundamental rights) or negative impacts (limitation of fundamental rights)?

Due to the fact that the 'normal retirement age' is determined differently depending on the gender of the applicant for support for early retirement from farming and, in the case of female applicants, on the number of children raised by the applicant, the early retirement support scheme impacts negatively on the principle of equal treatment between men and women and puts female farmers at a particular disadvantage vis-à-vis male farmers.

4. Do the foreseen action or measure have both a beneficial and a negative impact, depending on the fundamental rights concerned?

The foreseen action has solely a negative impact on the right concerned, notably for women who have raised more children. Women who have raised more children objectively enjoy a shorter period in which to submit an application for registration under the support scheme for early retirement than that granted to men or women who have raised fewer children.

5. Would the limitation of/negative impact on fundamental rights be provided for by law, in a clear and predictable manner?

Yes, the notion of 'normal retirement age' was defined in national law.

6. Would any such limitation/negative impact:

— Genuinely meet an objective of general interest of the Union or protecting the rights and freedoms of others

No, the difference in treatment does not meet an objective of general interest of the Union or to protect the rights and freedoms of others.

— Be necessary to achieve the desired aim? (This step should examine if the measure is appropriate and effective for attaining the objective pursued without going beyond what is necessary to achieve it? Why is no equally effective but less intrusive measure available?);

No, the measure is not necessary to achieve the desired aim, which is to encourage such farmers, regardless of their sex and of the number of children they have raised, to stop farming early and definitively, with a view to better ensuring the viability of agricultural holdings. Those farmers, both men and women, are entitled to claim such support, if they have definitively stopped all commercial farming activity after having practised farming for the 10 years preceding that cessation and were not less than 55 years old but not yet of normal retirement age at the time of the cessation. The desired aim could also have been reached by not making a distinction on the basis of gender or the number of children raised.

As these questions cannot be answered in the affirmative, the limitation of the affected fundamental right (equal treatment) cannot be considered to be legitimate, and thus amounts to a violation of Articles 20, 21(1) and 23 of the Charter.

ANNEX I

Examples of implementation of EU law by Member States in the context of ESI Funds

In Chapter 3 of this Guidance, the three phases of implementation of ESI Funds requiring compliance with the Charter were identified.

The list of the most relevant CPR provisions requiring actions and documents by a national (central, regional, or local level) authority/body is provided below. Examples of the Charter right or principle that could be relevant in the specific case as well as examples of possible fundamental rights' related issues are also indicated.

Where Member States draft documents and adopt acts implementing EU law (whatever form they may take: decision, letter, manual, law, etc.), this must be done with due regard to their obligations to respect all the rights enshrined in the Charter.

For instance, the right not to be discriminated, the right to property, data protection as well as the right to an effective remedy and to a fair trial (due process) need to be ensured throughout all procedures which are put in place to give effect to the provisions of the CPR, or its delegated or implementing acts.

1. Establishing the ESI Funds intervention strategy and drawing up the programming documents

Concerning the preparation of the ESI Funds intervention strategy and programming documents, the CPR provides for certain actions of Member States that are national measures of implementation of EU law and require compliance with the Charter. Member State actions:

- preparation and modification of Partnership Agreement — Member States should ensure the respect of the Charter in this process leading to the submission of the document to the Commission as well as in the document itself;
- preparation and modification of programmes (Article 26(2) and 30 of the CPR, Articles 4(4), 7, 8, 19(1) and Annex XI of the CPR; ERDF, ESF, CF: 96(2), 96(4)(a), 96(7), 96(10) of the CPR; ERDF: Article 8(7) and (12) of Regulation (EU) No 1299/2013 of the European Parliament and of the Council ⁽¹⁾; EAFRD: Articles 10 and 11 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council ⁽²⁾; EMFF: Articles 17, 18 and 20 of Regulation (EU) No 508/2014 of the European Parliament and of the Council ⁽³⁾ and Commission Implementing Regulation (EU) No 771/2014 ⁽⁴⁾ and Delegated Regulation (EU) No 1046/2014 ⁽⁵⁾);
- Programmes;

The following rights/principles of the Charter could be of particular importance: equality before the law, non-discrimination, equality between women and men, integration of persons with disabilities, the right to property, and environmental protection.

2. Setting up the management, monitoring and control systems

Member States or authorities designated by them are advised to pay particular attention to compliance with the Charter when setting up the management, monitoring and control system. The following non-exhaustive list of actions and documents is required by the Regulations:

I. **Member States:** relevant actions are: setting up of a management and control systems for programmes, organisation of a partnership and formulating the rules of membership of the monitoring committee.

A) *Setting up management and control systems for programmes* (Article 74(2) of the CPR), Articles 7, 72, 74(2) of the CPR, ERDF, ESF, CF, EMFF: 123 of the CPR, EAFRD: Articles 65 and 66 of Regulation (EU) No 1305/2013 and relevant provisions of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽⁶⁾; EMFF: Articles 97 and 99 of Regulation (EU) No 508/2014 and Commission Delegated Regulation (EU) No 1014/2014 ⁽⁷⁾.

⁽¹⁾ OJ L 347, 20.12.2013, p. 259.

⁽²⁾ OJ L 347, 20.12.2013, p. 487.

⁽³⁾ OJ L 149, 20.5.2014, p. 1.

⁽⁴⁾ OJ L 209, 16.7.2014, p. 20.

⁽⁵⁾ OJ L 291, 7.10.2014, p. 1.

⁽⁶⁾ OJ L 347, 20.12.2013, p. 549.

⁽⁷⁾ OJ L 283, 27.9.2014, p. 11.

Documents linked to the setting up of management and control systems for the programmes:

- documents containing the rules setting up management and control systems
- documents concerning procedures for ensuring effective and proportionate anti-fraud measures (Article 125(4)(c) of the CPR)
- documents concerning procedures to support the work of the monitoring committee
- documents concerning procedures for a system to collect, record and store in computerised form data on each operation necessary for monitoring, evaluation, financial management, verification and audit, including, where applicable, data on individual participants and a breakdown of data on indicators by gender when required
- documents concerning procedures for the supervision of the functions formally delegated by the managing authority under Article 123(6) and (7) of the CPR
- documents concerning procedures for appraising, selecting and approving operations and for ensuring their compliance, for the entire implementation period, with applicable rules (Article 125(3) of the CPR), including instructions and guidance ensuring the contribution of operations to achieving the specific objectives and results of the relevant priorities in accordance with the provisions of Article 125(3)(a)(i) of the CPR and procedures to ensure that operations are not selected where they have been physically completed or fully implemented before the application for funding by the beneficiary (including the procedures used by the intermediate bodies where the appraisal, selection and approval of operations have been delegated)
- documents concerning procedures to ensure the provision to the beneficiary of a document setting out the conditions for support for each operation, including procedures to ensure that beneficiaries maintain either a separate accounting system or an adequate accounting code for all transactions relating to an operation
- documents concerning procedures for the verifications of operations (in line with requirements under Article 125(4) to (7) of the CPR), including for ensuring the compliance of operations with the Union policies (such as those related to partnership and multi-level governance, promotion of equality between men and women, non-discrimination, accessibility for persons with disabilities, sustainable development, public procurement, State aid and environment rules), and identification of the authorities or bodies carrying out such verifications
- documents concerning the procedures by which applications for reimbursement are received from beneficiaries, verified, and validated, and by which payments to beneficiaries are authorised, executed and accounted for, in line with obligations set out in Article 122(3) of the CPR as from 2016 (including the procedures used by the intermediate bodies where processing of applications for reimbursement has been delegated), in view of respecting the deadline of 90 days for payments to beneficiaries under Article 132 of the CPR
- documents concerning procedures to draw up and submit to the Commission annual and final implementation reports (Article 125(2)(b) of the CPR), including the procedures for collecting and reporting reliable data on performance indicators (Article 125(2)(a) of the CPR)
- documents concerning procedures for drawing up the management declaration (Article 125(4)(e) of the CPR)
- documents concerning procedures for drawing up the annual summary of the final audit reports and of controls carried out, including an analysis of the nature and extent of errors and weaknesses identified in systems, as well as corrective action taken or planned (Article 125(4)(e) of the CPR)
- documents concerning procedures concerning the communication to staff of the above procedures, as well as an indication of training organised/foreseen and any guidance issued (date and reference)
- documents concerning procedures used by the intermediate bodies to carry out delegated tasks, and of the procedures of the certifying authority to supervise the effectiveness of the tasks delegated to the intermediate bodies
- documents concerning procedure on reporting and correction of irregularities (including fraud) and their follow-up and recording of amounts withdrawn and recovered, amounts to be recovered, irrecoverable amounts and amounts related to operations suspended by a legal proceeding or by an administrative appeal having suspensory effect

- documents concerning procedure to comply with the obligation to notify irregularities to the Commission in accordance with Article 122(2) of the CPR
- documents concerning procedures for drawing up and submitting payment applications
- documents concerning arrangements in place for the certifying authority to access any information on operations, necessary for the purpose of drawing up and submitting payment applications, including the results of management verifications (in line with Article 125 of the CPR) and all relevant audits
- documents concerning procedure by which payment applications are drawn up and submitted to the Commission, including procedure to ensure sending of the final application for interim payment by 31 July following the end of the previous accounting year
- documents concerning the accounting system used as a basis for certification of expenditure accounts to the Commission (Article 126(d) of the CPR)
- documents concerning procedures in place for drawing up the accounts referred to in Article 59(5) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ⁽⁸⁾ (Article 126(b) of the CPR)
- documents concerning arrangements for certifying the completeness, accuracy and veracity of the accounts and that the expenditure entered in the accounts complies with applicable law (Article 126(c) of the CPR) taking into account the results of all verifications and audits
- documents concerning the system for ensuring prompt recovery of public assistance, including Union assistance
- documents concerning procedures for ensuring an adequate audit trail by maintaining accounting records in computerised form, including amounts recovered, amounts to be recovered, amounts withdrawn from a payment application, amounts irrecoverable and amounts related to operations suspended by a legal proceeding or by an administrative appeal having suspensory effect, for each operation, including the recoveries resulting from the application of Article 71 of the CPR on durability of operations
- documents concerning arrangements for deducting amounts recovered or amounts to be withdrawn from expenditure to be declared
- documents concerning the information systems including a flowchart (central or common network system or decentralised system with links between the systems)
- documents concerning procedures to verify that IT systems security is ensured
- national eligibility rules for operational programmes and rural development programmes
- adoption of rules on eligibility of expenditure for cooperation programmes

When Member States establish the ESI Funds intervention strategy and draw up the programming documents they must respect the rights protected by the Charter and observe the principles therein. In this context, the most relevant provisions are Article 47 of the charter which recognises the right to an effective remedy and to a fair trial, including the right to be heard, Article 7 on the respect for private and family life and Article 8 on the protection of personal data.

