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I

(Resolutions, recommendations and opinions)

RESOLUTIONS

EUROPEAN PARLIAMENT

Completing the internal market for e-commerce

P7_TA(2010)0320

European Parliament resolution of 21 September 2010 on completing the internal market for e-commerce (2010/2012(INI))

(2012/C 50 E/01)

The European Parliament,

— having regard to the ECJ judgments on Google (Joined Cases C-236/08 to C-238/08, judgment of 23 March 2010) and BergSpechte (Case C-278/08, judgment of 25 March 2010) that define the notion of the 'normally informed and reasonably attentive internet user' as the standard internet consumer,

— having regard to its resolution of 9 March 2010 on consumer protection [1],

— having regard to SOLVIT's 2008 annual report on the development and performance of the SOLVIT network (SEC(2009)0142), the Commission staff working paper of 8 May 2008 on an action plan on an integrated approach for providing single market assistance services to citizens and business (SEC(2008)1882) and Parliament's resolution of 9 March 2010 on SOLVIT [2],

— having regard to the Commission communication of 3 March 2010 entitled 'Europe 2020: A strategy for smart, sustainable and inclusive growth' (COM(2010)2020),

— having regard to the Commission staff working document of 3 December 2009 entitled 'Guidance on the implementation/application of Directive 2005/29/EC on unfair commercial practices' (SEC(2009)1666),

— having regard to the Commission communication of 22 October 2009 on cross-border business to consumer e-commerce in the EU (COM(2009)0557),

— having regard to the 'Mystery shopping evaluation of cross-border e-commerce in the EU', a study conducted on behalf of the European Commission, DG SANCO, by YouGovPsychonomics and published on 20 October 2009,

[1] Texts adopted, P7_TA(2010)0046.
[2] Texts adopted, P7_TA(2010)0047.

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— having regard to the Commission staff working document of 22 September 2009 on the follow up in retail financial services to the Consumer Markets Scoreboard (SEC(2009)1251),

— having regard to the Commission communication of 7 July 2009 on a harmonised methodology for classifying and reporting consumer complaints and enquiries (COM(2009)0346) and to the accompanying draft Commission recommendation (SEC(2009)0949),

— having regard to the Commission communication of 2 July 2009 on the enforcement of the consumer acquis (COM(2009)0330),

— having regard to the Commission report of 2 July 2009 on the application of Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation) (COM(2009)0336),

— having regard to the Commission staff working document of 5 March 2009 entitled 'Report on cross-border e-commerce in the EU' SEC(2009)0283,

— having regard to its resolution of 5 February 2009 on international trade and the internet ([1]),

— having regard to the Commission communication of 28 January 2009 entitled 'Monitoring consumer outcomes in the single market: Second edition of the Consumer Markets Scoreboard' (COM(2009)0025) and to the accompanying Commission staff working document entitled 'Second Consumer Markets Scoreboard' (SEC(2009)0076),

— having regard to its resolution of 21 June 2007 on consumer confidence in the digital environment ([2]),

— having regard to Article 20(2) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market ([3]),

— having regard to Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (codified version) ([4]),

— having regard to its resolutions of 23 March 2006 on European contract law and the revision of the acquis: the way forward ([5]) and of 7 September 2006 on European contract law ([6]),

— having regard to current Community legislation in the area of consumer protection, e-commerce and the development of the information society,

— having regard to the Commission communication on the Review of the EU Regulatory Framework for electronic communications networks and services (COM(2006)0334),

— having regard to the First Application Report of 21 November 2003 on the E-Commerce Directive (COM(2003)0702,

— having regard to Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC ([7]),

([1]) OJ C 67 E, 18.3.2010, p. 112.
([2]) OJ C 146 E, 12.6.2008, p. 370.
([3]) OJ L 376, 27.12.2006, p. 36.
([4]) OJ L 376, 27.12.2006, p. 21.
([5]) OJ C 292 E, 1.12.2006, p. 109.
([6]) OJ C 305 E, 14.12.2006, p. 247.
([7]) OJ L 271, 9.10.2002, p. 16.

— having regard to the UNCITRAL Model Law on electronic commerce 1996, the UNCITRAL Model Law on electronic signatures 2001 and the UNCITRAL Convention on the Use of Electronic Communications in International Contracting 2005 ([1]),

— having regard to Article 11 TFEU, which stipulates that 'environmental protection requirements must be integrated into the definition and implementation of the Union policies and activities, in particular with a view to promoting sustainable development',

— having regard to Article 12 TFEU, which stipulates that 'consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities',

— having regard to Article 14 TFEU and Protocol 26 thereto on services of general (economic) interest,

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinions of the Committee on Industry, Research and Energy and the Committee on Legal Affairs (A7-0226/2010),

A. whereas Europe should not only seek ways to continue developing the internal market for e-commerce but also look into how a sustainable re-launch of the internal market could be achieved by the further development of e-commerce,

B. whereas Mario Monti's report of 9 May 2010 'A new Strategy for the Single Market' stresses that 'the single market is less popular than ever, yet it is more needed than ever'; whereas the report also notes that e-commerce together with innovative services and eco-industries holds the largest growth and employment dividends for the future and therefore represents a new frontier of the single market,

C. whereas e-commerce is a vital force of the internet and an important catalyst for achieving the aims of the EU 2020 strategy for the internal market; whereas it is important for all stakeholders to cooperate to overcome remaining barriers,

D. whereas e-commerce facilitates and promotes the development of new market niches for SMEs which would not otherwise exist,

E. whereas, with a view to unlocking the full potential of the EU single market, e-commerce traders should be encouraged to promote their products in all EU Member States using direct marketing or other communication tools,

F. whereas e-commerce is a key 21st century marketplace for the European Union, with the potential to reshape the European internal market, contribute to the knowledge economy, provide value and opportunities to European consumers and businesses at this time of financial strain, and impact significantly and positively on jobs and growth; whereas the development of e-commerce can improve the competitiveness of the EU economy, in the framework of the Commission's EU 2020 strategy, including the development and promotion of new forms of entrepreneurship for small and medium-sized enterprises,

G. whereas it is crucial to achieve an effective functioning of the internal market to fulfil the Lisbon agenda goals of increasing growth, competition and the creation of inclusive and competitive jobs to serve the 500 million consumers in the EU and their well-being;(whereas cross-border e-commerce brings important socio-economic benefits to European consumers, such as increased convenience and empowerment, reinforcement of consumer rights, increased transparency and competition, access to a wider variety of products and services to compare and choose from, and considerable potential for savings,

([1]) http://www.un.or.at/unictral.

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H. whereas, during the recent economic crisis, the development of the digital society and the completion of the internal market in ICT has enabled the e-commerce sector to continue growing and creating jobs, helping to keep online businesses economically active and allowing consumers to take advantage of greater choice and better prices; whereas cross-border e-commerce has significant benefits for EU companies – especially SMEs – which can provide innovative, high-quality and consumer-friendly services and products across the online European internal market, reinforcing their position and enabling them to remain competitive in the global economy,

I. whereas e-commerce offers a wider choice to consumers, especially to those living in less accessible, remote or outlying areas, as well as those with reduced mobility, who would otherwise not have access to a wide choice of goods; whereas e-commerce is especially beneficial for citizens in rural, remote and peripheral areas who may otherwise not have access to a wide choice of goods with such convenience or at such value,

J. whereas the Second Application Report on the E-Commerce Directive has been overdue since 2005, i.e. for five years (Article 21 of Directive 2000/31/EC),

K. whereas the Digital Agenda for Europe sets reasonable performance targets for high-speed and ultra-fast broadband coverage and for e-commerce take-up,

L. whereas European consumer and business confidence in the digital environment is low due to unnecessary barriers to e-commerce such as fragmentation of the EU market, consumers' uncertainty about data confidentiality, security of transactions and consumer rights in case of problems, and whereas in certain aspects of e-commerce Europe is lagging behind the United States and Asia; whereas the creation of a 'Digital Single Market', facilitating transactions across national borders in an on-line environment for all consumers across the European Union, is an important part of the reinvigoration of the Single Market as it provides citizens with a wider choice of products and services, whereas overcoming barriers to cross-border e-commerce and boosting consumer confidence is essential to achieving an attractive, integrated digital single market for Europe and stimulating consumer markets and the broader economy,

M. having regard to the Commission communication on the digital agenda, which recognises that consumers in the EU very often opt to engage in transactions with firms based outside the EU, for example in the US, a factor which points to the need to develop a policy for encouraging global forms of e-commerce, together with the necessity to promote the importance of internationalisation of internet governance in line with the Tunis Agenda, whereas neither consumers nor businesses can reap the benefits of a Digital Single Market since very few on-line retailers sell their products or services to other Member States and most of those sell only to a limited number of Member States; whereas there is a need to address consumer discrimination, including at the time of payment, by ensuring provisions are in place to make and receive payment and delivery; whereas e-commerce is now a significant part of the mainstream economy, and businesses and consumers increasingly utilise both online and offline commercial practices to their best advantage,

N. whereas e-commerce is international and cannot be confined within EU borders,

O. whereas the Digital Agenda for Europe sets reasonable performance targets for high-speed and ultra-fast broadband coverage and for e-commerce take-up,

P. whereas the fragmentation of part of the electronic market within the EU endangers the rights laid down in the acquis communautaire,

Q. whereas European consumers and businesses have little legal certainty as regards cross-border e-commerce and one single electronic transaction is subject to many legal provisions setting divergent requirements, which does not provide either business operators or consumers with clear and easily enforceable rules,

R. whereas the same is true for extra-European e-commerce, as European consumers often do not differentiate between European or third States when buying and selling online; whereas there is therefore a need to also involve third countries in efforts to make e-commerce more transparent, reliable and accountable,

S. whereas the increasing cross-border dimension of consumer markets raises new challenges for enforcement authorities, which are constrained by jurisdictional boundaries and the fragmentation of the regulatory framework,

T. whereas the existence of illegal services online seriously hampers the development of legitimate markets for certain digital services, notably for music, films and, increasingly, books and magazines; whereas intellectual property plays a crucial role in the digital world and whereas its protection, particularly on the internet, remains a significant challenge,

U. whereas e-commerce users have a right to compensation when they are affected by illegal practices, but in practice they face substantial barriers in bringing such cases to court due to lack of information on the legislation applying in the different Member States, long and complex procedures, the risks associated with litigation, particularly in cross-border cases, and high costs,

V. whereas the enforcement of the fundamental right to privacy and to the protection of personal data constitutes an important condition for e-commerce,

W. whereas, despite the potential of alternative dispute resolution, such systems are regularly used by only 5 % of retailers, and 40 % of retailers do not know about the possibilities of using these tools,

X. whereas uniformising the most essential consumer rights, as well as postal and banking costs, copyright levies, VAT procedures and data protection practices would go a long way towards creating a genuine single market for businesses and consumers; stresses that Member States must retain competency over VAT procedures,

Y. whereas different copyright levying systems across Member States need to be simplified and clarified so that it is easier for online goods and services providers to make products and services available to consumers of different Member States;.whereas this review of copyright levying systems would give online goods and services providers greater legal certainty in offering products and services to consumers; whereas it is crucial to ensure a high level of consumer protection to promote trust in online goods and services, ensuring that the online marketplace respects trading practices; whereas there remain a number of severe structural and regulatory barriers to a fully functioning European internal e-commerce market, such as the fragmentation along national lines of consumer protection rules and rules on VAT, recycling fees and levies, and the abuse of rules governing exclusive and selective distribution agreements,

Z. whereas access to affordable, reliable and high-quality postal services throughout the European Union is a priority for realising an effective internal market for e-commerce; whereas the existing vertical distribution agreements are often used to avoid or restrict online sales, thus denying retailers access to wider markets, undermining consumers' rights to a wider choice and better prices, and thus creating barriers to the expansion of commerce; whereas cross-border business-to-business e-commerce can boost the competitiveness of European companies, allowing them to source components, services and know-how easily from all over the internal market (also creating new economies of scale), and, moreover, represents an opportunity for enterprises, SMEs in particular, to internationalise their customer base without having to invest in a physical presence in another Member State,

AA. whereas e-commerce encourages the development of an ecological single market through the use of low-carbon and environmental technologies, standards, labels, products and services,

AB. whereas the legal protection and confidence of purchasers in e-commerce need to be enhanced, while not forgetting that sellers and businesspeople also need legal protection,

AC. whereas flexibility in markets is the most effective way to encourage growth; calls for the European Institutions to ensure that online markets are as flexible as possible to allow for greater enterprise and enlargement in this sector; whereas the Digital Single Market can only be completed if important Single Market legislation, including the Services Directive, is correctly implemented across all EU Member States; whereas it is crucial to ensure legal certainty and transparency in the process of rights clearance when an e-retailer uploads content protected by copyright onto a website; whereas, whilst the Internet is the fastest-growing retail channel and e-commerce is steadily increasing at national level, the gap between domestic and cross-border e-commerce in the EU is widening and European consumers in some EU Member States face geographical, technical and organisational restrictions in their choices,

AD. whereas the Commission's 'Consumer Market Scoreboard' is a good tool for monitoring the status of cross-border e-commerce in the EU by indicating to what extent consumers can exploit goods and services in the Single Market,

AE. whereas the roll-out of internet broadband services across EU Member States within the target set for 2013 is vital in providing both consumers and businesses with access to the digital economy,

Introduction

1. Welcomes the Commission communication of 22 October 2009 on cross-border business to consumer e-commerce in the EU;

2. Welcomes the Commission communication of 19 May 2010 on a Digital Agenda for Europe setting out the Commission strategy aimed, among others, at making online transactions straightforward and at building digital confidence;

3. Calls on the Commission to respond to the urgency outlined in Monti's report 'A New Strategy for the Single Market', which concludes that, as a vital tool for the future of the internal market, the EU should urgently address the remaining obstacles to create a pan-European online retail market by 2012;

4. Welcomes the EU2020 Strategy's promotion of a knowledge-based economy and encourages the Commission to take swift action on increasing the speed of broadband services as well as streamlining the charges of such services throughout the Union, so as to better achieve a single market for e-commerce;

5. Calls on the Commission to harmonise all the principal definitions in this field over a reasonable period of time, while acknowledging the hard work already done in areas relevant to e-commerce;

6. Stresses that the completion of the e-commerce single market requires a horizontal approach by the Commission, involving effective coordination between Directorates- General; therefore, welcomes the Commission's recent commitment to establish a 'Commissioners' Group' (in its Digital Agenda for Europe report) to ensure effective joined-up policy;

7. Points out that e-commerce should be seen as an extra tool for SMEs in increasing their competitiveness, and not as a goal in itself;

8. Stresses the importance of making full use of the potential of e-commerce as part of making the EU more competitive on the global level;

9. Calls on the Commission to address the promotion of a well-functioning digital single market for goods and services as a matter of urgency in order to benefit from its huge untapped potential for growth and jobs;

10. Stresses the need for an active policy to enable citizens and businesses to benefit fully from the internal market, which offers good quality goods and services at competitive prices; considers that this is all the more essential in the current economic crisis as a means of fighting against growing inequalities and protecting consumers who are vulnerable, live in remote locations or have reduced mobility, low-income groups, and small and medium-sized businesses which are particularly concerned to join the world of e-commerce;

Counteracting fragmentation of the on-line internal market

11. Calls for better approximation of pre-contractual information for e-commerce for a high level of consumer protection and insofar as this harmonisation can be adapted, so as to ensure greater transparency and confidence between consumers and sellers, while retaining a minimum harmonisation approach for contracts in specific sectors;

12. Recalls that there are major differences between the rules and practices of distance traders as to the guarantees and liability they offer within and beyond their national borders and as to the benefits which harmonisation would bring them; calls for an in-depth impact analysis of the consequences for e-commerce of any harmonisation of rules concerning the legal guarantee of conformity with existing national legislation;

13. Calls for uniformisation of rules and practices to allow distance traders to move beyond their national borders in the guarantees and liability offered;

14. Advocates the development of an appropriate, efficient, safe and innovative system of on-line payment which can offer consumers freedom and choice as regards mode of payment, does not involve fees which might undercut or limit choice, and ensures protection of the consumer's data;

15. Stresses the importance of enhancing confidence in cross-border Internet payment systems (e.g., credit and debit cards and e-purses) by promoting a range of payment methods, enhancing interoperability and common standards, tackling technical barriers, supporting the most secure technologies for electronic transactions, harmonising and strengthening legislation on privacy and security issues, combating fraudulent activities and informing and educating the public;

16. Calls on the Commission to come forward with a proposal for establishing a European financial instrument for credit and debit cards, with a view to facilitating online processing of card transactions;

17. Reaffirms the importance of cross-border business-to-business e-commerce as a means whereby European companies, SMEs in particular, can grow, become more competitive and create more innovative products and services; calls on the Commission and the Member States to provide a sound and certain legal and regulatory framework to give companies the guarantees they need in order to carry out cross-border business-to-business e-commerce transactions with confidence;

18. Welcomes the Commission proposal to promote electronic invoicing and calls on the Council to arrive speedily at an agreement with Parliament; also calls on the Commission and the Member States to propose measures and reach agreements respectively with a view to simplifying and streamlining VAT reporting obligations for cross-border e-commerce and simplifying VAT registration procedures;

19. Welcomes the Commission's proposal on the simplification of the Value Added Tax (VAT) reporting obligations and on 'simplified invoicing' for distance selling, and emphasises that, in the area of tax legislation, including VAT, the principle of subsidiarity should be respected;

20. Calls on the Commission to make available an integrated VAT collection scheme to encourage SMEs to trade across borders at lower administrative cost;

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21. Stresses the need to clarify the impact of the VAT package on cross-border postal services, with a view to avoiding legal uncertainty and price increases; takes the view that the VAT exemption for universal postal services under the EU's VAT directive must not be affected by a new fiscal rule based on the place of supply of services;

22. Calls on the Commission to conduct an impact assessment on the creation or designation of national authorities to handle registration requests for on-line cross-border e-commerce from companies or entrepreneurs from their Member States, and a European authority to correlate the national authorities, so as to permit the rapid completion of the internal market;

23. Stresses the need to simplify and streamline measures on electric and electronic waste, cross-border management of copyright levies on blank media and recording devices, the EU-wide licensing of content, and EU rules governing cross-border electronic invoicing ('e-invoicing') for distance selling;

24. Supports a simplification of the present copyright levies due to the severe hindrance to consumers and barriers to the functioning of the Single Market that result from the current system;

25. Calls on the Commission to come up with measures to support the e-invoice initiative with a view to ensuring Europe-wide use of electronic invoices by 2020;

26. Suggests creating a 'one-stop shop' system at European level with a view to finding cross-border solutions for administering Member States' different rules and regulations, as in the case of declaration and payment of VAT or other applicable taxes;

27. Calls on the Commission to explore options on how to promote better access to creative content on the internet such as music and audiovisual works and on how to respond to citizens' demand for consumer-friendly cross-border services;

28. Calls on Member States and the Commission to better integrate Single Market centres incorporating SOLVIT, points of single contact (as required by the Services Directive), product centres (provided for in the Mutual Recognition Regulation), and further information, including legal requirements, required by businesses to sell their goods cross-border and over the internet; emphasises that the functioning of this 'one-stop shop' is essential for completing the single market for e-commerce;

29. Reminds the Commission that there are still gaps in the legal framework for on-line services and calls on the Commission to come forward with targeted legislative proposals in order to strengthen consumer access to and trust in products and services traded online, and offer consumers a simple one-stop shop approach;

30. Points out the significance of simplifying cross-border rules and lowering compliance costs for retailers and entrepreneurs by providing practical solutions on issues such as VAT reporting and invoicing, e-waste and recycling fees, copyright levies, consumer protection, labelling and sector-specific rules; calls, to this end, for the establishment of 'one-stop' schemes and the promotion of cross-border e-government solutions such as e-invoicing and e-procurement;

31. Regrets that the Services Directive has still not been fully transposed in some Member States; calls on the Commission and the Member States to put an end to discrimination against consumers on the grounds of electronic address or residence, ensuring the effective implementation of Article 20(2) of the Services Directive, as well as the proper enforcement by national authorities and courts of the national provisions implementing this non-discrimination rule in the legal systems of Member States;

32. Stresses the significance, for the further development of the e-commerce, of the free movement of goods and services, with particular emphasis on the principle of non-discrimination, within the internal market, on grounds of a recipient's nationality or place of residence; reiterates that this principle of non-discrimination is incompatible with the imposition of additional legal and administrative requirements on nationals of other Member States seeking to benefit from a service or from more advantageous terms or prices; calls, therefore, on the Commission to act, on the basis of Article 20(2) of the Services Directive, against such discrimination;

33. Highlights the importance of eliminating discrimination against consumers online and their country of origin online, by making provisions for online payment from all 27 EU Member States, including the possibility for consumers to choose from different means of online payment;

34. Calls for an integrated political approach to the completion of the single market in transport, covering all modes (including cabotage by road and rail freight), as well as to environmental legislation, with a view to preventing inefficiencies in the supply chain or unnecessary cost increases for distance sellers and e-commerce clients;

35. Believes that reform of the postal sector and the promotion of interoperability and cooperation among postal systems and services can have a significant impact on the development of cross-border e-commerce, which requires inexpensive and efficient distribution and tracking of products; highlights, therefore, the need for rapid implementation of the Third Postal Directive (2008/6/EC);

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36. Calls for measures to be taken in order to contribute towards an increase in the number of internet users and the improvement of the quality, price and speed of the net in those countries and regions within the Union that do not have a good-quality connection, ensuring that broadband access is available throughout the EU by 2013; stresses the need to develop availability for each citizen of broadband access, and underlines that, in rural, remote or peripheral areas, access to a fast internet connection should also be possible, paying particular attention to consumers and businesses in mountain areas or island regions where, in addition to more restricted Internet access, postal charges are very high and delivery times very long for goods purchased or sold;

37. Notes that, in the context of revision of the Universal Service Directive, the further development, as a priority, of fast and affordable broadband access is essential to the development of e-commerce, as a lack of Internet access remains one of the most significant barriers to European citizens' use of e-commerce;

38. Supports the Commission's broadband targets to enable all EU citizens to access basic broadband by 2013, to enable access to broadband at a minimum of 30Mbps for all citizens by 2020, with half of EU citizens having access to broadband of 100Mbps, and calls for concrete measures to ensure that these targets are met; stresses that specific measures should be put in place for the protection of children and young people, notably via the development of age verification systems and the prohibition of online marketing practices that have a negative impact on children's behaviour;