- B) *Organisation of a partnership* (Article 5(1) and (2) of the CPR), Articles 5, 7, 15(1)(c) and (d) of the CPR, Articles 2, 3, 4 of Commission Delegated Regulation (EU) No 240/2014 ⁽⁹⁾

Relevant documents for the organization of a partnership: documents concerning arrangements for the partnership in the Partnership Agreement and other documents concerning the organisation of partnership

Relevant Charter's rights/principles include:

non-discrimination, linguistic diversity, equality between women and men, integration of persons with disabilities

⁽⁸⁾ OJ L 298, 26.10.2012, p. 1.

⁽⁹⁾ OJ L 74, 14.3.2014, p. 1.

- C) *Formulating the rules of membership of the monitoring committee as well as rules of procedures of the monitoring committee* (Article 10(1) of Commission Delegated Regulation (EU) No 240/2014), Articles 7, 47(1) to (3)⁽¹⁰⁾, 48(1) of the CPR.

Relevant documents: documents concerning rules on membership of the monitoring committee and rules of procedures of the monitoring committee

Relevant Charter's rights/principles include: non-discrimination, equality between women and men, linguistic diversity

II. **Monitoring committee**

- *Examination and approval of the communication strategy for the operational programme and any amendment of the strategy, the criteria for selection of operations* (Article 110(2 (a) and)(d) CPR, EAFRD: Article 74(a) of Regulation (EU) No 1305/2013.)

Relevant Charter's rights/principles include: protection of personal data, non-discrimination, linguistic diversity, equality between women and men, integration of persons with disabilities

- *Establishing additional eligibility rules of expenditure under ETC programmes* (Article 18(2) of ETC Regulation)

Relevant documents: document establishing additional eligibility rules of expenditure under ETC programmes

Relevant Charter's rights/principles include: non-discrimination, equality between women and men, linguistic diversity, integration of persons with disabilities, equality before the law, right to an effective remedy and to a fair trial

3. **Implementation of the programmes**

In the implementation of programmes, hereunder is a list of examples of actions and documents stemming from CPR, where Member States or authorities designated by them should pay particular attention to compliance with the Charter.

I. **Managing authority/intermediate body**

Relevant action: drawing up and, once approved by the Monitoring committee, applying appropriate selection procedures and criteria, including preparation of calls for proposal (125(3)(a) of the CPR, Articles 4(4), 7, 8, 34, 36(3), 47(1) of the CPR, ERDF, ESF, CF, EMFF: 125(3)(a) of the CPR and Commission Delegated Regulations (EU) 2015/288⁽¹¹⁾ and (EU) 2015/852⁽¹²⁾, EAFRD: Article 49 of Regulation (EU) No 1305/2013, Article 113 of Regulation (EU) No 508/2014, Article 12 ETC Regulation⁽¹³⁾, Article 19(1), second subparagraph, Treaty of the European Union

Relevant documents for this action:

- documents concerning the selection procedure
- documents concerning selection criteria

Relevant Charter's rights/principles include: protection of personal data, linguistic diversity, equality before the law, non-discrimination, equality between women and men, integration of persons with disabilities, environmental protection, right to an effective remedy and to a fair trial and safe working conditions.

Relevant action: implementation of programmes, providing cumulative data on operations selected for funding, Articles 4(4) and (5), 7, 8, 74, of Regulation (EU) No 1305/2013, ERDF, ESF, CF, EMFF: 122, 123 of the CPR, Article 21 ETC Regulation, EAFRD: Articles 65 and 66 of Regulation (EU) No 1305/2013 and relevant provisions of Regulation (EU) No 1306/2013, EMFF Article 97 Regulation (EU) No 508/2014 and Commission Implementing Regulations (EU) No 1242/2014⁽¹⁴⁾ and (EU) No 1243/2014⁽¹⁵⁾.

⁽¹⁰⁾ For ETC programmes.

⁽¹¹⁾ OJ L 51, 24.2.2015, p. 1.

⁽¹²⁾ OJ L 135, 2.6.2015, p. 13.

⁽¹³⁾ Under Article 12(1) ETC Regulation operations under ETC programmes are selected by the Monitoring committee or where relevant, the steering committee.

⁽¹⁴⁾ OJ L 334, 21.11.2014, p. 11.

⁽¹⁵⁾ OJ L 334, 21.11.2014, p. 39.

Relevant documents for this action:

- documents setting out the conditions for support for each operation including the specific requirements concerning the products or services to be delivered under the operation, the financing plan, and the time-limit for execution (Article 125(3)(c) of the CPR)
- notifications of selected major projects (Article 102(1), first subparagraph, of the CPR, Article 1 and Annex I to Commission Implementing Regulation (EU) No 1011/2014 ⁽¹⁶⁾)

Relevant Charter's rights/principles include: protection of personal data, Freedom of expression and information, Freedom of assembly and association, Right to education, Freedom to conduct a business, Right to property, Protection in the event of removal, expulsion or extradition, Equality before the law, Non-discrimination, Equality between women and men, Integration of persons with disabilities, Environmental protection, Right to an effective remedy and to a fair trial

Relevant action: informing potential beneficiaries about funding opportunities (Article 115(1)(c) of the CPR): Articles 7, ERDF, ESF, CF: 115(1)(c) of the CPR, EAFRD: Article 66(1)(i) of Regulation (EU) No 1305/2013 ⁽¹⁷⁾

Relevant Charter's rights/principles include: equality before the law, Non-discrimination

Relevant action: maintaining and providing the access to the list of operations accessible through the single website or website portal (Article 115(2) of the CPR): ERDF, ESF, CF: Article 115(2) of the CPR ⁽¹⁸⁾; EMFF Annex V to Regulation (EC) No 508/2014 and Commission Implementing Regulation (EU) No 763/2014 ⁽¹⁹⁾.

Relevant documents for this action: information on a website or website portal

Relevant Charter's rights/principles include: respect for private and family life, Protection of personal data

II. **Monitoring committee**

Relevant action: selection of operations (Article 12(1) of Regulation (EU) No 1299/2013): Articles 4(4), 7, 8, 29(4), 47(1) of the CPR, ERDF, EAFRD: Article 49 of Regulation (EU) No 1305/2013, Article 19(1), second subparagraph, Treaty of the European Union

Relevant Charter's rights/principles include: equality before the law, Non-discrimination, Equality between women and men, Integration of persons with disabilities, Environmental protection, Right to an effective remedy and to a fair trial

Relevant action: examination and approval of the annual implementation report

Relevant Charter's rights/principles include: protection of personal data

III. **Certifying authority**

Relevant actions: drawing up, certifying and submitting payment applications, drawing up the accounts, certifying the completeness, accuracy and veracity of the accounts and that the expenditure entered in the accounts complies with applicable law and has been incurred in respect of operations selected for funding in accordance with the criteria applicable to the operational programme and complying with applicable law, ensuring that there is a system which records and stores in computerised form, accounting records for each operation (and other functions from Article 126 of the CPR)

Relevant Charter's rights/principles include: protection of personal data

⁽¹⁶⁾ OJ L 286, 30.9.2014, p. 1.

⁽¹⁷⁾ Under Art 23.(2) ETC Regulation, this is a task of the joint secretariat.

⁽¹⁸⁾ See footnote 17.

⁽¹⁹⁾ OJ L 209, 16.7.2014, p. 1.

IV. Audit authority

Relevant action: carrying out of audits (Article 127(1) and (2) of the CPR)

Relevant documents: audit strategy (Article 127(4) of the CPR) an audit opinion in accordance with the second subparagraph of Article 59(5) of the Financial Regulation, a control report (Article 127(5)(a) and (b) of the CPR)

Relevant Charter's rights/principles include: protection of personal data, respect for private and family life, non-discrimination

ANNEX II

Fundamental rights in the EU beyond the Charter

The Charter is consistent with the **European Convention on Human Rights** adopted in the framework of the Council of Europe. When the Charter contains rights that stem from this Convention, their meaning and scope are the same (Article 52(3) Charter) ⁽¹⁾.

Regarding the integration of persons with disabilities (Article 26 Charter), EU ratified the **UN Convention on the Rights of Persons with Disabilities (UNCRPD)** in December 2010. Hence the UNCRPD forms an 'integral part of the European Union legal order' ⁽²⁾. Furthermore, international agreements concluded by the European Union have primacy over instruments of secondary law. Thus, the latter must be interpreted in a manner that is consistent with the UN CRPD ⁽³⁾. As both the EU and its Member States are separate contracting parties, and each has competence in the fields covered by the UN CRPD, the convention is a 'mixed' agreement in the context of the EU. All UN CRPD provisions falling within EU competence are binding on the EU institutions. In addition, EU law obliges Member States to implement the convention to the extent that its provisions fall within EU competence. Implementation of the Convention in areas not under EU competence rests exclusively with the Member States. Despite their different competences, the Union and its Member States are subject to a duty of sincere cooperation when fulfilling the obligations set out in such 'mixed' agreements. In its declaration upon ratification, the EU provided the UN with a list of Union acts which 'illustrate the extent of the area of competence of the Community in accordance with the Treaty establishing the European Community. (...)' Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999 ⁽⁴⁾ is explicitly mentioned in the declaration. In order to assist Member States in respecting their obligations under the UNCRPD, the European Commission services have developed two Guidance documents ⁽⁵⁾ and a Toolbox on De-institutionalisation ⁽⁶⁾.

Regarding the prohibition of discrimination on any ground such as race, colour, and ethnic or social origin (Article 21 Charter), the Commission has issued a guidance document on desegregation in housing and education for marginalised communities ⁽⁷⁾.

Regarding environmental protection and procedural fundamental rights, the **UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the Aarhus Convention)** was signed by the Community and subsequently approved by Council Decision 2005/370/EC ⁽⁸⁾. Therefore, the provisions of that convention form an integral part of the legal order of the European Union ⁽⁹⁾. Moreover, they take precedence over EU secondary law and thus the latter must be interpreted in a manner that is consistent with the Aarhus Convention ⁽¹⁰⁾.

In addition, Article 7 TEU can be triggered in case of risk of a serious breach by a Member State of the values of the Union referred to in Article 2, which include respect for human rights and equality before the law. The procedure can result in suspension of certain rights deriving from the application of the Treaties to the Member State in question.

⁽¹⁾ The Press Service of the European Court of Human Rights has compiled factsheets by theme on the Court's case-law and pending cases. These factsheets are very useful in case of doubts on interpretations of certain fundamental rights. They are accessible here:

http://www.echr.coe.int/Pages/home.aspx?p=press/factsheets&c=#n1347890855564_pointer

See in particular, the recent factsheet on environment and the ECHR with an overview of issues related, among others, to nuisance (smells, noise and polluting fumes) which in certain cases amounted to a violation of Article 8 ECHR on the right to respect for private and family life, which is enshrined in Article 7 of the Charter (the wording of Article 8 ECHR and of Article 7 of the Charter are similar):

http://www.echr.coe.int/Documents/FS_Environment_ENG.pdf

⁽²⁾ See for example: CJEU, Joined Cases C-335/11 and C-337/11 *HK Danmark*, Judgement of 11 April 2013, para 30.

⁽³⁾ See for example: CJEU, Joined Cases C-335/11 and C-337/11 *HK Danmark*, Judgement of 11 April 2013, para 29.

⁽⁴⁾ OJ L 210, 31.7.2006, p. 25.

⁽⁵⁾ Common European Guidelines on the Transition from Institutional to Community Based Care,

<http://www.deinstitutionalisationguide.eu/wp-content/uploads/2016/04/Toolkit-07-17-2014-update-WEB.pdf>; and Thematic guidance note on Transition from Institutional to Community-based Care (Deinstitutionalisation), http://ec.europa.eu/regional_policy/sources/docgener/informat/2014/guidance_deinstitutionalisation.pdf

⁽⁶⁾ Toolkit on the Use of European Union Funds for the Transition from Institutional to Community Based Care,

<http://www.deinstitutionalisationguide.eu/wp-content/uploads/2016/04/GUIDELINES-Final-English.pdf>

⁽⁷⁾ http://ec.europa.eu/regional_policy/sources/docgener/informat/2014/thematic_guidance_fiche_segregation_en.pdf

⁽⁸⁾ OJ L 124, 17.5.2005, p. 1.

⁽⁹⁾ Case C-240/09 *Lesoochránárske zoskupenie* [2011] ECR I-01255, para 30.

⁽¹⁰⁾ See footnote 3.

Finally, it should be borne in mind that the general principles of EU law established in the CJEU jurisprudence are an additional fundamental rights source in primary EU law. Pursuant to Art 6 TEU and the CJEU case law, they have a continuing relevance for the protection of fundamental rights in the EU's legal system alongside the Charter.

The general principles apply, alongside the Charter, whenever the Member States act within the scope of EU law. For instance, Article 41 of the Charter containing the right to good administration is not addressed to the Member States, but only to the Union. However, in those cases where the Member States act within the scope of Union law, the general principle of good administration might still apply.

ANNEX III

Key questions

The questions below ⁽¹⁾ give general guidance on what concrete issues could be considered when checking compliance with Fundamental Rights of the actions and documents mentioned in Annex I.

Fundamental rights Impacts	Key questions
General	<ul style="list-style-type: none"> — What fundamental rights are affected? — Are the rights in question absolute rights (which may not be subject to limitations, examples being human dignity and the ban on torture)? — Does the action ⁽¹⁾ have both a beneficial and a negative impact, depending on the fundamental rights concerned (for example, a negative impact on freedom of expression and beneficial one on intellectual property)?
Dignity	<ul style="list-style-type: none"> — Does the action affect human dignity, the right to life or to the integrity of the person? — Does the action raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing, use of genetic information)? — Would it entail risks in terms of torture and inhuman or degrading treatment or punishment? — Would it have an impact in terms of forced labour or trafficking in human beings?
Individuals, private and family life, freedom of conscience and expression	<ul style="list-style-type: none"> — Does it affect the right to liberty of individuals? — Does the action affect the right to private life privacy (including their home and communications)? — Does it affect an individual's right to move freely within the EU? — Does it affect the right to marry and to found a family or the legal, economic or social protection of the family? — Does the action affect freedom of thought, conscience and religion? — Does it affect freedom of expression and information? — Does it affect freedom of assembly and of association? — Does it affect the freedom of the arts and science?
Personal data	<ul style="list-style-type: none"> — Does the action involve the processing of personal data? — Who processes personal data and for which purpose? — Are the individual's right to access, rectification and objection guaranteed?

⁽¹⁾ These questions were developed and also used by the Commission for the purpose of the screening of impact assessment in the context of the better regulation package.

Fundamental rights Impacts	Key questions
	<ul style="list-style-type: none"> — Was the data processing activity notified to the competent authority? — Do the data processing/transfer chains imply also international transfers and if so are there any specific safeguards in place in case of international transfers? — Is the security of the data processing activities provided for from a technical and organisational point of view? — Are any safeguards which render the interference into the right of data protection proportionate and necessary provided for? — Are appropriate/specific review and oversight mechanisms in place?
Asylum and protection of removal, expulsion or extradition	<ul style="list-style-type: none"> — Does the action affect the right of asylum and does it guarantee the prohibition against collective expulsion or extraditions to states of individuals where they risk being subject to death penalty, torture or degrading treatment.
Property rights and the right to conduct a business.	<ul style="list-style-type: none"> — Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? — If yes, will there be a complete loss of property? If so what are the justifications and compensation mechanisms? — Does the action affect the freedom to conduct a business or impose additional requirements increasing the transaction costs for the economic operators concerned?
Gender equality, equality treatment and opportunities, non-discrimination, and rights of persons with disabilities	<ul style="list-style-type: none"> — Does the action safeguard the principle of equality before the law and would it affect directly or indirectly the principle of non-discrimination, equal treatment, gender equality and equal opportunities for all? — Does the action have (directly or indirectly) a different impact on women and men? — How does the action promote equality between women and men? — How does the action entail any different treatment of groups or individuals directly on grounds of sex, racial or ethnic origin, religion or belief, disability, age, and sexual orientation? Or could it lead to indirect discrimination? — Does the action ensure respect for the rights of people with disabilities in conformity with the UN Convention on the rights of persons with disabilities? How? (see http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010D0048)
Rights of the child	<ul style="list-style-type: none"> — Does it strengthen or restrict the rights of the child (or group)? What is the justification for a possible restriction? — Does the action take into account the principle of the best interests of the child? — Does the action help to promote the protection of the rights of the child? In doing so, does it also take into account the rights and principles of the UN CRC? If so, which articles may be concerned? — How are the guiding principles of the UN CRC promoted in the action?

Fundamental rights Impacts	Key questions
	<ul style="list-style-type: none"> — Does the action impede any of the guiding principles of the UNCRC? — What steps have been taken to improve or compensate for any adverse effects of the action? — Has the child's right to be heard on all matters that affect him/her been respected? — Does the action contribute to the promotion of child-friendly justice systems adapted to the needs, age and maturity of a child?
Good administration/ Effective remedy/ Justice	<ul style="list-style-type: none"> — Will the administrative procedures in place become more burdensome? — Will they guarantee the right to be heard, the right of access to the file with due regards to professional and business secrecy as well as the obligation of the administration to give reasons for its decisions? — Is the individual's access to justice affected? — In case that the action affects rights and freedoms guaranteed by the law of the Union, does it foresee the right to an effective remedy before a tribunal? — If the action concerns criminal law or envisages criminal law sanctions have safeguards been provided ensuring the Presumption of innocence and right of defence, the principles of legality and proportionality of criminal offences and penalties, as well as the right not to be tried or punished twice in criminal proceedings for the same criminal offence?
Solidarity and worker's rights	<ul style="list-style-type: none"> — Does the action respect worker's rights such as: worker's rights to information and consultation within the undertaking; the right of collective bargaining and action; the right of access to placement services; protection in the event of unjustified dismissal; fair and just working conditions; the prohibition of child labour and protection of young people at work, and the entitlement to social security benefits and social services?
Environmental Protection	<ul style="list-style-type: none"> — Does the action contribute to a high level of environmental protection and the improvement of the quality of the environment in accordance with the principle of sustainable development?

(¹) Actions implementing programmes and carrying out concrete actions outlined in a project description for works carried out when implementing ESI funds (action).

Non-opposition to a notified concentration**(Case M.8100 — IK/Five Arrows/I@D)****(Text with EEA relevance)**

(2016/C 269/02)

On 15 July 2016, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ⁽¹⁾. The full text of the decision is available only in English language and will be made public after it is cleared of any business secrets it may contain. It will be available:

- in the merger section of the Competition website of the Commission (<http://ec.europa.eu/competition/mergers/cases/>). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,
- in electronic form on the EUR-Lex website (<http://eur-lex.europa.eu/homepage.html?locale=en>) under document number 32016M8100. EUR-Lex is the online access to the European law.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1.

Non-opposition to a notified concentration**(Case M.8082 — General Motors France/Groupe Dubreuil/Claro)****(Text with EEA relevance)**

(2016/C 269/03)

On 18 July 2016, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ⁽¹⁾. The full text of the decision is available only in the French language and will be made public after it is cleared of any business secrets it may contain. It will be available:

- in the merger section of the Competition website of the Commission (<http://ec.europa.eu/competition/mergers/cases/>). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes.
- in electronic form on the EUR-Lex website (<http://eur-lex.europa.eu/homepage.html?locale=en>) under document number 32016M8082. EUR-Lex is the online access to European law.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

COUNCIL

Council conclusions on food product improvement

(2016/C 269/04)

THE COUNCIL OF THE EUROPEAN UNION,

RECALLS:

1. Article 168 of the Treaty on the Functioning of the European Union (TFEU) ⁽¹⁾, which states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities and which provides that the Union shall encourage cooperation between the Member States in the field of public health and, if necessary, support their action.