39. Calls on the Commission to begin formulating European standards to facilitate cross-border e-commerce, to bridge variations between the laws in force within the various Member States and to remove the obligation within a selective distribution network of having an off-line shop prior to selling online, where it is shown that such an obligation is in contradiction with competition law, or is not justified by the nature of the contract for goods and services sold, thus enabling consumers and small and medium-sized enterprises to fully exploit the internal market's potential in the electronic environment; expresses concern regarding the Commission's decision on the obligation of having an off-line shop prior to selling online as this requirement radically hampers online sales;

40. Considers that online platforms have played an important role in boosting (especially cross-border) e-commerce in Europe, enabling market access by hundreds of thousands of SMEs, and offering consumers greater choice whilst introducing many examples of good practice for boosting trust and transparent information about rights and obligations and facilitating the resolution of disputes between parties to an online transaction, where necessary; calls for online platforms to provide their goods and services to all European consumers without any territorial discrimination based on Member States;

41. Highlights the importance of an open document exchange format for electronic business inter-operation and calls on the Commission to take concrete steps to support its emergence and spread;

42. Stresses the importance of better guidance and accessible financial facilities for SMEs in order to help them set up an e-commerce dimension as an addition to their off-line shop;

43. Stresses the importance of open and neutral access to a high-speed internet connection, without which e-commerce would be impossible;

44. Highlights that the completion of the single market for e-commerce must not be limited to legislative measures and controls but must be accompanied, in addition, by the strengthening of other areas of the internet, namely those of e-government and e-learning;

45. Stresses the need to monitor the application of the rules recently adopted in Commission Regulation (EU) No 330/2010 of 20 April 2010 on exclusive and selective distribution, on the basis of market information from the interested parties and national competition authorities, and, where necessary, to review those rules in order to reduce barriers to online sales; calls on the Commission to come up with proposals to tackle these problems before the end of 2011;

46. Calls on the Commission to strengthen consumers' privacy and to ensure all consumer data, including purchasing and viewing data, is available to consumers upon request and is held by suppliers for a duration that is accepted under EU law;

47. Calls on the Commission also to work towards creating rules and standards so that the non-inter-operability of software on commercial and social networking websites does not prevent consumers from changing their purchasing options;

48. Stresses the importance of electronic signatures and of the public key infrastructure (PKI) for pan-European secure e-government services, and calls on the Commission to set up a European Validation Authorities Gateway to ensure cross-border interoperability for electronic signatures;

49. Calls on the Commission and the Member States, bearing in mind how important it is to realise the full potential of the single market, to ensure that, by 2015, at least 50 % of all public procurement procedures are conducted electronically, in accordance with the action plan agreed by the Ministerial Conference on e-Government, held in Manchester in 2005;

50. Believes that mobile commerce (m-commerce) can be a significant part of e-commerce, capable of reaching the millions of European citizens who use mobile phones but not personal computers, thus furthering the convergence of Internet and mobile technologies and fostering the EU lead in mobile communications;

51. Believes that the development of, and support for, common, open technical and operational specifications and standards (for compatibility, interoperability, accessibility, security, logistics, delivery, etc.) will facilitate cross-border e-commerce by assisting consumers, especially vulnerable and inexperienced computer users, and by bridging the operational, technical, cultural and language barriers that exist between the various Member States;

52. Recognises the particular legal challenges linked to the development of an internal market for m-commerce capable of ensuring consumer rights, personal privacy and the protection of underage customers; calls on the Commission to examine this issue in detail;

53. Emphasises the need to make the e-commerce supply chain more transparent so that the consumer always knows the identity of the supplier, as well as the latter's business name, geographical address, contact details and tax registration number, and whether the supplier is an intermediary or an end supplier, which is especially important in the context of online auctions;

54. Calls on the Commission to set the clear standards required for cross-border e-commerce at EU level, including, for example, an obligation on merchants to give their customers and the public authorities easy, direct and permanent access, free of charge, to information regarding the name and registration number of the merchant or service provider, prices for the goods and services offered and any additional delivery costs that could add to the bill;

55. Calls on the Commission to establish the requirement for entrepreneurs who voluntarily use standardised contracts and standardised general commercial terms and conditions to highlight those provisions which differ therefrom;

56. Considers that the rules governing distance contracts should also cover contracts concluded between consumers and professional traders in online auctions and calls on the Commission to further examine and assess the rules governing specific distance contracts for tourist services (airline tickets, hotel accommodation, car rental, leisure time services, etc.) ordered individually over the internet, primarily in order to increase the liability of online auctions to better protect consumer rights;

57. Calls on the Commission to clarify rules on soliciting (direct or indirect) using the internet in other Member States;

Enhancing users' legal protection in cross-border e-commerce

58. Calls for the introduction of a requirement that an external audit be carried out in respect of certain specific types of electronic services where there is a greater need to ensure that those services are fully secure, to protect personal information and data (in the case, for example, of internet banking);

59. Stresses that users (consumers and vendors) require legal certainty when operating on-line, and welcomes the Commission's suggestion in its communication 'A digital agenda for Europe' of updating the rules on the limited liability of information society services so as to keep up with technological progress, in the context of the e-commerce directive (see the communication's footnote no 13);

60. Urges the Commission to take steps to create legal certainty and tackle the severe fragmentation that exists as regards the process of rights clearance and multiple Member State jurisdictions when uploading media content to websites;

61. Believes that priority should be given to removing the administrative and regulatory barriers to cross-border e-commerce by 2013 through the introduction of a single set of rules for consumers and businesses across the 27 EU Member States that will create a favourable digital environment, provide legal certainty to both enterprises and consumers, simplify procedures, reduce compliance costs, reduce unfair competition and unlock the potential of the EU e-commerce market; stresses that, to this end, the uniform interpretation and application of legislative tools such as a consumer rights directive, the e-commerce Directive (2000/31/EC), Article 20(2) of the Services Directive (2006/123/EC) and the Unfair Commercial Practices Directive (2005/29/EC) can be of major importance; calls therefore on the Commission to further its ongoing assessment of the Community acquis affecting the digital single market and to propose targeted legislative action on key impediments;

62. Considers that enhancing market surveillance, transparency of rules and enforcement mechanisms to encourage users' confidence is crucial as consumer spending will be an important factor for the economic recovery; takes the view that public authorities must be given more resources to investigate and ultimately stop illegal commercial practices; calls on the Commission to create a European early-warning system, including a database, to combat fraudulent activities in the digital market; calls on the Commission to update RAPEX (rapid alert system) as necessary; stresses that such initiatives must respect data protection rules;

63. Calls on public authorities to quickly act against rogue websites by paying greater attention to consumer rights, including measures aimed at introducing labels for safe and secure websites and ensuring that companies providing sponsored advertising services do not advertise illegal websites;

64. Believes that consumer confidence can be built by standards and codes of conduct that allow online service providers to keep up with fast-changing technological developments;

65. Stresses that online targeting and profiling should fully respect data protection rules;

66. Emphasises the need to ensure consistent interpretation of the EU rules governing data privacy in order to ensure enhanced data protection and to promote consumer trust in online payment systems;

67. Considers that an improvement of the consumer protection regimes across the EU can ensure consumer confidence in online cross-border transactions, including protection against credit card fraud;

68. Calls on the Commission to ensure that the consistent enforcement of copyright laws in the area of e-commerce is not undermined;

69. Believes that cross-border web searching and advertising should provide consumers and traders with better information and enhance their ability to make comparisons and identify offers; is concerned, in this regard, about possible distortions of competition that consumers and entrepreneurs may be experiencing in some EU Member States; calls on the Commission, in cooperation with the industry, to address the shortcomings of web searching and advertising platforms and to encourage their cross-border operation, for example through the promotion of the.eu domains;

70. Calls on the Commission to ensure, by means of monitoring, that the coherent application of copyright law is not circumvented in e-commerce;

71. Asks the Commission to take the initiative and carry out an urgent impact assessment on the most appropriate method of tackling copyright levies, including the possibility of charging the levy when and where the product is first placed on the market in the European Union, since stakeholders are unable to reach agreement;

72. Shares the Commission's view that alternative dispute resolution mechanisms (ADR), such as mediation and arbitration or out-of-court settlements, can be an expedient and attractive option for consumers; notes that some private operators, such as online platforms, have established successful initiatives to boost consumer confidence, using internal dispute resolution instruments; urges Member States to encourage the development of ADR in order to enhance the level of consumer protection and maximise compliance with legislation; recalls the positive experiences of SOLVIT and of the network of European Consumer Centres; calls for the creation of a European e-consumer information system which would offer detailed guidance and information about rights and obligations in the digital market; but emphasises that such mechanisms should complement and not substitute judicial or administrative means of enforcement;

73. Notes the importance of enhancing the current low level of consumer confidence and trust in cross-border transactions by strengthening the online and cross-border enforcement of existing rules, empowering consumer protection authorities, promoting cooperation between public authorities and setting up efficient EU-wide mechanisms for market monitoring and audits, complaint handling and dispute resolution;

74. Encourages recourse to alternative dispute resolution mechanisms, with the option of having recourse to them through an online procedure, accessible without delay through the European e-Justice portal as and when it becomes available;

75. Stresses the need to develop and standardise rules offering a high level of legal protection to minors, and encourages the launching of information and training campaigns for parents, teachers and guardians to make them aware of their responsibility in educating children about risks in the use of on-line commerce and the importance of vigilance with regard to children's use of the internet;

76. Calls for the Commission and the Member States to take swift action to fight illegal online services which do not respect the rules on consumer protection, protection of minors, copyright, tax, and most other applicable laws;

77. Stresses that care should be taken to avoid the risks posed by illegal product offers on the web – in particular counterfeit medicines and healthcare products – by promoting health literacy and using specific websites of the.eu domains to draw attention to misleading information;

78. Calls for a proposal from the Commission to address appropriate actions or sanctions regarding e-commerce in counterfeit goods and medicines, including labels for safe and secure websites such as certification systems for authorised pharmacies;

79. Emphasises the need for proper training and education of civil servants and judicial authorities as regards EU consumer protection rules;

An e-confidence strategy to raise e-commerce users' confidence

80. Calls for a single legal instrument combining the various texts currently in force in order to clarify the rules applicable to e-commerce; welcomes the Commission's proposal for a Directive on Consumer Rights and calls, where relevant, for an appropriate level of harmonisation of certain aspects of consumer contract law, especially regarding the handling of certain types of warranty claims; considers that this should include other directives, such as those on distance selling of financial services and e-commerce;

81. Calls on the Commission to assess whether the creation of a portal for e-commerce monitored by the Commission, involving stakeholders and Member States, could better contribute to the dissemination of best practices and information and therefore enhance consumer trust and increase cross-border e-commerce;

82. Invites the Commission to continue investigating the reasons why consumers reject e-commerce, with a view to drawing up effective guidelines for suitable legislation, and suggests creating a 'scoreboard' dedicated exclusively to e-commerce with the aim of obtaining a behavioural picture of the on-line consumer and identifying the factors which affect and determine such consumers' choices;

83. Recognises that citizens will refrain from interacting, expressing their opinions freely and entering into transactions if they do not have sufficient confidence in the legal framework of the new digital space; whereas the guarantee and enforcement of fundamental rights in this context is an essential condition for confidence on the part of citizens; whereas the guarantee of protection of intellectual property rights (IPR) and other rights is an essential condition for confidence on the part of business;

84. Calls on the Commission to remove the obligation of having an off-line shop prior to selling on-line, as this requirement radically hampers online sales;

85. Stresses the importance, for the further development of cross-border e-commerce, of establishing a coherent EU-wide framework, within the limits of the acquis communautaire, for the protection and enforcement of intellectual property rights, stepping-up the fight against illegal and counterfeit goods and raising awareness of these issues among European consumers;

86. Points out that it is necessary to introduce legislation applicable to all electronic transactions, this being essential to protect the rights of e-commerce service users;

87. Calls for the development, under the framework research programmes, of innovative research projects aimed at promoting and unifying the EU e-commerce market by increasing consumer confidence, empowerment and choice in the digital environment;

88. Calls for the efficient monitoring of legal, technical and economic developments in e-commerce and points out the need for an impact assessment of all decisions affecting the digital single market and the information society; to this end an 'e-commerce scoreboard' for assessing the European online market environment would be a useful tool;

89. Believes that consumer confidence can be developed by removing barriers to cross-border e-commerce, while preserving the highest level of consumer protection and can be built up through European trusted authorities or trust marks that guarantee the reliability and quality of goods placed on the cross-border electronic market; considers that a sustainable European trust mark needs to be established, with clear, transparent and supervised rules, by the Commission; whereby such a European trust mark scheme needs to be backed with a standards-control or enforcement mechanism, as is already the case at national level in some Member States; recognises that a cross-border European trust-mark scheme may only function in the context of EU law on which the European trust mark can be based; believes that any European trust mark scheme must be subject to a thorough impact assessment and must be implemented in cooperation with existing trust mark labels in Member States;

90. Stresses the significance of promoting and enforcing EU-wide logos, trust marks and quality marks that will help consumers in identifying reputable online traders, reward best practices and encourage innovation, thus supporting EU companies in their efforts to reach beyond their home market;

91. Underlines that in the online environment, where the buyer and seller are remote and the buyer has limited ability to assess the physical quality of products, access to accurate and clear information is essential for transparency;

92. Emphasises the efforts of the Commission and the national postal regulators for the correct and timely implementation of the third Postal Services Directive (2008/6/EC) in the 27 Member States in order to achieve an increase in competition, lower prices and better services, to improve the conditions for delivery of goods purchased in cross-border e-commerce; emphasises also the importance of ensuring the availability of insurance services for parcel delivery;

93. Calls for a programme to be established and for use to be made of existing financial instruments for projects to increase users' confidence in e-commerce, including educational and information campaigns at both European and national level, and projects verifying online services in practice (such as 'mystery shopping'); emphasises the need to develop online tools to educate consumers about e-commerce and new digital technology (principal rights of internet consumers, e-commerce, data protection rules, etc.) such as the Dolceta project (Development of On-Line Consumer Education Tools for Adults); thus enabling citizens to enhance their digital skills and their knowledge of their rights and obligations, and to benefit from the advantages of e-commerce in a digital society;

94. Believes that consumer confidence can be further enhanced by ensuring public trust in the online environment, addressing concerns over the protection of personal data, regulating data collection, behavioural targeting, profiling and advertising, and raising consumer awareness through educational and information campaigns; calls on the Commission to submit a proposal for the adaptation of the Data Protection Directive to the current digital environment;

95. Stresses the need to make the supply chain and the terms and conditions of cross-border online trade simpler and more transparent by establishing rules on misleading or incomplete information about consumer rights, total costs and traders' contact details and by promoting best and fair practices, recommendations and guidelines for electronic shops; recognises the efforts made by the EU in this area to clarify the terms, conditions and prices of air fares as a positive example to be followed;

96. Stresses the importance of fast and effective implementation of the European Progress Microfinance Facility, operational as of June 2010, which could provide new impetus for the promotion of on-line businesses, especially amongst the recently unemployed;

97. Believes that media and computer literacy and awareness are essential to the development of the European digital environment; calls, therefore, for the launch of a 'Digital literacy and inclusion action plan' at EU and Member State levels, comprising, in particular: specific digital literacy training opportunities for unemployed people and groups at risk of exclusion, incentives for private-sector initiatives to provide digital skills training to all employees, a Europe-wide 'Be smart online!' initiative to make all students, including those engaged in life-long learning and professional training, familiar with the safe use of ICT and online services, and a common EU-level ICT certification scheme;

98. Welcomes the Commission commitment to issue a Code of EU Online Rights by 2012 summarising existing digital user rights and obligations in the EU in a clear and accessible way, complemented by an annual review of breaches of online consumer protection law and appropriate enforcement measures, in coordination with the European Network of Consumer Protection Agencies;

99. Believes that the development of self-regulatory codes of conduct by trade, professional, and consumer associations, and implementation of the provisions of Parliament's report on 'a new Digital Agenda for Europe: 2015.eu' calling for the creation of a European charter of citizens' and consumers' rights in the digital environment and developing a 'fifth freedom' permitting the free circulation of content and knowledge, would enhance consumer confidence in e-commerce by clarifying the rights and obligations of all information-society players;

100. Calls on the Commission to act swiftly and to report in 2012 on its progress in tackling the ten barriers to cross-border e-commerce, as stated in its communication of 22 October 2009 on cross-border business to consumer e-commerce in the EU (COM(2009)0557); calls on the Commission and the Member States to ensure a high level of consumer protection in e-commerce and the removal of the barriers to the development of e-commerce identified in the Commission's 2010 communication on the Digital Agenda and its 2009 communication on cross-border business to consumer e-commerce in the EU, through both legislative and non-legislative means;invites the Commission to launch a dialogue between interested parties and the US, with a view to examining means of developing a transatlantic electronic market;

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

Trade and economic relations with Turkey

P7_TA(2010)0324

European Parliament resolution of 21 September 2010 on trade and economic relations with Turkey (2009/2200(INI))

(2012/C 50 E/02)

The European Parliament,

— having regard to the Commission's Turkey 2009 Progress Report (SEC(2009)1334),

— having regard to the Agreement of 12 September 1963 establishing an Association between the European Economic Community and Turkey,

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— having regard to the Additional Protocol to that Agreement of 23 November 1970, and in particular Article 41(1) thereof ('Standstill Clause'),

— having regard to Decision No 1/80 of the EC-Turkey Association Council of 19 September 1980,

— having regard to Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (96/142/EC),

— having regard to the rulings of the European Court of Justice concerning the four fundamental movements, in particular in the Demirel, Sevince, Savas, Abatay-Sahin, Tum-Dari and Soysal cases,

— having regard to the latest WTO Trade Review on Turkey, published in 2007,

— having regard to its previous resolutions on Turkey,

— having regard to the Policy Department's analysis of the 2009 annual programme for Turkey under the Pre-accession Instrument (IPA) in the context of the 2009 enlargement package,

— having regard to the Council Conclusions of 11 December 2006,

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on International Trade (A7-0238/2010),

A. whereas the Customs Union with Turkey remains one of the most advanced and close commercial relationships that the EU has with any third country,

B. whereas Turkey is the seventeenth largest economy in the world, according to World Bank statistics, and the sixth largest economy in Europe, with industrial goods amounting to over 90 % of its exports; whereas in 2008 Turkey ranked as the world's twentieth largest receiver of FDI and its FDI inflow amounted to 18 billion,

C. whereas Turkey has become the EU's seventh largest trade partner and the EU is Turkey's largest trading partner,

D. whereas in 2009 Turkey exported EUR 33,6 billion's worth of products to the EU and imported EUR 40,4 billion's worth of products from the EU,

E. whereas average unemployment in Turkey reached an alarming 12,5 % in 2009 and decreased to 10,8 % in April 2010 according to OECD data, youth unemployment stands at 25 % and the 2010 Millennium Development Goals Report on Turkey indicates that the extreme poverty ratio is 17,1 %,

1. Welcomes the fact that the EU's trade relations with Turkey are at an advanced level; calls on Turkey to simplify procedures and bureaucracy and remove remaining tariff and non-tariff barriers; stresses the importance of constructive dialogue between the two parties in order to further improve these relations;

2. Recalls that, according to the combined reading of Article 205 of the Treaty on the Functioning of the European Union and Article 21 of the EU Treaty, the Union's external action, including the common commercial policy, seeks to promote '(…) democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity, and respect for the principles of the United Nations Charter and international law' as well as to build partnership with third countries which share the principles referred to above;

3. Calls on the Commission to continue its engagement and dialogue with Turkey on trade, particularly within the Joint Consultative Committee and the EC-Turkey Customs Union Joint Committee; encourages both sides to use these platforms more effectively, by rapidly resolving outstanding issues such as Turkey's ban on imports of beef meat, live bovine animals and derivative products and some EU Member States' road quotas applied to vehicles registered in Turkey;

4. Notes Turkey's long-term growth potential and demographic specificities; encourages both the EU and Turkey to pay due attention to their interlinked economies, to maintain open trade and investment regimes and their ability to withstand domestic protectionist pressures in line with their commitments in various international platforms, and to use trade defence instruments in compliance with the WTO;

5. Is concerned about the low level of participation of women in the labour market and their employment in the informal sector; encourages Turkey to put women's employment at the core of its economic, social and employment policies;

6. Stresses the severity of the youth employment situation and the lack of specific actions to tackle the problem; refers to a recent ILO study which describes employment creation in general and women's and youth employment in particular as the key labour-market challenge for Turkey's development; calls, therefore, for an employment strategy which targets youth employment in general and the situation of young women in particular;

7. Welcomes the establishment of the Customs Union (CU) in 1996, which has provided increased market access and allowed trade volumes between the EU and Turkey to reach EUR 100 billion per annum at their peak in 2008;

8. Highlights the fact that the CU covers manufactured goods and processed agricultural products; looks forward to the inclusion of agricultural products in the CU as soon as possible; considers that the CU can be deepened to include coverage of other areas such as services and public procurement;

9. Finds it regrettable that, according to the latest WTO review, the average tariff rate on agricultural products applied by Turkey is relatively high and in some cases extremely high (on corn, for example the duty applied is 130 %); calls on the Turkish Government to substantially reduce these barriers;

10. Welcomes the alignment of the Turkish Customs Code with that of the EU and, in particular, the adoption of the Generalised System of Preferences (GSP); calls for greater alignment of Turkish legislation with the Community acquis as regards free trade, combating counterfeiting, and post-clearance checks and authorisations for duty-free shops;

11. Deplores the fact that, for the fifth consecutive year, Turkey has neither fully implemented the Additional Protocol to the Association Agreement nor removed all the obstacles to the free movement of goods; calls on Turkey to implement fully and without delay all its obligations deriving from this Protocol in a non-discriminatory way that will contribute to the further development of its trade relations with all EU Member States, and recalls that failure to do so may further seriously affect the negotiating process;

12. Reiterates that Turkey's full compliance with its undertakings under the customs union is essential; considers also that there is a need for further harmonisation with the Community acquis in certain sectors such as free trade zones and customs duty relief;

13. Stresses that the CU would greatly benefit from a review of the Dispute Settlement Mechanism, which would allow a swift and fair resolution of pending issues;

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14. Calls for the removal of all unnecessary barriers to trade between the EU and Turkey, including technical ones such as non-recognition of certification, duplicative testing, duplicative inspections, mandatory technical regulations and standards, in compliance with the WTO; also calls on the Commission to share good practice in this area;