Article 26 TFEU, which states that the internal market shall comprise an area without internal frontiers in which the free movement of goods is ensured.

2. The Council conclusions of 6 December 2007 on the Commission White Paper on a strategy for Europe on nutrition, overweight and obesity-related health issues ⁽²⁾, which, in the context of an integrated approach to tackle nutritional challenges, called upon Member States to support activities aimed at reformulating foods to reduce levels of salt, saturated fat, trans-fatty acids, added sugar and energy density, given the role these elements play in the development of non-communicable diseases, overweight and obesity.
3. The Council conclusions of 8 June 2010 on action to reduce population salt intake for better health ⁽³⁾, which called upon Member States to strengthen or develop coordinated and sustainable national nutritional policies, including salt reduction programmes, to reduce salt consumption to an appropriate level.
4. The EU Framework for National Initiatives on Selected Nutrients ⁽⁴⁾, established in 2011 following the positive results of the EU Framework for National Salt Initiatives ⁽⁵⁾, to which were added, in 2012, Annex I on saturated fat ⁽⁶⁾ and, in 2015, Annex II on added sugars ⁽⁷⁾, providing political guidance for action.
5. The Council conclusions of 20 June 2014 on nutrition and physical activity ⁽⁸⁾, and the Action Plan on Childhood Obesity, recognising the beneficial impact of disease prevention on both citizens and health systems and the importance of healthy diet in reducing the risk of chronic conditions and non-communicable diseases, which invited the Member States to continue to make healthy diet a top priority, thus contributing to better health and quality of life of EU citizens and the sustainability of the health systems.
6. EU Member States' support for the World Health Organisation's (WHO) global action plan for the prevention and control of NCDs 2013-2020, of 27 May 2013 ⁽⁹⁾, which called for a reduction in the preventable and avoidable burden of morbidity, mortality and disability due to non-communicable diseases by means of multisectoral collaboration and cooperation at national, regional and global levels, so that populations reach the highest attainable standards of health and productivity at every age and those diseases are no longer a barrier to well-being or socio-economic development.

⁽¹⁾ OJ C 326, 26.10.2012, p. 47 (consolidated version).

⁽²⁾ 15612/07.

⁽³⁾ OJ C 305, 11.11.2010, p. 3.

⁽⁴⁾ http://ec.europa.eu/health/nutrition_physical_activity/docs/euframework_national_nutrients_en.pdf

⁽⁵⁾ http://ec.europa.eu/health/archive/ph_determinants/life_style/nutrition/documents/salt_initiative.pdf

⁽⁶⁾ http://ec.europa.eu/health/nutrition_physical_activity/docs/saturated_fat_eufnisn_en.pdf

⁽⁷⁾ http://ec.europa.eu/health/nutrition_physical_activity/docs/added_sugars_en.pdf

⁽⁸⁾ OJ C 213, 8.7.2014, p. 1.

⁽⁹⁾ http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf

7. The conclusions of the report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population ⁽¹⁾.
8. The Conference on Food Product Improvement, organised by the Presidency in Amsterdam on 22 and 23 February 2016 ⁽²⁾, where a roadmap for action on food product improvement ⁽³⁾, to develop more concerted action to move step by step towards a healthier product offer, was endorsed by the majority of the Member States and by Norway and Switzerland as well as by food business operators and health-related non-governmental organisations.

NOTES WITH CONCERN THAT:

9. The prevalence of overweight, obesity and other diet-related non-communicable diseases in the European population is too high and is still rising. This has a negative impact on life expectancy, reducing Union citizens' quality of life and affecting society, for example by threatening the availability of a healthy and sustainable workforce and inducing high healthcare costs which may affect the sustainability of the healthcare systems. It thus also imposes an economic burden on the Union and its Member States.
10. In particular, the high prevalence and rise of overweight and obesity among children is a serious concern, calling for strong concerted action, as already addressed at the level of the Member States, the Union and the World Health Organisation (WHO) ⁽⁴⁾.
11. Nutrition plays an important role in this context, alongside other lifestyle-related matters: the diet of many Europeans contains too much salt, saturated fats, sugars and energy value, mostly through consumption of processed or prepared foods, whilst at the same time most people do not consume enough fruits, vegetables and wholegrain products. In some Member States, people are still exposed to high amounts of trans-fatty acids.

RECOGNISES THAT:

12. For people's diet to improve, the healthy choice should be the easy choice.

To achieve such an objective, a holistic approach is needed: physical and social environments that support and encourage healthy patterns of food consumption as well as objective nutrition information and public-health driven education are key for policies and actions at national and local level.

Food product improvement, by reducing among others the levels of salt, saturated fats, added sugars ⁽⁵⁾ and energy value, as well as improving the availability of small and/or reduced portion sizes ⁽⁶⁾, is an important tool to make the healthy choice easy. In general such reduction should not lead to an increase in energy value ⁽⁷⁾ and should not decrease the quality and safety of the products.

13. To reach the majority of the population, in particular children and vulnerable groups, more action is needed on mainstream products that are consumed by the majority of the European population on a daily basis.

⁽¹⁾ http://ec.europa.eu/food/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf

⁽²⁾ <http://english.eu2016.nl/events/2016/02/22/thematic-conference-on-product-improvement>

⁽³⁾ <https://www.rijksoverheid.nl/documenten/formulieren/2016/02/22/roadmap-for-action-on-food-product-improvement>

⁽⁴⁾ Non-exhaustive list: EU Strategy on Nutrition, Overweight and Obesity-Related Health Issues 2007; Political Declaration of the High-level Meeting of the General Assembly (of the United Nations) on the Prevention and Control of Non-communicable Diseases' of 2011; WHO European Food and Nutrition Action Plan 2015–2020; Vienna Declaration on Nutrition and Non-Communicable Diseases in the Context of Health 2020; EU Action Plan on Childhood Obesity 2014 – 2020.

⁽⁵⁾ In the sense used in Annex II to the EU framework for national initiatives on selected nutrients (http://ec.europa.eu/health/nutrition_physical_activity/docs/added_sugars_en.pdf) 'added sugars' refers to sucrose, fructose, glucose, starch hydrolysates (glucose syrup, high-fructose syrup) and other isolated sugar preparations used as such or added during food preparation and manufacturing, as well as sugars present in honey, syrups and fruit juices and fruit-juice concentrates.

⁽⁶⁾ A number of foods are packed (biscuits, chocolate bars, milk drinks, yogurts, nuts, salads, preserves, etc.) or sold (hamburgers, dishes in canteens, etc.) in portions designed to be consumed immediately or once open. There are no unified 'sizes' for such portions, but it is clear that the size chosen by the producer is a clear invitation to consumption, as people avoid wasting food. Smaller portions offer more flexibility for the consumer, as a second portion will only be eaten through an active decision.

⁽⁷⁾ However, even if the energy value remains unchanged, reductions of saturated fats or added sugars can be encouraged through an increase of recommended nutritional components that are not generally consumed in sufficient amounts (e.g. fibre, fruits and vegetables).

14. Accessible and affordable improved food products can contribute to the goal of decreasing health inequalities, as vulnerable groups, for whom it might be difficult to make healthy choices, could more easily opt for improved products as they become more widely available.
15. Governments have the responsibility for setting public health objectives, which should, subsequently, be achieved in cooperation with food business operators and other relevant stakeholders. Food business operators ⁽¹⁾ throughout the food chain have a responsibility towards improving the products and meals they offer and, by doing so, contribute to making the healthy choice the easy choice. Guidelines on the composition of foods to be provided by public bodies (such as hospitals, schools and residences for elderly people or students), including through public procurement, can also play a major role in supporting these objectives.
16. The point of departure varies between Member States, some of which already have a history in food product improvement, for example by setting compositional criteria for products, criteria for school meals and other food provided via public procurement by validating the proposals of food business operators, criteria relating to labelling or to the marketing of food products to children and criteria for portion sizes.
17. Cultural differences in preferences and dietary patterns can partly determine the approach, the pace of reduction of salt, saturated fat, added sugars and the final results. Every approach should acknowledge those cultural differences and dietary patterns. Local and traditional foods, including geographical indications ⁽²⁾, intrinsically tied to a country's culture and heritage, could be subject to special consideration, taking into account the national situation, for example their contribution to the overall dietary intake.
18. Salt, saturated fats and added sugars should be reduced in food gradually to enable consumer acceptance of improved products. Food for infants and children deserves specific attention to develop broad tastes, including for fruits and vegetables and avoid early development of taste preference for high-sugar and high-salt foods.
19. Food is extensively traded across borders within the internal market; therefore, food product improvement calls for cross-border cooperation in order to be effective from the public health and industry points of view, thus ensuring a high level of consumer and health protection and better functioning of the internal market.
20. Small and medium-sized enterprises (SMEs) which would like to participate in food product improvement initiatives may lack the necessary resources or skills to work on food product improvement. Raising awareness among SMEs and encouraging support and attention for SMEs through the voluntary sharing of knowledge and best practices is important in view of their market share.
21. The improvement of the composition of food products opens up great possibilities for innovation and business opportunities and can lead to a market advantage. Within companies, increased coherence between the development of improved food products and marketing investment is desirable and expected in order to promote the healthiest options in the portfolio of companies and make the healthy choice easy.
22. Including companies' nutrition and health activities specifically related to food product improvement in auditing initiatives concerning corporate social responsibility could be a valuable incentive.
23. Research provides the necessary information for a solid approach to food product improvement. In general, the necessary know-how for the first important steps in improvement is available, but such information could be better distributed and exploited.
24. Data on current consumption and product composition help to make it possible for actions to be targeted at the most relevant product groups. The transparency and accessibility of such data facilitate the adoption of good practices.
25. Regular, transparent, credible and independent monitoring of product composition is essential for insight into the market situation and into the results of actions undertaken.
26. Other factors, such as technological possibilities, food safety and sustainability goals, may influence results in food product improvement.