15. Acknowledges the difficulties faced by Turkey in concluding Free Trade Agreements (FTAs) with third countries, which has negative effects on the Turkish economy by enabling unilateral preferential access to the Turkish market for the EU's FTA partners with which Turkey has not yet been able to sign FTAs; calls on the Commission and the Council to ensure that Turkey is included in the impact assessment studies of prospective FTAs between the EU and third countries and to further strengthen the transmission of information on the EU's position and the state of play of the FTA negotiations; encourages the Commission to take account, in the FTAs, of the CU between the EU and Turkey;

16. Calls on Turkey to remove the remaining import licences for goods which are in breach of the commitments under the Customs Union and to agree to update Decision 2/97 of the EC-Turkey Association Council on the removal of technical barriers to trade;

17. Welcomes the legislation on standardisation in foreign trade adopted by the Turkish Government in 2009; notes, however, the introduction of conformity assessment procedures and physical customs checks; encourages both the EU and Turkey to fully apply the principles of mutual recognition;

18. Calls on Turkey to withdraw the burdensome import procedures and to align its duty-free quota system for processed agricultural products which do not comply with the Customs Union;

19. Welcomes the positive conclusions of the latest WTO review on Turkey; urges the Turkish Government, however, to take the necessary measures to fulfil the recommendations therein and to accelerate structural and legislative reforms;

20. Calls on Turkey to suspend the new requirements on Good Manufacturing Practices as they de facto ban imports of certain pharmaceutical products, as well as to participate in, and adhere to, international initiatives for harmonising Good Manufacturing Practices procedures and standards such as those of the WHO and the EU;

21. Notes Turkey's dynamic international trade strategy and its conclusion of 16 FTAs to date; encourages the EU and Turkey to work together to deepen trade relations with Central Asia;

22. Notes the fact that 88 % of total FDI stock in Turkey comes from the EU; points out, however, that the share of FDI in Turkey's GDP is relatively small;

23. Notes the role of Turkey within regional platforms such as the Black Sea Economic Cooperation Organisation, the Black Sea Trade and Development Bank and the South East European Cooperation Process; encourages Turkey to take a leading role in promoting open and fair trade with due regard for social, economic and environmental wellbeing;

24. Notes Turkey's role in the Mediterranean region as a founding partner of the Barcelona Process and calls on Turkey to fully respect all the states partners of the Process; emphasises that there is huge scope to improve Turkey's trade in the Mediterranean basin;

25. Notes that while the EU remains Turkey's largest trade partner, Russia, China, the United States and Iran were amongst Turkey's main trade partners as of 2009; underlines that the trade volume between Turkey and the EU decreased during 2009, while an increasing trend has been noted in the first two quarters of 2010; notes also that Turkey is diversifying its trade partners; asks the Commission to conduct a study on the causes, which may involve the financial crisis, and economic impact of the relative decline of EU's share in Turkey's foreign trade volume;

26. Notes that Turkey and the EU face similar challenges in energy supply; underlines the importance of the Nabucco project for the security of energy supply in the EU and therefore calls on Turkey to take the initiative to swiftly implement the Nabucco Intergovernmental Agreement; stresses the need to define a common external energy strategy and the opening of the energy chapter that would further increase cooperation in the field of energy; urges Turkey to ratify the Energy Charter Treaty Trade Amendment and encourages Turkey to invest in the enormous potential of its renewable energy sources;

27. Notes that the recurrent visa problems under GATS 4 substantially limit the movement of Turkish businessmen and lorry drivers into the EU; underlines the successive ECJ rulings on this matter and calls on the Commission to ensure that Member States respect these rulings; calls on the Commission and the Council to re-examine visa procedures with a view to eliminating obstacles to trade;

28. Finds it regrettable that the legislation ensuring full respect for trade union rights in line with EU standards and the relevant International Labour Organisation conventions has not yet been completed, particularly with regard to the rights of trade union organisation and collective bargaining and the right to strike;

29. Urges Turkey to avoid discriminatory practices against foreign enterprises by giving a 15 % price advantage to Turkish bidders in the field of public procurement; invites Turkey to become a party to the Agreement on Government Procurement (GPA) within the WTO;

30. Stresses that counterfeit products, including pharmaceuticals and cosmetics, represent a problem in EU-Turkey trade relations and reduce the attractiveness of Turkey for FDI; encourages Turkey to enforce the new IPR legislation effectively in order to foster trade relations with the EU; underlines the need to strike a better balance between international requirements in intellectual property law and domestic economic development needs when developing an intellectual property regime;

31. Notes that SMEs make up 99 % of Turkish enterprises and provide 70 % of employment opportunities in Turkey; encourages Turkey to improve SMEs' access to finance; welcomes Turkey's Ninth Development Plan, which focuses on the R&D spending that is crucial to increasing SME competitiveness;

32. Welcomes the outcome of the referendum in support of constitutional reform;

33. Instructs its President to forward this resolution to the Council, the Commission and the Government of Turkey.

EU legislation aiming at the conservation of biodiversity

P7_TA(2010)0325

European Parliament resolution of 21 September 2010 on the implementation of EU legislation aiming at the conservation of biodiversity (2009/2108(INI))

(2012/C 50 E/03)

The European Parliament,

— having regard to the communication from the Commission on halting the loss of biodiversity by 2010 – and beyond: sustaining ecosystem services for human well–being (COM(2006)0216),

— having regard to the Commission communication on the mid-term assessment of implementing the EC biodiversity action plan (COM(2008)0864),

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— having regard to the Commission communication on options for an EU vision and target for biodiversity beyond 2010 (COM(2010)0004),

— having regard to the report from the Commission on the conservation status of habitat types and species as required under Article 17 of the Habitats Directive (COM(2009)0358),

— having regard to Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds [1] (Birds Directive) and to the European Parliament resolution of 17 January 2001 [2] on implementation of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [3] (Habitats Directive),

— having regard to the Environment Council conclusions of 25 June 2009 on the 'Mid-term assessment of implementing the EU biodiversity action plan' and 'Towards an EU Strategy on invasive alien species',

— having regard to the informal Council held on 26-27 January 2010 in Madrid, which adopted the so-called 'Cibeles' priorities, and the Environment Council conclusions of 15 March 2010 on biodiversity post-2010 – EU and global vision and targets and international access and burden sharing regime,

— having regard to the European Council conclusions of 25-26 March 2010, in particular paragraph 14,

— having regard to its resolution of 22 May 2007 on halting the loss of biodiversity by 2010 [4],

— having regard to the European Summit in Gothenburg in 2001, where it was agreed to halt the loss of biodiversity by 2010 as part of a Sustainable Development Strategy,

— having regard to the study on The Economics of Ecosystems and Biodiversity (TEEB) (http://www.teeb-web.org),

— having regard to the Commission communication towards an EU strategy on invasive species (COM(2008)0789),

— having regard to the EU's Blue Paper on an Integrated Maritime policy (COM(2007)0575 and SEC(2007)1278) and the ongoing preparations for the reform of the common fisheries policy,

— having regard to the measures aiming at enhancing nature conservation and biodiversity forming part of the 'Health check of the CAP' and the opportunities offered by the reform of the CAP currently being discussed,

— having regard to the findings of independent experts in 'National implementation of Council Directive Habitats' - Study PE 410.698 - Policy Department C, 2009, on the application of the Habitats Directive, notably as regards a lack of assessment of alternative options to and the cumulative effects of projects, inadequate site management and, when compensatory measures are decided upon, the failure to verify such measures and the fact that they are often carried out too late, if at all,

— having regard to the fact that the United Nations has declared 2010 the Year of Biodiversity,

— having regard to the outcome of the 15th meeting of the Conference of the Parties (COP15) to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which took place in Doha, Qatar, from 13 to 25 March 2010,

— having regard to the upcoming fifth meeting of the Conference of the Parties serving as the Meeting of the Parties of the Cartagena Protocol on Biosafety (COP-MOP 5) and the Conference of the Parties (COP 10) of the UN Convention on Biodiversity (CBD),

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[1] OJ L 103, 25.4.1979, p. 1. Directive as last amended by Directive 2006/105/EC (OJ L 363, 20.12.2006, p. 368).
[2] OJ C 262, 18.9.2001, p. 132.
[3] OJ L 206, 22.7.1992, p. 7. Directive as last amended by Directive 2006/105/EC.
[4] OJ C 102 E, 24.4.2008, p. 117.

— having regard to EEA Report No 4/2009 'Progress towards the European 2010 biodiversity target', in particular the annex 'SEBI 2010 Biodiversity indicator',

— having regard to the Commission Guidance document 'Guidelines for the establishment of the Natura 2000 network in the marine environment – Application of the Habitats and Birds Directives' (May 2007),

— having regard to the EU 2020 strategy,

— having regard to the third United Nations Global Biodiversity Outlook,

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Fisheries and the Committee on Petitions (A7-0241/2010),

A. whereas EU law-making should have an impact on biodiversity, as was the case with the Water Framework Directive (2000/60/EC) and the Marine Strategy Framework Directive (2008/56/EC),

B. whereas it has become clear from the Commission's communications that the EU has not met its 2010 biodiversity target,

C. whereas the health check of species and habitat types protected under the Habitats Directive shows that a majority of species and habitat types have an unfavourable conservation status, that the extinction rate is disturbingly high – according to certain estimates the biodiversity rate has fallen by 30 % in the last 40 years – and that the drivers of excessive biodiversity loss show no evidence of declining; whereas habitats and species of EU interest are potentially threatened by anthropogenic climate change; whereas scientists estimate there are many unrecorded species, making it impossible to gauge the full extent of biodiversity loss,

D. whereas several factors have prevented the EU from achieving its 2010 target, such as the failure to recognise and deal with the driving forces behind the reduction in biological diversity, incomplete implementation of legislation, incomplete and poor integration into sectoral policies, insufficient scientific knowledge and data gaps, lack of political will, insufficient funding, lack of additional efficiently-targeted instruments to tackle specific problems such as invasive alien species,

E. whereas biodiversity, as the world's natural capital, is essential to the existence of human life on Earth and societies' well-being, both directly and indirectly through the ecosystem services it provides; whereas biodiversity plays a central role in the global fight against hunger and in favour of food security; whereas conservation and sustainable use of biodiversity is one prerequisite for mitigation of and adaptation to climate change,

F. whereas biological biodiversity is the irreplaceable pillar on which mankind has evolved and its loss and that of the natural heritage it brings with it creates disequilibrium and gives rise to substantial economic and welfare losses, of the same order of magnitude as the cost of inaction on climate change,

G. whereas the study on The Economics of Ecosystems and Biodiversity (TEEB) also confirms that the loss of biodiversity gives rise to substantial economic and welfare losses,

H. whereas a recent study by Eurobarometer shows that EU citizens are largely unfamiliar with the term biodiversity and the consequences of the loss of biodiversity,

I. whereas the disappearance of species may break the food chain that is key to the survival of other animal and plant species of vital importance for food production, adaptation to climatic conditions, resistance to external agents and the preservation of genetic values,

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General remarks

1. Is deeply concerned about the very fast pace of human-induced biodiversity loss which, if it continues as in the last decades, will leave us with a greatly impoverished and irreversibly damaged nature by 2050 and underlines that functioning ecosystems are a prerequisite for our subsistence;

2. Highlights the fact that biodiversity is the most important indicator of good environmental status;

3. Is aware that failure to stop biodiversity loss is unacceptable, not only from an ethical but also from an ecological and economic perspective, as it deprives future generations of the ecosystem services and welfare aspects of a rich, natural biodiversity; calls therefore on the Commission and the Member States to improve biodiversity governance and compliance in internal as well as in external relations;

4. Is aware, moreover, that a successful tackling of the threefold crises of food security, biodiversity loss and climate change requires a coherent approach and a future EU biodiversity strategy that is fully integrated with the strategies for combating poverty and hunger and for the mitigation and adaption of climate change;

5. Recognises that NGOs have an important role to play in biodiversity protection, as regards contributing to the decision-making process, as actors on the ground and in raising the public awareness;

6. Underlines that ongoing studies, such as the TEEB study, estimate that the welfare loss from biodiversity loss is currently around EUR 50 billion per year (just under 1 % of GDP), rising to EUR 14 trillion or 7 % of estimated GDP per year in 2050;

7. Agrees, nevertheless, with the TEEB study report that there are methodological limitations to measurement of the economic value of biodiversity and this should not overshadow the ethical and inter-generational aspects of biodiversity conservation;

8. Is deeply concerned about the absence of any sense of urgency in halting the loss of biodiversity in the international political agenda;

The EU and biodiversity

9. Deeply regrets that the EU's objective, as agreed to at the European Summit in Gothenburg in 2001, to halt biodiversity loss by 2010 has not been met and shares the concern expressed by many petitioners to the European Parliament;

10. Welcomes the Commission's communication on options for an EU vision and target for biodiversity beyond 2010;

11. Welcomes furthermore the conclusions on biodiversity of the Environment Council of 15 March 2010, including the new headline target of halting the loss of biodiversity and the degradation of ecosystem services in the EU by 2020 and restoring them in so far as feasible, without prejudice to natural changes in biodiversity, as well as the European Council Conclusions of 25-26 March 2010 confirming the urgent need to reverse continuing trends of biodiversity loss and ecosystem degradation;

12. Believes that halting biodiversity loss constitutes the absolute minimum level of ambition to be realised by 2020;

13. Points to the valuable initiatives aimed at restoring biodiversity and ecosystem services already taking place and believes that such restoration activities must also be part of the 2020 headline target;

14. Considers that a thorough environmental, economical and social impact assessment is needed in cases where data are lacking;

15. Given the global character of biodiversity and ecosystem services and their crucial role for the global objectives of sustainable development, reducing poverty and hunger and improving health and human well-being, is convinced that the future EU strategy must also step up EU international efforts to avert biodiversity loss, as studies such as TEEB have delivered sufficient evidence that doing this is cost effective and feasible, and thereby contribute more effectively to achieving the Millennium Development Goals by 2015;

16. Underlines furthermore that, as a part of a policy aimed at protecting and improving biodiversity, a common EU policy to tackle the problem of invasive alien species is necessary, and points out the particularly close link between transport corridors and the large-scale introduction of alien species;

Natura 2000

17. Recognises that a full and correct implementation of Natura 2000 legislation plays a major role in achieving the EU's biodiversity, climate change, and sustainable development objectives; in this regard, considers it vital that future cooperation with land users in implementing Natura 2000 be thoroughly reinforced and cooperative; emphasises that the Natura 2000-approach has already shown some remarkable successes;

18. Calls on the Commission and Member States, to fully implement Article 6 of the Habitats Directive;

19. Remains concerned, despite the positive and tangible results achieved by some Member States in the conservation status of several species, about the full and thorough implementation of Natura 2000 legislation; urges the Member States to give higher priority to the implementation of Natura 2000;

20. Welcomes the fact that the Natura 2000 network represents 18 % of EU territory (on land) and the early progress made in the formulation of conservation measures or management plans; is dismayed at the failure of Member States to respect the deadlines laid down in the Directives; and therefore urges Member States to take prompt action to achieve full implementation of the Birds and Habitats Directives;

21. Expresses its concern about the lack of progress in the establishment of the Natura 2000 network in the marine environment and asks the Commission and Member States to speed up the necessary procedures;

22. Calls on the Commission to adopt a model network of marine protected areas (MPAs) making it possible to reconcile preserving the environment and practising sustainable fishing; asks it to report regularly on the progress made by Member States in implementing the Habitats and Birds Directives, in particular the establishment of the Natura 2000 network in the marine environment, since currently less than 10 % of protected areas are marine sites, as well as on the reporting and monitoring obligations of the Member States;

23. Notes that marine species and habitats enjoy less protection than terrestrial species and habitats in EU biodiversity legislation, and therefore calls on the Commission to assess the weaknesses in the legislation and its implementation, and to develop MPAs in which economic activities, including fishing, are the subject of strengthened ecosystem-based management;

24. Further notes that the various conventions for the regional seas around the EU, such as OSPAR, HELCOM and Barcelona, provide an important framework for protecting marine ecosystems;

25. Considers that Member States must be allowed to take initiatives to protect marine biodiversity going beyond the action required under EU legislation;

26. Recalls that the establishment of a coherent NATURA 2000, requires the maintenance of those features of the landscape which are of major importance for wild flora and fauna; calls therefore on the Commission and Member States to actively engage in maintaining and developing the connectivity of protected areas, whether terrestrial or marine, as well as agricultural areas of high nature value;

27. Supports the findings of the European Environment Agency when it states that the conservation status of species and habitats protected under the EU Habitats Directive is a cause for concern and that we should not 'focus all our efforts on preserving islands of biodiversity, while losing nature everywhere else', as this reflects the views very often expressed by European citizens in their petitions to the European Parliament;

28. Reminds the Commission and Member States that the Marine Strategy Directive does not limit the use of marine protected areas to Natura 2000, and therefore requests that Member States and the Commission take account of and create linkages between all marine protected areas, including those designated under regional seas conventions, with the aim of creating a coherent and comprehensive network;

29. Takes note of a certain unavoidable degree of subsidiarity in EU environmental legislation, but is concerned that this degree of flexibility can lead to abuses by Member States when implementing it; regrets the striking differences between Member States regarding, for example, the 'external effect' of Natura 2000 sites, block exemptions for certain 'existing activities' or the application of the precautionary principle; calls, in the event of such striking differences, for inquiries into whether the Member States in question are not applying the rules in such a way as to hamper the effective achievement of the intended biodiversity goals;

30. Given these differences between Member States, invites the Commission to provide further clarification of the Directives or guidance where necessary, with such clarification or guidance ideally being based on and/or illustrated by best practices;

31. Emphasises the importance of implementing the precautionary principle on nature related to biodiversity in line with the decisions of the Court of Justice;

32. Encourages Member States to ensure that environmental impact assessments and strategic environmental assessments are of sufficient quality in relation to biodiversity, in order to guarantee a sound implementation of Natura 2000 legislation;

33. Calls for a strengthening of the Environmental Impact Assessment Directive, and a much more rigorous interpretation of its objectives, in order to achieve no net loss, and, where possible, gains in biodiversity, and to introduce specific requirements for the ongoing monitoring of the biodiversity impacts of projects and the effectiveness of mitigation measures, with appropriate provisions for access to this information and for enforcement;

34. Believes that better cross-border cooperation could have significant benefits for meeting the Natura 2000 objectives;

35. Furthermore expresses its concern about the lack of cross-border cooperation, which can lead to identical areas being approached differently, and stresses the usefulness of harnessing existing instruments, such as the European Grouping for Territorial Cooperation (EGTC), a judicial tool;

36. Urges the Commission to focus more on ecosystem services in its future biodiversity strategy and within the context of Natura 2000 while at the same time building on and strengthening efforts to achieve favourable conservation status for species and their habitats;

Integration into other policy areas

37. Is convinced that the Natura 2000 land and marine network is not the only EU instrument for biodiversity conservation, but that a more integral approach is needed for the EU biodiversity policy to be successful;

38. Therefore, calls on the Commission to ensure a further mainstreaming of biodiversity into other EU policy areas – such as agriculture, forestry, fisheries, regional policy and cohesion, energy, industry, transport tourism, development cooperation, research and innovation – in a mutually reinforcing way and to make the European Union's sectoral and budgetary policies more consistent; stresses the great opportunities that exist, particularly in the common agricultural policy, regional policy and the common fisheries policy, to give biodiversity a higher priority;

39. Highlights the link between water management and biodiversity as a key factor in supporting life and in sustainable development;

40. Takes the view that farmers play a vital role in achieving the EU's biodiversity objective; points out that in 1992 an initial impetus was given to integrating protection of biodiversity into the common agricultural policy (CAP), and that subsequently the 2003 reform has introduced measures such as cross compliance, the single farm payment (decoupling) and rural development which have benefits for biodiversity;

41. Expresses, however, its concerns about the EU farmers' ability to continue to produce high-quality food competitively; believes that the CAP reform should properly reward EU farmers for their efforts in achieving the EU's biodiversity objective;

42. Points out that agricultural and forestry-related activity in Europe has contributed substantially to a diversity of species and biotopes and a varied agricultural landscape now considered in need of protection; underlines, therefore, that in the long term it is only through agricultural and forestry-related activity that the agricultural landscape can be retained and biological diversity conserved in Europe;

43. Welcomes the previous attempts to integrate environmental considerations as an integral part of the common agricultural policy (CAP), such as the introduction of agri-environment measures and good agricultural and environmental conditions; calls on the Commission to use the reform of the CAP as an opportunity to further enhance this trend, working towards fully sustainable farming in the EU, whereby the benefits to nature constitute a guiding principle, for example through the introduction of remuneration for eco-services or the delivery of well defined public goods, including sustainable farming in ecologically sensitive areas, such as Natura 2000 sites, so as to ensure that sustainable ways of farming are funded in the future, that where good practice exists it is properly rewarded and encouraged and that farmers are not financially or otherwise disadvantaged, thus creating the conditions for farms to be able to continue contributing to biodiversity in the future;

44. Calls on the Commission to pay greater attention to ensuring compliance with all European regulations and directives dealing in particular with maintaining biodiversity;

45. Finds that the EU has, in the Union's agricultural policy, laid down regulations under cross compliance which conserve biodiversity, but regrets that they are often not implemented and monitored throughout the EU;

46. Is aware that land use policy is another key element in the conservation of nature and urges the Commission and Member States to continue to improve the integration of biodiversity criteria in decision-making processes at local and regional level in matters concerning land use and territorial policy, including in regional and cohesion policy;

47. Emphasises that land management and the conservation of biodiversity are not opposites and that integrated management creates habitats for biodiversity;

48. Stresses the importance of halting and reversing the decline in the diversity of cultivated plant species and varieties, which leads to the erosion of the genetic basis on which human and animal nutrition depends; underlines the need to promote the use of traditional agricultural varieties specific to certain regions;

49. Taking into account the economic, social and environmental value of agricultural and livestock genetic diversity, urges the Commission to define specific priority targets to halt the loss of genetic diversity and halt the loss of native species; calls further for the adoption of a definition of 'native' / 'non-native' breeds and measures for their conservation;

50. Considers that the CAP should reward farmers who provide additional ecosystem services which help conserve biodiversity via an EU-funded top-up direct area payment; reiterates its request for 'bonus' cross-compliance that awards farmers bonus points for actions fostering biodiversity and implemented in addition to the obligations arising from good agro-environmental cross-compliance;

51. Notes that much progress has been made in environmental legislation, such as the introduction of integrated pest management and the new EU pesticide legislation, which makes it possible for pest management to target harmful organisms, thereby protecting beneficial organisms;