⁽¹⁾ This includes, among others, manufacturers, retailers, caterers, bars, restaurants and other providers of food.

⁽²⁾ <http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/geographical-indications/>

CALLS UPON THE MEMBER STATES TO:

27. Have a national plan for food product improvement in place by the end of 2017, either as a new plan or integrated into an existing plan, in cooperation with the relevant stakeholders, to make the healthy choice easier for consumers by 2020 through an increased availability of food with lower levels of salt, saturated fats, added sugars, energy value and, where appropriate, through reduced portion sizes and to provide information on the nutritional composition of processed foods. Local and traditional foods, including geographical indications ⁽¹⁾, intrinsically tied to a country's culture and heritage could be subject to special consideration, taking into account the national situation, for example their contribution to the overall dietary intake.
28. Make full use of all existing structures and tools, including the online tools of the EU Health Policy Platform ⁽²⁾, for sharing experiences on new initiatives and actions, as well as best practices, aimed at promoting food product improvement.

CALLS UPON THE MEMBER STATES AND THE COMMISSION TO:

29. Report regularly, at least every two years, on progress achieved in food product improvement initiatives and share benchmarks, where available, best practices of implementation and results, within the framework of the High Level Group (HLG) on Nutrition and Physical Activity ⁽³⁾.
30. Integrate the multidimensionality of food product improvement by involving representatives responsible for the areas of health, agriculture, food, economy and distribution, innovation, research and the internal market in the actions undertaken.
31. Support technological and research projects in the field of food product improvement aimed at developing and applying sound and up-to-date scientific knowledge.
32. Raise awareness and facilitate involvement of SMEs, e.g. by supporting research projects aimed at improving food composition, disseminating information on food product improvement techniques and applying criteria relating to food product improvement to relevant structural funds, thus providing affordable solutions for SMEs when improving food products.

CALLS UPON THE COMMISSION TO:

33. Assess existing benchmarks for the reduction of salt and saturated fats in the context of the EU Frameworks for National Salt Initiatives and National Initiatives on Selected Nutrients and support the development of new possible benchmarks within the context of the HLG within a clear timeframe.
34. While respecting Member States' competence, continue to involve the stakeholders concerned at Union level, including food business operators, in the food product improvement process, by:
 - (a) continuing to support coordination and cooperation between the HLG on Nutrition and Physical Activity and the EU Platform for Action on Diet, Physical Activity and Health ⁽⁴⁾ for more focused discussions and exchanges of information on food product improvement;
 - (b) establishing working groups with experts from both Member States and stakeholders within the EU Platform for Action on Diet, Physical Activity and Health:
 - to work on improving the methodology, quality and share the results of monitoring activities ⁽⁵⁾;
 - to suggest possible criteria regarding salt, saturated fats, added sugars and, where appropriate, portion sizes for food categories throughout the food chain;
 - to look for other possible ways to increase the availability of healthy choices, particularly by also increasing beneficial nutritional elements that are recommended to be consumed and in general are not sufficiently consumed;

⁽¹⁾ <http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/geographical-indications/>

⁽²⁾ http://ec.europa.eu/health/interest_groups/policy_platform/index_en.htm

⁽³⁾ http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/index_en.htm

⁽⁴⁾ http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm

⁽⁵⁾ For monitoring purposes the focus should be on total sugars instead of added sugars, since (currently) only total sugars can be analysed.

(c) supporting clear, transparent and flexible working procedures (e.g. exchange of information by electronic means and guidance for public-private cooperation) and making the progress achieved and results attained by the working groups publicly available, for example via the online EU Health Policy Platform, to optimise the work of the groups.

35. Continue to support the improvement of the scientific basis, monitoring and data collection and sharing at EU level regarding improved products, consumption and new production methods.

Monitoring of progress to be outlined with the Joint Action on Nutrition and Physical Activity (JANPA) ⁽¹⁾ coordinated by France and to be seen in the light of the work of ongoing activities of WHO Europe, the European Commission and the Joint Research Centre (JRC).

36. Invite the JRC to participate in the autonomous verification and monitoring of EU Platform commitments with regard to food product improvement, which should be measurable, comparable and monitored in a sound and transparent way.

37. Increase coordination and alignment of research activities and open research data to underpin the development of improved food products through the Joint Programming Initiative: Healthy Diet for a Healthy Life.

38. Where possible, closely coordinate all new activities with regard to food product improvement with existing groups and actions, such as the JANPA and the WHO European Salt Action Network (ESAN, coordinated by Switzerland).

39. Facilitate the exchange of best practices, in particular through the following actions:

(a) setting up special pages on food product improvement on the online multi-stakeholder EU Health Policy Platform, with links to existing databases where possible, where all stakeholders involved can share experiences, challenges, knowledge, showcase results, identify obstacles in the EU internal market and share possible solutions to these obstacles;

(b) updating all stakeholders on planned and implemented actions at the regular meetings of the HLG and the EU Platform for Action on Diet, Physical Activity and Health.

⁽¹⁾ <http://www.janpa.eu/>

Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance

(2016/C 269/05)

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLS the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine ⁽¹⁾ and the reports of December 2005, April 2010 from the Commission to the Council on its implementation ⁽²⁾ and the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections ⁽³⁾ and the reports of November 2012 and June 2014 from the Commission to the Council on its implementation ⁽⁴⁾.
2. RECALLS the Council conclusions of 10 June 2008 on antimicrobial resistance (AMR) ⁽⁵⁾, the Council conclusions of 1 December 2009 on innovative incentives for effective antibiotics ⁽⁶⁾, 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 ⁽⁷⁾ and the Council conclusions of 1 December 2014 on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance ⁽⁸⁾.
3. RECALLS the European Parliament Resolution of 12 May 2011 on antibiotic resistance ⁽⁹⁾, the European Parliament Resolution of 27 October 2011 on the public health threat of antimicrobial resistance ⁽¹⁰⁾, the European Parliament Resolution of 11 December 2012 on the Microbial Challenges – Rising Threats from AMR ⁽¹¹⁾ and the European Parliament Resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance ⁽¹²⁾.
4. RECALLS the 2001 Community Strategy against AMR ⁽¹³⁾ and the European Commission Communication of 15 November 2011 on an action plan against the rising threats from Antimicrobial Resistance ⁽¹⁴⁾ and the outcome of the evaluation of the 5 years action plan of the European Commission.
5. WELCOMES the Global Action Plan (GAP) on Antimicrobial Resistance ⁽¹⁵⁾ developed by the World Health Organisation (WHO) with the contribution of the Food and Agricultural Organization (FAO) and the World Organization for Animal Health (OIE) and unanimously adopted in May 2015 by the 68th World Health Assembly, calling all Member States of the World Health Organization to put in place national action plans against AMR by mid-2017.
6. WELCOMES the Resolution on Antimicrobial Resistance adopted in June 2015 by the 39th Conference of the FAO and the Resolution combating Antimicrobial Resistance and promoting the prudent use of antimicrobial agents in animals in May 2015 at the World Assembly of Delegates of the OIE.
7. WELCOMES the Codex Alimentarius Commission ⁽¹⁶⁾ initiative with regard to the need to review and update standards, codes and guidelines related to AMR.
8. WELCOMES other international and regional initiatives, such as the declaration by the G7 on Antimicrobial Resistance ⁽¹⁷⁾ and the decision to put antimicrobial resistance on the agenda of the G20.
9. RECALLS that regarding human health, the Union’s action is defined by Article 168 of the Treaty on the Functioning of the European Union.

⁽¹⁾ OJ L 34, 5.2.2002, p. 13.

⁽²⁾ 5427/06 [COM(2005)684 final] and 8493/10 [COM(2010)141 final]

⁽³⁾ OJ C 151, 3.7.2009, p. 1.

⁽⁴⁾ COM(2012)0658 and COM(2014)0371

⁽⁵⁾ 9637/08

⁽⁶⁾ OJ C 302, 12.12.2009, p. 10.

⁽⁷⁾ OJ C 211, 18.7.2012, p. 2.

⁽⁸⁾ OJ C 438, 6.12.2014, p. 7.

⁽⁹⁾ P7_TA(2011)0238

⁽¹⁰⁾ P7_TA(2011)0473

⁽¹¹⁾ 2012/2041 (INI)

⁽¹²⁾ 2014/2207 (INI)

⁽¹³⁾ COM/2001/0333 final Volume I.

⁽¹⁴⁾ 16939/11 [COM(2011)748]

⁽¹⁵⁾ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_ACONF1Rev1-en.pdf?ua=1

⁽¹⁶⁾ CAC 39-C-2015/21

⁽¹⁷⁾ https://www.g7germany.de/Content/EN/Artikel/2015/06_en/g7-gipfel-dokumente_en.html

10. RECALLS that antimicrobial resistance is a cross-border health threat that cannot be sufficiently addressed by one Member State alone and cannot be confined to a geographical region or a Member State and hence needs intensive cooperation and coordination between Member States, as stated in the Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health ⁽¹⁾.
11. RECALLS that in the veterinary sector a number of legislative and non-legislative measures have already been taken and are taken at EU level to coordinate and ensure a common EU approach reducing the risk of AMR. These measures include especially those set out in the Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽²⁾, prohibiting the use of antibiotics as growth promoters, Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria ⁽³⁾, Commission Decisions following referral procedures under Directive 2001/82/EC, resulting in modifications of marketing authorisations for products containing critically important antimicrobials in order to reflect specific measures against development of AMR and in the Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C-299/04) ⁽⁴⁾.
12. WELCOMES the ongoing work of the Organisation for Economic Cooperation and Development (OECD) and the World Bank on the economic impact of AMR.
13. EXPRESSES ITS CONCERN regarding the data provided by OECD, according to which, it is estimated that about 700 000 deaths may be caused globally each year by AMR. Compared to a world with no AMR, the economic impact associated with current rates of AMR may reach about 0,03 % of GDP in 2020 in OECD countries, 0,07 % in 2030 and 0,16 % in 2050. This would result in cumulative losses of about USD 2,9 trillion by 2050 ⁽⁵⁾.
14. ACKNOWLEDGES the Scientific Opinions and reports on antimicrobial resistance published by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).
15. RECOGNISES that due to the complexity of the problem, its cross-border dimension and the high economic burden, the impact of antimicrobial resistance goes beyond its severe consequences for human and animal health and has become a global public health concern that affects the whole of society and requires urgent and coordinated inter-sectoral action, where necessary based on the precautionary principle ⁽⁶⁾.
16. UNDERLINES that in order to stimulate the development of new antimicrobials, alternative therapies and (rapid) diagnostics, EU and global coordination and cooperation on research programmes and incentives are needed and RECOGNISES the work done by the Innovative Medicines Initiative (IMI) project DRIVE-AB (Driving reinvestment in research and development and responsible antibiotic use), the proposals of the Antimicrobial Resistance Review team ⁽⁷⁾ and the Joint Programming Initiative on Antimicrobial Resistance ⁽⁸⁾ among others.
17. STRESSES that more cooperation between Member States and with the Commission and pharmaceutical industry is crucial regarding the reduced availability including possible withdrawals from the market of antimicrobials that may lead to shortages in antimicrobials and inadequate replacement therapy.
18. HIGHLIGHTS that to make progress in the fight against AMR, the new EU Action Plan should contain measurable (clearly defined quantitative or qualitative) goals, benchmarks and effective measures to achieve these goals.
19. HIGHLIGHTS that the success of the fight against antimicrobial resistance relies heavily on the commitment and willingness of governments to take actions to ensure the implementation of the initiatives under the One Health approach involving all relevant sectors and on the will of the EU Member States to cooperate within the EU and at an international level.

⁽¹⁾ OJ L 293, 5.11.2013, p. 1.

⁽²⁾ OJ L 268, 18.10.2003, p. 29.

⁽³⁾ OJ L 303, 14.11.2013, p. 26.

⁽⁴⁾ OJ C 299, 11.9.2015, p. 7.

⁽⁵⁾ <http://www.oecd.org/els/health-systems/Antimicrobial-Resistance-in-G7-Countries-and-Beyond.pdf>;

NB: in the quoted report the amount 'trillion' means 10¹²

⁽⁶⁾ Communication from the Commission on the precautionary principle (COM(2000) 1 final of 2 February 2000).

⁽⁷⁾ Lead by J. O'Neill (<http://amr-review.org/>)

⁽⁸⁾ <http://www.jpamr.eu/>

20. WELCOMES the EU Ministerial One Health Conference on AMR ⁽¹⁾ held in Amsterdam on 9 and 10 February 2016, at which the political will to tackle the AMR problem, by means of a One Health approach was expressed, including among others, enhanced cooperation between the Member States through an EU One Health Network on AMR. The EU One Health Network will not be a new governance structure, but it will work through joint meetings of existing groups or bodies in the human health, food and veterinary field, such as the AMR working group and the Health Security Committee. The EU One Health Network will be used on a regular basis to discuss AMR related issues from a one health perspective, i.a. the exchange of information between Member States about the progress made on the implementation of the National Action Plans against AMR and the development and implementation of the EU Action Plan.
21. CALLS UPON THE MEMBER STATES TO:
1. have in place before mid-2017 a national action plan against Antimicrobial Resistance based on the One Health approach and in line with the objectives of the WHO Global Action Plan. The national action plan, adapted to the national situation, should:
 - a) ensure that measures and actions in the different domains take into account the public health concerns of AMR;
 - b) be developed and implemented in cooperation between all relevant ministries and the relevant stakeholders in the public and private sector;
 - c) include measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human and veterinary sector and antimicrobial resistance in all domains. These goals could be qualitative and/or quantitative and should be addressed through effective measures adapted to the Member States' national situations;
 - d) include measures to reduce the risk of AMR and strengthen the prudent use of antimicrobials in veterinary medicine according to EU ⁽²⁾ and national guidelines, including actions to avoid the routine preventive use of veterinary antimicrobials and actions to restrict the use in animals of antimicrobials that are of critical importance to human health (e.g. use on the basis of antimicrobial susceptibility testing);
 - e) include measures to reduce the risk of AMR and strengthen the prudent use of antimicrobials in human medicine, including actions to improve prescribing practices and prudent use of antimicrobials that are of critical importance to human health (e.g. use on the basis of antimicrobial susceptibility testing);
 - f) include the mechanism for implementation of national action plans and monitoring of their progress, including the way to further strengthen surveillance and to improve the quality and comparability of the data reported to ECDC, EFSA and EMA on the use of antimicrobials and on resistance in humans, animals, the food chain and possibly the environment;
 - g) include the way enforcement of legislation relevant to AMR is organised and ensured in the Member State;
 - h) include education programmes, where appropriate, and targeted campaigns to raise awareness among consumers, animal keepers and relevant professionals;
 2. within the EU One Health Network, present their national action plans and share best practices, discuss policy options, ways to better coordinate responses and keep each other updated on the progress made on the implementation of the action plans;
 3. support dialogue with the pharmaceutical industry in order to keep existing effective antimicrobials used in human and veterinary medicine on the market, and explore alternative solutions to ensure availability of these antimicrobials on the market;
 4. join or strengthen their commitment to the existing Joint Programming Initiative on AMR ⁽³⁾;

⁽¹⁾ <http://english.eu2016.nl/events/2016/02/10/ministerial-conference-on-amr>

⁽²⁾ Commission Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C-299/04) http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf

⁽³⁾ <http://www.jpamr.eu/>

5. promote and facilitate the implementation of measures to prevent infections in animals such as the use of vaccines and biosecurity measures in order to reduce infection pressure and therefore the need to use antibiotics;
6. promote the use of diagnostic tools, including rapid tests and their uptake in the human and veterinary sector as means to improve the prescription of antimicrobials.

22. CALLS UPON THE MEMBER STATES AND THE COMMISSION TO:

1. develop together, while respecting Member States competencies, a new and comprehensive EU Action Plan on Antimicrobial Resistance based on the One Health approach, taking into account the evaluation of the current Action Plan, the discussion at the EU Ministerial One Health Conference on AMR of 10 February 2016 and the WHO Global Action Plan. The new EU Action Plan should include the following measures and measurable ⁽¹⁾ goals:
 - a) measures to prevent infections and to ensure prudent use of antimicrobials in human and veterinary medicine;
 - b) measures to combat illegal practices related to the trade and use of antimicrobials in human and veterinary medicine;
 - c) align surveillance on AMR in humans, food, animals and environment at EU level;
 - d) decrease, over the period of the new EU Action Plan, antimicrobial resistance in humans, animals and in the environment in the EU;
 - e) decrease, over the period of the new EU Action Plan, the differences between Member States in use of antimicrobials in both human and animal health, whereas Member States with a relatively low use should also try to further pursue prudent use of antimicrobials;
 - f) decrease, over the period of the new EU Action Plan, healthcare associated infections in the EU;
 - g) develop indicators to assess the progress made on addressing AMR and on the implementation of the EU Action Plan.
2. strengthen coordination and cooperation between Member States, between Member States and the Commission, and between human, food, veterinary, environmental, research and other relevant sectors and actively participate in the joint discussions of the EU One Health Network as defined in paragraph 20;
3. within the One Health Network, discuss the development, progress and implementation of the EU Action Plan;
4. strive for ambitious legislative measures that address the public health risk of AMR, in the areas where there is competence to do it, for example in the area of veterinary medicinal products and medicated feed;
5. develop European Union guidelines on prudent use of antimicrobials in human medicine to support national guidelines and recommendations;
6. set up a voluntary country-to-country peer review system in which representatives from one or several Member States evaluate each other's national action plan, reflect about policy options and provide recommendations to support Member States to improve measures taken. This country-to-country peer review system is complementary to other existing assessment tools or audit activities (e.g. ECDC, Directorate on Health and Food Audits and Analysis ⁽²⁾ or WHO);
7. ensure that the EU has a common approach in the global discussions on AMR, especially on the implementation of the GAP of the WHO, the FAO and the OIE Resolutions on AMR and on the implementation and updating the intergovernmental standards related to AMR published by Codex Alimentarius and the OIE;

⁽¹⁾ See paragraph 18.

⁽²⁾ The Directorate on Health and Food Audits and Analysis of the European Commission's Directorate-General for Health and Food Safety, formerly the 'Food and Veterinary Office'.

8. in the framework of the One Health Network on AMR align strategic research agendas of existing EU R & D initiatives on new antibiotics, alternatives and diagnostics, set priorities based on societal needs in the field of public health, animal health and the environment, taking into account the gaps analysis in this domain;
 9. actively engage in initiatives and proposals to implement a new business model to bring new antibiotics to the market, including models in which investment costs or revenues are de-linked from sales volumes;
 10. encourage all relevant partners, including national regulatory authorities to launch a reflection, within the existing appropriate fora (e.g. the One Health Network), regarding the regulatory framework with regards to antibiotics in order to stimulate research and development and to facilitate marketing authorization procedure for new antimicrobials;
 11. encourage the use of alternative treatment and prevention options including vaccines and the development and use of affordable diagnostics tests in human and veterinary medicine;
 12. support, in close cooperation between the Member States and the Commission, the proposal to put AMR on the agenda of the United Nations General Assembly in September 2016, as mandated by the WHO GAP and the FAO Resolutions on AMR, in order to raise awareness of the issue at the highest political level, involving all Heads of State and all relevant UN organisations and aim for ambitious outcomes.
23. CALLS UPON THE COMMISSION TO:
1. facilitate and support Member States in the development, assessment and implementation of national action plans against AMR, including support to strengthen monitoring and surveillance systems and consider financial support within existing frameworks;
 2. facilitate and support the regular meetings of the EU One Health Network on AMR as defined in paragraph 20;
 3. report to the Council at least once a year on the activities of the One Health Network including the developments in the area of the implementation of the EU Action Plan against AMR;
 4. establish a harmonised approach to prevent introduction and spread of emerging antimicrobial resistance in animal husbandry and the food chain with potential impact in public health (e.g. carbapenem resistance);
 5. develop as a matter of priority specific acts under the Regulation on transmissible animal diseases ('Animal Health Law')⁽¹⁾, including infection prevention measures, good management practices in animal husbandry and harmonised surveillance systems of relevant animal pathogens;
 6. actively promote and defend in multilateral and bilateral dialogues and agreements between the EU and its counterparts the EU standards and EU policies on AMR, especially:
 - a) the importance of infection prevention, prudent use of antimicrobials and strengthening the awareness of the risks of AMR in human and veterinary medicine;
 - b) the ban on the use of antibiotics as growth promoters in livestock farming;
 - c) the avoidance of the routine preventive use of antimicrobials in veterinary practice;
 - d) the restrictions on the use in veterinary practice of antimicrobials that are not authorised or which use has been restricted in the EU due to the fact that they are critically important for the prevention and treatment of life-threatening infections in humans;
 - e) the EU requirements for the import of live animals and products thereof;
 - f) the concept of the precautionary principle⁽²⁾.
 7. promote economic impact studies in the human and animal sector to assess the cost of AMR.