52. Welcomes the reform of the common fisheries policy currently being prepared and calls on the Commission to mainstream biodiversity criteria in its future legislative proposals; furthermore, insists that, as a possible alternative to fishing, sustainable aquaculture models should be developed along the lines proposed by the Commission in its communication on building a sustainable future for aquaculture (COM(2009)0162), taking into account the European Parliament's position in its resolution of 17 July 2010;

53. States that the major tools for achieving biodiversity objectives in the marine environment, in addition to the Habitats and Birds Directives, are the Water Framework Directive for coastal waters and the Marine Strategy Framework Directive for all marine waters;

54. Considers that a reduction in discards must be a major objective of the CFP and calls on the Commission to identify the causes of discards and to work out solutions specific to each fishery, in particular through the introduction of multi-species or biomass quotas, through the selectivity of gear, such as the general use of square-meshed nets, and through spatial management of stocks;

55. Considers that regional fisheries management organisations (RFMOs) are responsible for the management of fisheries and guarantors of responsible fishing on the high seas; considers that it is therefore essential to strengthen their powers, in particular with regard to controls and deterrent penalties, and that it is first and foremost up to RFMOs to manage the stocks of certain marine species of commercial importance and to require the use of catch certificates;

56. Stresses the need for further action in the field of integrated coastal zone management (ICZM) and maritime spatial planning as these could be important elements of a participatory ecosystem approach, ensuring the conservation and sustainable management of marine and coastal resources, respecting natural processes and ecosystem carrying capacity;

57. Given the significant decline in aquatic biodiversity and degradation of freshwater ecosystems, emphasises the importance of ensuring the full implementation of the Water Framework Directive and stresses the need to address biodiversity decline in river basin management planning;

58. Urges Member States to design their forestry policy in a way that takes fully into account the role of forests as a reserve for biodiversity, soil retention and formation, carbon sequestration and air purification characteristics and for purposes of recreation for our citizens;

59. Welcomes the Commission's communication on addressing the challenges of deforestation and forest degradation to tackle climate change and biodiversity loss (COM(2008)0645 final), which calls for halting the global forest cover loss by 2030 at the latest;

60. Points out that growing demand for agri-fuels and the consequent intensification of pressure for their production are threatening biodiversity, notably in developing countries, owing to the degradation and conversion of habitats and ecosystems such as wetlands and forests, among others;

61. Stresses the need to increase the budget for research dedicated to the environment and biodiversity under the Eighth Framework Programme, proportionate to the huge needs and challenges of tackling both biodiversity loss and climate change;

62. Notes that paragraph 8 of the Council conclusions of 21 October 2009 invites the Commission to undertake an urgent sector-by-sector review of subsidies which have an adverse environmental impact; calls on the Commission to act on those conclusions immediately in order to avoid subsidies to policies which have a negative impact on European biodiversity;

63. Calls on the Commission and the Member States to use the preparatory phase of the development of the Seventh Environment Action Programme to advance and promote the debate as well as specific actions on biodiversity in the EU;

Biodiversity and climate change

64. Underlines the vital importance of biodiversity and resilient ecosystems for climate change mitigation and adaptation, given the fact that terrestrial and marine ecosystems currently absorb around half of anthropogenic CO_2 emissions;

65. Welcomes the increasing support for measures to reduce the impact of climate change from which biodiversity can also benefit, but which should not have a negative impact on the funding for biodiversity as such;

66. Calls on the Commission to ensure that actions taken in the context of climate change mitigation and adaptation do not have adverse effects on marine and terrestrial biodiversity;

67. Underlines that soil plays a vital role in achieving the EU's biodiversity objective; recognises that soil degradation has primarily local and regional causes and impact, and that the principle of subsidiarity should consequently be respected; calls on all Member States to fulfil their obligations in terms of guaranteeing soil quality and keep the soil in good condition and urges those Member States without soil protection legislation to shoulder their responsibilities;

Economic value of biodiversity

68. Stresses the essential role played by fisheries from an economic and social point of view in coastal development and from an environmental point of view in marine ecosystems; considers that the CFP must not hinder but facilitate Member States' compliance with biodiversity legislation, in particular the establishment of adequate protection measures in marine Natura 2000 sites;

69. Recognises the considerable job potential that is linked to the development of a sustainable economy and green infrastructure, which by their nature would imply local jobs (which cannot be relocated to third countries), thus contributing considerably to the EU's 2020 Strategy;

70. Furthermore, strongly believes that resource efficiency, sustainable economic development and nature conservation can and should go hand in hand; draws particular attention to the development of eco- and agri-tourism, whereby recreation and conservation are mutually reinforcing;

71. Emphasises the importance of biodiversity conservation in the implementation of the Europe 2020 strategy, owing not only to the employment potential it can generate, but also to the contribution it makes to the efficient and sustainable use of resources; recognises that rising levels of materials production, trade, and consumption are an important driving force behind biodiversity loss, and therefore calls on the Commission and Member States to adopt measures to promote and develop resource efficiency and sustainable consumption and production (SCP) policies;

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Financing

72. Takes note of the Commission's estimates in 2004 for the annual cost of managing the Natura 2000 network at EUR 6.1 billion; points out however, that according to the TEEB report, the return on biodiversity conservation investment is up to a hundred times more;

73. Deplores, however, the fact that no additional sources of funding for the implementation of the NATURA 2000 directives have been made available by the Commission, and that a clear breakdown of the actual amounts being spent per annum on biodiversity conservation in the EU is lacking, and insists that Member States and the Commission cooperate to provide a clearer picture;

74. Believes that the Community should take greater responsibility for safeguarding natural values in the Natura 2000 network, particularly in the context of funding;

75. Welcomes the increase in spending for LIFE+ (+ 8 % in the 2011 draft budget), but underlines that this instrument continues to represent only a very small part of the EU budget (0,2 %); notes, moreover, that EU-funded conservation measures are not always continued once Community financing stops; calls on the Commission to give fuller consideration to the various factors relevant to the sustainability of projects and to introduce systematic monitoring of projects after the final payment;

76. Is aware that additional funding for biodiversity conservation is available through other instruments, such as the Structural Funds and the Rural Development Fund, but deplores the limited use most Member States make of this possibility; recalls that the biggest contribution for financing biodiversity is currently available through the EAFRD;

77. Without pre-empting future discussions and decisions about the new multiannual financial framework (from 2014 onwards) and the mid-term review of the current budgetary framework (2007-2013), expects that budgetary constraints will make it more necessary than ever to achieve high added value and increased effectiveness of European spending, including biodiversity spending;

78. Therefore, underlines the need to gain greater insight into the effectiveness of biodiversity spending and calls on the Commission to provide examples of good practice in terms of effectiveness and added value;

79. Welcomes the recommendation made by IUCN for 0,3 % of GDP to be spent on national biodiversity conservation measures;

80. Notes with concern that the number of projects financed under the LIFE+ programme each year is below the indicative allocation in various Member States; invites the Commission to assess the reasons for this under-implementation and where necessary to propose changes to the rules governing the programme, particularly as regards co-financing levels;

81. Is convinced that public spending alone will not suffice to reach the EU headline target and underlines the importance of corporate responsibility to also take into account biodiversity; calls on the Commission to look into means of implementing policies that encourage positive investments in conserving biodiversity and discourage investment which impacts on biodiversity, in both the public and private sectors; welcomes in this regard the launch of the Business and Biodiversity Platform by the Commission to engage the private sector in the biodiversity agenda;

82. Recommends that greater flexibility be injected into the rules on eligibility for financing biodiversity-related projects and to encourage all the relevant players to apply for it;

83. Underlines the need to incorporate external costs, risks and effects, such as the preservation of agricultural land, the damage done to biodiversity or the costs incurred to support biodiversity, into the final price of products on the market; points out that this is in the long-term interest of companies if they wish to continue to have access to natural resources; urges the European Commission to publish the communication that it has announced on the future financing of Natura 2000 as soon as possible and in any event during 2010 so that this aspect can be examined together with the new biodiversity strategy for the period up to 2020;

Data and knowledge base

84. Stresses the importance of integrated environmental accounting in analysing the link between the environment and the economy at European, national and regional level in order to assess the effects of production and consumption patterns on the natural resources and calls on the Member States to regularly provide Eurostat and the European Environment Agency with the necessary data;

85. Points out that research and development are of key importance in order to close current knowledge gaps and ensure regular monitoring of biodiversity trends, as well as for developing policy tools to halt biodiversity loss;

86. Welcomes the Commission's composite report 2001-2006, evaluating the conservation status of protected habitats and species in the EU and the progress made by Member States in implementing Natura 2000 legislation, but regrets the high number of 'unknown' qualifications; calls on Member States to improve their reporting and on the EEA and the Commission to ensure a better reliability and comparability of data in its future reports;

87. Stresses the need to develop a clear baseline, on the basis of which the Commission is to measure progress towards the (sub-)targets; welcomes in this regard the work of the European Environment Agency with regard to the Biodiversity Information System (BISE) and the biodiversity baseline, which will provide useful tools to improve and fine-tune biodiversity policy-making, in particular for the strategic plan being developed by the Commission; underlines that existing data should be used rather than insisting on the collection of new data;

88. Given the current lack of knowledge among the general public about the importance of biodiversity, welcomes the Commission's information campaign and calls on the Member States to substantially increase their awareness-raising efforts and best practice exchanges;

International aspects

89. Expresses its concern about the failure to realise or even approach the global target to reduce the rate of biodiversity loss by 2010, as defined at the World Summit on Sustainable Development in 2002, and about the implications of the continuous biodiversity loss and ecosystem degradation for the Millennium Development Goals (MDGs) and the 2015 objective of reducing poverty and hunger and improving health and human well-being and calls on the Commission and Member States to support the mainstreaming of biodiversity into global processes such as the Millennium Development Goals;

90. Welcomes the Conference of the Parties to the Convention on Biological Diversity in Nagoya in October 2010 and urges the EU to send a broad delegation, well prepared and coordinated, to this conference; underlines the necessity for the EU to define a strong and coherent position upstream; is concerned, however, about the fact that only environment ministers will attend the conference, whereas securing progress on the global biodiversity agenda requires a cross-sector approach;

91. Urges the Commission to support the creation of an intergovernmental platform for policies in the field of biodiversity and ecosystem services science, under the auspices of the United Nations Environment Programme, and to help create that platform;

92. Supports the idea, discussed at a July 2008 meeting under the French Presidency, to develop 'Natura 2000-like' networks in the EU's Overseas Countries and Territories and Outermost Regions, which host some of the richest biodiversity hot-spots on the planet and underlines the need to support this development through EU policy instruments, such as development policy;

93. Points out that deforestation accounts for more CO_2 emissions than the whole transport sector and that conservation of forests is one of the core elements for the global conservation of biodiversity and ecosystem services;

94. Encourages the Commission and Member States to effectively mainstream environmental sustainability in their relations with third countries alongside respect for social rights and guarantees regarding the protection and participation of local communities and indigenous populations in decision-making processes, with particular regard to soil use and forest protection and to continue the 'Green Diplomacy'; calls on Member States and the European Commission to ensure that the 'twelve-point EU action plan in support of the Millennium Development Goals' recognises the imperative for environmental sustainability to be mainstreamed through its development cooperation and external actions and provides for a focused financial intervention in support of biodiversity and ecosystem services;

95. Underlines that innovative financial systems are needed to promote the recognition of the (economic) value of biodiversity; encourages Member States and the Commission to engage in a global discussion on the need for and possible modalities of innovative systems for the payment of ecosystem services;

96. Insists that, in international trade agreements, sustainability of the products being traded is a key element; underlines in this regard the need to incorporate 'non-trade concerns', including production methods and respect for biodiversity, in any future WTO agreement;

97. Strongly regrets the disappointing outcome of the CITES conference, where the main elements of the EU mandate were not realised, such as the protection of marine species of high commercial interest;

98. Strongly urges the Commission and Member States to improve the speed and efficiency of their internal decision-making procedure and to devote more resources and time to their diplomatic efforts vis-à-vis third countries and to strengthen capacities and synergies between Conventions; considers that, since many Natura 2000 protected areas are directly or indirectly affected by pollution and environmental damage also originates outside Europe, the need to include European environmental standards in our partnership agreements with neighbouring countries should be stressed;

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

Commission communication: A community approach on the prevention of natural and man-made disasters

P7_TA(2010)0326

European Parliament resolution of 21 September 2010 on the Commission communication: A Community approach on the prevention of natural and man-made disasters (2009/2151(INI))

(2012/C 50 E/04)

The European Parliament,

— having regard to the Commission Communication of 23 February 2009 entitled 'A Community approach on the prevention of natural and man-made disasters' ([1]) and the corresponding impact assessment ([2]), and to the Commission working document of 14 December 2007 on strengthening early warning systems in Europe ([3]),

([1]) COM(2009)0082.
([2]) SEC(2009)0202.
([3]) SEC(2007)1721.