⁽¹⁾ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

⁽²⁾ See also paragraph 15.

Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States

(2016/C 269/06)

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, that Union action, which shall complement national policies, shall be directed towards improving public health, that the Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care and allocation of the resources to them;
2. RECALLS that under Article 168(4)(c) of the Treaty on the Functioning of the European Union, the European Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products and devices for medical use;
3. RECALLS that under Article 4(3) of the Treaty on European Union, the Union and the Member States shall assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation;
4. RECALLS that under Article 5(2) of the Treaty on European Union, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein and that competences not conferred upon the Union in the Treaties remain with the Member States;
5. RECALLS that under Article 3(1)(b) of the Treaty on the Functioning of the European Union, the Union has exclusive competence in relation to the competition rules necessary for the functioning of the internal market for medicinal products;
6. STRESSES that it is fully Member States' competence and responsibility to decide which medicinal products are reimbursed and at what price and that any voluntary cooperation on pricing and reimbursement between Member States should remain Member States driven;
7. RECOGNISES that a balanced and strong, functioning and effective intellectual property environment, that is line with international commitments of the European Union, is important for supporting and promoting access to innovative, safe, effective and quality medicinal products in the European Union;
8. NOTES that the pharmaceutical sector in the European Union has the potential to be a major contributor to innovation and the health and life sciences sector, through the development of new medicinal products;
9. RECOGNISES that new medicinal products however may also pose new challenges to individuals patients and public health systems, in particular regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their post-market surveillance and patient access and affordability;
10. UNDERLINES that Health Technology Assessment is an important tool in achieving sustainable health care systems and to promote innovation that delivers better outcomes for patients and society as a whole and RECOGNISES that EU cooperation in line with the Strategy for EU cooperation on Health Technology Assessment and the adopted work programme of EUnetHTA can support the decision-making of Member States, while acknowledging the potential added value of health technology assessments in the context of national health systems;
11. TAKES NOTE that the EU pharmaceutical legislation provides harmonised regulatory standards for the authorisation and supervision of medicinal products for human use and lays down certain regulatory schemes for the earlier marketing authorisation of medicines with less comprehensive data, such as the conditional marketing authorization or the authorisation under 'exceptional circumstances';
12. RECOGNISES that the exact conditions for the inclusion of innovative and specialised medicinal products in the existing schemes of early marketing authorisation could be further clarified in order to improve transparency, to ensure a continuous positive benefit risk balance of medicinal products put on the market under special conditions and to focus on medicinal products of major therapeutic interest for public health or to meet unmet medical needs of patients;

13. BEARING IN MIND that specific legislation has been put in place promoting the development and marketing authorisation of medicinal products targeting – *inter alia* – products to treat patients suffering from rare diseases commonly known as orphan medicinal products, paediatric medicinal products and advanced therapy medicinal products, incorporating specific incentives, including supplementary protection certificates, data exclusivity or market exclusivity and protocol assistance for orphan medicinal products;
14. BEARING IN MIND that the incentives in this specific legislation need to be proportionate to the goal of encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact, and it should be avoided that circumstances are created that might encourage inappropriate market behaviour of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit patients' access to new medicines for unmet medical needs and that can affect the sustainability of health systems;
15. NOTES that there are indications that the post-market compliance with certain obligations for marketing authorisation holders is not always optimal, which may cause that independent research data and information from patient registries are not structurally generated, collected and made available for research and proof of effectiveness and safety;
16. NOTES WITH CONCERN an increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances;
17. NOTES the increasing trend of marketing authorisation of new medicinal products for small indications, including, in some cases, the authorisation of a single product for 'segmented' patient groups within a disease area and the authorisation of one substance for several rare diseases and in this respect NOTES WITH CONCERN that companies may seek very high prices while the added value of some of these products is not always clear;
18. RECOGNISES that special attention should be given to the access to medicines for patients in smaller Member States;
19. UNDERLINES the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems;
20. STRESSES that both public and private investments are essential for the research and development of innovative medicinal products. In those cases where public investment has played a major role in the development of certain innovative medicinal products, a fair share of the return on investment in such products should preferably be used for further innovative research in the public health interest for example through agreements made on benefit sharing during the research phase;
21. STRESSES that the functioning of the pharmaceutical systems in the EU and its Member States depends on a delicate balance and a complex set of interactions between marketing authorisation and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products and that several Member States expressed concerns that these systems may be imbalanced and that it may not always promote the best possible outcome for patients and society;
22. RECALLS the Council Conclusions on the reflection process on modern, responsive and sustainable health systems adopted on 10 December 2013 ⁽¹⁾, the Council Conclusions on the economic crisis and healthcare adopted on 20 June 2014 ⁽²⁾, the Council Conclusions on innovation for the benefit of patients adopted on 1 December 2014 ⁽³⁾ and the Council Conclusions on personalised medicine for patients adopted on 7 December 2015 ⁽⁴⁾;
23. RECALLS the discussion at the Informal Meeting of Ministers of Health in Amsterdam on 18 April 2016 on 'Innovative and Affordable Medicines' which highlighted the important role of the life sciences industry in Europe, in particular, in developing effective new treatments for patients with high unmet medical needs. At the same time challenges in the pharmaceutical systems in the EU and its Member States were noted and that several Member States

⁽¹⁾ OJ C 376, 21.12.2013, p. 3, with corrigendum in OJ C 36, 7.2.2014, p. 6.

⁽²⁾ OJ C 217, 10.7.2014, p. 2.

⁽³⁾ OJ C 438, 6.12.2014, p. 12.

⁽⁴⁾ OJ C 421, 17.12.2015, p. 2.

may wish to cooperate and take action on a voluntary basis to face common challenges identified by those several Member States to the sustainability of national healthcare systems, which may be linked to a number of potential factors, for example the affordability of medicinal products related to high prices, possible unintended or adverse consequences of incentives and the lack of leverage of individual Member States in negotiations with industry;

24. WELCOMES the discussion during the informal meetings of relevant high level representatives of the Member States responsible for pharmaceutical policy on 11 December 2015 and 26 April 2016, who met for the first time and recognised the added value of an informal reflection and exchange of views on strategic policy level between Member States;
25. RECOGNISES that a number of Member States have expressed interest in pursuing voluntary cooperation between two or more Member States in the field of Health Technology Assessment as well as in exploring voluntary cooperation in different areas, for example on issues related to pricing and reimbursement of medicinal products, activities aimed at 'horizon scanning', the exchange of information and knowledge, the collection and exchange of price data such as the EURIPID collaboration, and in some cases by bringing together of facilities and resources as well as instruments for joint price negotiations and the conducting of early dialogue with companies developing new products; all these activities should remain to be voluntary, focused on clear added value, shared interests and objectives;
26. RECOGNISES that further analysis to examine the current functioning of the pharmaceutical systems in the EU and its Member States would be useful, in particular in relation to the impact of certain incentives in EU pharmaceutical legislation, the use thereof by economic operators and the consequences for the innovation, availability, accessibility and affordability of medicinal products for the benefit of patients including as regards innovative treatment solutions to common diseases that cause a heavy burden for individuals and health systems;
27. RECALLS also the relevant findings of the European Commission's 2009 Pharmaceutical Sector Inquiry Report ⁽¹⁾, which stressed that a healthy and competitive market for medicinal products benefits from vigilant competition law scrutiny;
28. UNDERLINES the importance of a continuing open and constructive multi-stakeholder dialogue with pharmaceutical industry, patient organizations and other stakeholders, which is necessary in order to ensure future developments of new and innovative medicinal products as well as the sustainability of the pharmaceutical system in the EU and its Member States, while reinforcing, at the same time, public health interests and guaranteeing the sustainability of the EU Member States health systems;
29. RECOGNISES that the pharmaceutical systems in the EU and its Member States, which are characterised by a division of competences between Member States and the EU level, can benefit from dialogue and a more holistic approach regarding pharmaceutical policy, by enhancing voluntary cooperation between Member States aimed at greater transparency, to safeguard common interests, ensuring access of patients to safe, effective and affordable medicinal products as well as the sustainability of national health systems;
30. RECALLS the Report on the implementation of the EMA-EUnetHTA three-year work plan 2012-2015 ⁽²⁾ published by the European Medicines Agency and EUnetHTA;
31. RECOGNISES potential benefits of the exchange of information across Member States on implementation and application of Managed Entry Agreements;
32. RECOGNISES that while these Council conclusions mainly refer to medicinal products, given the specific nature of the sector, the same concerns regarding sustainability and affordability, as well as considerations regarding research and development and HTA, are also applicable to medical devices and *in-vitro* diagnostic medical devices.

INVITES THE MEMBER STATES TO:

33. Consider further development of exclusively Member States driven voluntary cooperation between relevant authorities and payers from Member States, including cooperation within groups of Member States, that share common interests in relation to pricing and reimbursement of medicinal products and to explore possible areas in which

⁽¹⁾ 12097/09 + ADD1 + ADD2

⁽²⁾ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/04/WC500204828.pdf

such voluntary cooperation can contribute to higher affordability and better access to medicinal products. Where relevant and appropriate, groups of Member States that would like to explore cooperation on a voluntary basis, may also make use of international expertise, with full respect of Member States' competences. This voluntary cooperation could include activities such as:

- Assessment of future introduction of new medicinal products with a possibly significant financial impact on health systems at an early stage through so called 'joint horizon scanning', which entails a forward looking scan of emerging trends and future developments in pharmaceutical research and development aimed at better anticipating the arrival of new, expensive, innovative medicinal products that might potentially affect current policy and practice;
 - Pro-active exchange of information between Member States (e.g. national pricing and reimbursement authorities), particularly in the pre-launch phase, with due respect for existing national rules and frameworks, e.g. in relation to business confidentiality;
 - Exploring possible strategies on voluntary joint price negotiations in coalitions of Member States, that have expressed interest to do so;
 - Consider reinforcing existing cooperation schemes and initiatives to foster agreement on approaches to address unavailability of medicinal products and market failure situations.
34. Exchange HTA-methodologies and assessment outcomes through EUnetHTA and the HTA Network as already foreseen under the Joint Action EUnetHTA, while recognizing that financial impact and pricing must be addressed separately from the HTA, and that the applicability of HTA results need to be assessed by national health systems.
35. Without prejudice to existing cooperation in the context of EUnetHTA, and where appropriate, further explore closer voluntary cooperation on HTA between two or more Member States as a Member States' initiative, such as mutual recognition of HTA reports and/or joint HTA reports.
36. Consider organising during each EU Presidency an informal meeting of relevant high level representatives from the Member States responsible for pharmaceutical policy (e.g. national directors of pharmaceutical policy), encouraging strategic reflection and discussion on current and future developments in the pharmaceutical system in the EU and its Member States, thereby avoiding duplication and respecting the division of competences. These discussions are purely informal and, where relevant and appropriate, can be used as an input for further reflection in the appropriate EU fora, in particular the Working Party on Pharmaceuticals and Medical Devices when areas of EU competence are concerned.
37. The Presidency-trio (the Netherlands, Slovakia and Malta) is invited to identify with the Member States a set of mutual experienced concerns and challenges which could be considered and/or modified by the future Presidencies in the period from 2017-2020, with full respect for Member States' and EU level competences.
38. Where appropriate, these common concerns and challenges will be followed up concretely through dialogue, exchange and (international) cooperation as well as through information exchange, monitoring and research at Member States and EU level in the appropriate fora and, in particular, when EU competences are concerned, through the Working Party on Pharmaceuticals and Medical Devices, with the input from Member States, existing technical and policy fora and, where relevant, the European Commission.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

39. Explore possible synergies between the work of regulatory bodies, HTA bodies and payers, whilst respecting their specific responsibilities in the pharmaceutical chain and fully respecting Member States competences, in order to ensure timely and affordable access of patients to innovative medicinal products that reach the market especially through EU regulatory tools of accelerated assessment, marketing authorisation in exceptional circumstances and conditional marketing authorisation while also analysing the effectiveness of these tools and examining possible clear and enforceable (pre-) conditions and exit options for the products that enter the market through these mechanisms in order to ensure high level of quality, efficacy and safety of the respective medicinal product. These products will therefore continue to be appropriately evaluated and examined with regard to their benefits and risks and appropriateness to be included in these tools.
40. Foster enhanced cooperation between Member States under the 3rd Joint Action of the European Network for Health Technology Assessment (EUnetHTA) as adopted and to reflect about the future of HTA cooperation at European level for the period beyond 2020 when the current Joint Action comes to an end.

41. Improve and strengthen existing dialogue and cooperation between Member States and at EU level, in particular through and within existing fora and technical working bodies and by continuing investment in and facilitating the work of the Network of Competent Authorities on Pricing and Reimbursement (NCAPR), the Pharmaceutical Committee and the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP).
42. Assess the relevance and functioning of the various technical bodies operating at EU level within the EU pharmaceutical framework, including those operating under the auspices of the European Commission, to clarify and confirm existing tasks, roles and mandates with the aim to avoid duplication and fragmentation of work, and to give Member States a better insight and overview of ongoing developments and discussions in these fora.
43. Consider further investments at national and EU level in the availability of registries and in the developments of methods to assess the effectiveness of pharmaceuticals including through the use of relevant digital means. The implementation of means to inform on post-marketing effectiveness of medicines should allow exchange of information between Member States although in full respect of individual competences, applicable legislation on data protection and other legislation.
44. Consider further investments at national and EU level in the development of innovative medicines for clearly defined unmet medical needs, in particular also through Horizon 2020 and the Innovative Medicines Initiative (IMI) and with the involvement of the European Medicines Agency, whilst promoting open access to research data while fully respecting applicable legislation on data protection and, where applicable, the information that is considered commercially confidential, and considering conditions such as equitable licensing to ensure a fair return on investment for publicly funded research that delivered a major contribution to the development of successful medicinal products.
45. Explore obstacles for deploying existing methods and consider new solutions to address market failure, in particular also in small markets, when established products become unavailable or new products are not introduced to national markets, for example for business economic reasons.

INVITES THE EUROPEAN COMMISSION TO:

46. Pursue the ongoing activities to streamline the implementation of the current legislation on orphan medicinal products and to ascertain correct application of the current rules and fair distribution of incentives and rewards and if necessary consider revision of the regulatory framework on orphan medicinal products without discouraging the development of medicinal products needed for the treatment of rare diseases.
47. Prepare as soon as possible and with the close involvement of the Member States, while fully respecting Member States competences, the following:
 - a. an overview of the current EU legislative instruments and related incentives that aim to facilitate the investment in the development of medicinal products and the marketing authorization of medicinal products given to the holders of a marketing authorisation as implemented within the EU: Supplementary Protection Certificates (Regulation (EC) No 469/2009), medicinal products for human use (Directive 2001/83/EC and Regulation (EC) No 726/2004), orphan medicinal products (Regulation (EC) No 141/2000) and paediatrics (Regulation (EC) No 1901/2006);
 - b. an evidence based analysis of the impact of the incentives in these EU legislative instruments, as implemented, on innovation, as well as on the availability, *inter alia*, supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products. Among those incentives, particular attention should be given to the purpose of supplementary protection certificates as defined in the relevant EU legislative instrument and the use of the 'Bolar' patent exemption ⁽¹⁾, the data exclusivity for medicinal products and the market exclusivity for orphan medicinal products.

Where relevant, the analysis of impacts should also address – *inter alia* — the development of medicinal products and the effects of the pricing strategies of industry in relation to these incentives.

The Commission will conduct the analysis on the basis of the information that is made available or gathered, including from the Member States and other relevant sources.

To this end, the Commission should prepare by the end of 2016 a timetable and methodology for conducting the analysis as mentioned in this paragraph.

⁽¹⁾ Article 10.6 of the Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use.

48. Continue and where possible intensify, including through a report on recent competition cases following the pharma sector inquiry of 2008/2009, the merger enforcement pursuant to the EC Merger Regulation (Regulation (EC) No 139/2004) and the monitoring, methods development and investigation — in cooperation with national competition authorities in the European Competition Network (ECN) — of potential cases of market abuse, excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union.
 49. Based on the above mentioned overview, analysis and report in paragraphs 47 and 48, and taking into account the international commitments of the EU and — *inter alia*— also the needs of the patient, health systems and the competitiveness of the EU based pharmaceutical sector, discuss the outcome and possible solutions proposed by the Commission in the Working Party on Pharmaceuticals and Medical Devices and, when public health issues are concerned, the Working Party on Public Health at Senior Level.
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EUROPEAN COMMISSION

Euro exchange rates ⁽¹⁾

22 July 2016

(2016/C 269/07)

1 euro =

Currency	Exchange rate	Currency	Exchange rate		
USD	US dollar	1,1014	CAD	Canadian dollar	1,4436
JPY	Japanese yen	116,86	HKD	Hong Kong dollar	8,5420
DKK	Danish krone	7,4390	NZD	New Zealand dollar	1,5748
GBP	Pound sterling	0,84108	SGD	Singapore dollar	1,4934
SEK	Swedish krona	9,4979	KRW	South Korean won	1 251,19
CHF	Swiss franc	1,0860	ZAR	South African rand	15,6920
ISK	Iceland króna		CNY	Chinese yuan renminbi	7,3500
NOK	Norwegian krone	9,3847	HRK	Croatian kuna	7,4863
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	14 445,45
CZK	Czech koruna	27,023	MYR	Malaysian ringgit	4,4696
HUF	Hungarian forint	313,34	PHP	Philippine peso	51,836
PLN	Polish zloty	4,3554	RUB	Russian rouble	71,0806
RON	Romanian leu	4,4609	THB	Thai baht	38,463
TRY	Turkish lira	3,3560	BRL	Brazilian real	3,6138
AUD	Australian dollar	1,4717	MXN	Mexican peso	20,4913
			INR	Indian rupee	73,8783

⁽¹⁾ Source: reference exchange rate published by the ECB.

COURT OF AUDITORS

Special Report No 18/2016

‘The EU system for the certification of sustainable biofuels’

(2016/C 269/08)

The European Court of Auditors hereby informs you that Special Report No 18/2016 ‘The EU system for the certification of sustainable biofuels’ has just been published.

The report can be accessed for consultation or downloading on the European Court of Auditors’ website: <http://eca.europa.eu> or on EU Bookshop: <https://bookshop.europa.eu>

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(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION
POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case M.8108 — CVC/Sisal Group)

Candidate case for simplified procedure

(Text with EEA relevance)

(2016/C 269/09)

1. On 15 July 2016, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾ by which CVC Capital Partners SICAV-FIS SA, together with its subsidiaries, and CVC Capital Partners Advisory Group Hoding Foundation and its subsidiary, (the 'CVC Group', Luxembourg) acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control over the Sisal Group S.p.A of Italy, by way of purchase of shares.
2. The business activities of the undertakings concerned are:
 - for the CVC Group: advice to and management of investments funds, which hold interests in a number of companies, including Sky Bet. Sky Bet is active in the provision of online gaming and betting services to customers in the United Kingdom, Ireland, Finland, Gibraltar, Isle of Man, and the Channel Islands.
 - for the Sisal Group: provision of gambling and betting services in Italy.
3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under the Council Regulation (EC) No 139/2004 ⁽²⁾ it should be noted that this case is a candidate for treatment under the procedure set out in this Notice.
4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by e-mail to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number M.8108 — CVC/Sisal Group, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

⁽²⁾ OJ C 366, 14.12.2013, p. 5.

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