— having regard to its resolutions of 16 September 2009 on forest fires in the summer of 2009 ([1]), 4 September 2007 on natural disasters ([2]), 7 September 2006 on forest fires and floods ([3]), 5 September 2002 on floods in Europe ([4]), 14 April 2005 on the drought in Portugal ([5]), 12 May 2005 on the drought in Spain ([6]), 8 September 2005 on natural disasters (fires and floods) in Europe ([7]), its resolutions of 18 May 2006 on natural disasters (forest fires, droughts and floods) – agricultural aspects ([8]), regional development aspects ([9]) and environmental aspects ([10]), its resolution of 11 March 2010 on the major natural disaster in the autonomous region of Madeira and the effects of the storm 'Xynthia' in Europe ([11]), and its position of 18 May 2006 on the proposal for a regulation of the European Parliament and of the Council establishing the European Union Solidarity Fund ([12]),

— having regard to the Council conclusions of 16 June 2008 on reinforcing the Union's disaster response capacity ([13]), and points 12 to 15 of the Presidency conclusions of the Brussels European Council of 15-16 June 2006 on the European Union's responsiveness to emergencies, crises and disasters ([14]),

— having regard to Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument ([15]),

— having regard to Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances ([16]) (Seveso II Directive),

— having regard to Directive 2007/60/EC of the European Parliament and Council of 23 October 2007 on the assessment and management of flood risks ([17]) (Floods Directive),

— having regard to Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment ([18]) (EIA Directive),

— having regard to the Framework for Action 2005-2015: Building the Resilience of Nations and Communities to Disasters, adopted on 22 January 2005 in Kobe, Hyogo ([19]),

— having regard to the Convention on Biological Diversity adopted on 5 June 1992 in Rio de Janeiro,

— having regard to Article 196 of the Treaty on the Functioning of the European Union (TFEU),

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Regional Development, the Committee on Agriculture and Rural Development, and the Committee on Civil Liberties, Justice and Home Affairs (A7-0227/2010),

A. whereas prevention should constitute an increasingly important stage in disaster management and be given greater social importance,

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([1]) OJ C 224 E, 19.8.2010, p. 1.
([2]) OJ C 187 E, 24.7.2008, p. 55.
([3]) OJ C 305 E, 14.12.2006, p. 240.
([4]) OJ C 272 E, 13.11.2003, p. 471.
([5]) OJ C 33 E, 9.2.2006, p. 599.
([6]) OJ C 92 E, 20.4.2006, p. 414.
([7]) OJ C 193 E, 17.8.2006, p. 322.
([8]) OJ C 297 E, 7.12.2006, p. 363.
([9]) OJ C 297 E, 7.12.2006, p. 369.
([10]) OJ C 297 E, 7.12.2006, p. 375.
([11]) Texts adopted, P7_TA(2010)0065.
([12]) OJ C 297 E, 7.12.2006, p. 331.
([13]) 10128/08.
([14]) 10633/1/06.
([15]) OJ L 71, 10.3.2007, p. 9.
([16]) OJ L 10, 14.1.1997, p. 13.
([17]) OJ L 288, 6.11.2007, p. 27.
([18]) OJ L 175, 5.7.1985, p. 40.
([19]) A/CONF.206/6.

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B. whereas natural disasters compromise ecosystems and biodiversity, affect sustainable development and jeopardise social cohesion,

C. whereas factors such as, inter alia, intensive land use, haphazard industrial and urban growth, abandonment of the countryside, desertification and the increased frequency of extreme weather events make Member States, and convergence regions in particular, more vulnerable to disasters, both natural and man-made,

D. whereas climate change is causing ever more frequent natural disasters (floods, extreme droughts and fires), resulting in loss of human life and serious environmental, economic and social damage,

E. whereas disasters generally have many causes, they are not always solely attributable to extreme natural phenomena, but are frequently made more likely by mankind's flawed relationship with the surrounding physical environment,

F. whereas disasters may be caused by technological and industrial accidents which can entail the release of dangerous chemical, biological, radiological or nuclear (CBRN) agents with major effects on health, crops, infrastructure, or livestock,

G. whereas often to a large extent damage caused by natural and man-made disasters could have been prevented; whereas, furthermore, EU policies must ensure consistent incentives for the national, regional and local authorities to develop, fund and implement more efficient prevention and conservation policies,

H. whereas a holistic, proactive, intelligence-led and effective approach to disaster prevention should incorporate various levels of cooperation between local, regional and national authorities and should also involve other actors with links to and, therefore, a knowledge of the land,

I. whereas disaster prevention measures in force have been shown to be lacking, and the previous European Parliament proposals have not yet been fully implemented, thus hindering the implementation of a consolidated strategy for the prevention of natural and man-made disasters at EU level,

J. whereas persistent drought and fires are also speeding up the process of desertification, especially in southern Europe, above all affecting Mediterranean forest areas and extensive woodlands comprising a single, non-native species which is highly vulnerable to fire, threatening the lives of citizens and the quality of life of the populations affected,

K. whereas the balanced occupation/utilisation of land, economic and social development that are in harmony with nature, respect for energy, natural resources and the environment, reinforced cohesion across the EU, combating rural depopulation, desertification and soil erosion, and maintaining an environmentally sustainable agricultural activity are some of the fundamental elements of disaster prevention,

L. whereas forests play a crucial role in preserving the environment through the balances created in both the carbon cycle and the water cycle,

1. Notes that natural and man-made disasters may have very serious consequences for the economic and social development of regions and Member States; points out that the main objective of disaster prevention is to safeguard human life, the safety and physical integrity of individuals, fundamental human rights, the environment, economic and social infrastructures, including basic utilities, housing, communications, transport and the cultural heritage;

2. Stresses that a proactive approach is more effective and less costly than one based simply on reacting to disasters; takes the view that knowledge of the local geographical, economic and social context is fundamental to the prevention of natural and man-made disasters;

3. Welcomes the commitment made by the Commission to ensuring that disaster-prevention-related issues are taken into account more coherently in EU policies and programmes, and stresses the need for a holistic approach to disaster prevention; recalls that all types of natural and man-made disasters must be taken into account and that these may include, among other hazards ([1]), floods, storms, droughts, tsunamis, earthquakes, forest fires, extreme temperature events, volcanic eruptions, avalanches, landslides, technological and industrial accidents, soil erosion, contamination of the subsoil and groundwater and pollution of the seas, lakes and rivers;

4. Invites the Commission to encourage the exchange of good practices between Member States in preventing man-made disasters, and calls on the Member States to ensure that regional authorities undergo disaster management training;

5. Considers that, given the scale and/or the cross-border nature that disasters may assume, it is appropriate and necessary to enhance cooperation, both at regional and EU level, based on complementarity of action, dissemination of best practices and the principle of solidarity between Member States;

6. Takes note of the proposal to set up a network made up of representatives of the various competent national services of all the Member States; stresses that this network should operate within the scope of the cooperation between national, regional and local authorities with responsibilities in disaster management, spatial planning and risk mapping and management; emphasises the role of this network in exchanging experience and prevention measures and in establishing a common methodology and minimum requirements for hazard and risk mapping at EU level; calls for the inclusion in this network of representatives from agriculture and for consideration also to be given to hearing UNEP, social and non-governmental organisations working in this area and other actors with links to and, therefore, a knowledge of the land;

7. Regards as essential cooperation on the dissemination of information and experience, technical and scientific applications and also the coordination of strategies for the development of intervention capacities;

8. Calls on regions to build on already existing territorial and cross-border coordination networks in order to develop cooperation focusing more specifically on disaster prevention; believes that cross-border cooperation structures, such as the macro-regions, with their functionally-oriented cooperation, can become effective platforms for cooperation in the field of disaster prevention; advocates making use of the valuable experience acquired in this field through projects implemented in the past under the Community's INTERREG Initiative;

9. Takes the view that coordinated actions and strategies between Member States, the different sectors and the different actors involved in the disaster management cycle can lead to real advances in the field of disaster prevention; highlights the role that voluntary work can play in these strategies and calls on the Member States to foster cooperation to this end at national, regional and local level; suggests that the possibility be assessed, in the context of the European Year of Volunteering 2011, of organising voluntary work cooperation at Member State level with a view to disaster prevention;

10. Urges cooperation between Member States, countries neighbouring the EU and developing countries in cross-border projects sharing best practice and disseminating practical knowledge through the EU's neighbourhood policy programmes and development programmes;

11. Emphasises that the principle of non-discrimination must be included in aid provision; notes that assistance should be provided on the basis of need, without discrimination based on the race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status of recipients;

12. Points out that environmental problems, caused and exacerbated by climate change, are currently responsible for a growth of forced migration and therefore wishes to highlight the increasing link between asylum seekers and areas of environmental decline; calls for better protection and resettlement of 'climate refugees';

([1]) This is a non-exhaustive list of natural and man-made disasters; therefore other types of natural and man-made disaster which are not set out in this report may be included in the list.

13. Stresses that it is the regions and local communities that bear the brunt of natural disasters and that, generally speaking, neither their material and human resources nor their know-how or financial resources are sufficient to cope with these disasters under a purely national and/or regional approach, and that these disasters call for an effective European-level solidarity-based response;

14. Points out the importance of reducing inequalities between regions and Member States in terms of their capacity to protect their populations, and their property, including the cultural heritage, by supporting their efforts to improve prevention, particularly in the regions and Member States that are highly vulnerable to the risk of disasters; urges that particular attention be paid to the most isolated, most sparsely populated, mountainous and border regions of Europe, and the most economically disadvantaged European regions;

15. Stresses that the natural characteristics and constraints of isolated regions, mountainous regions, regions with low population density and those suffering from depopulation, outlying and outermost regions, islands, naturally disadvantaged regions, as well as regions facing a combination of risks, need to be acknowledged and taken into due account; draws attention to the added difficulties faced by these regions in tackling disasters; asks for special attention to be paid to those regions through the various financial instruments available and calls for the conditions for mobilising the Solidarity Fund for those areas to be made more flexible;

16. Highlights the need for the Solidarity Fund Regulation to be revised by adapting the eligibility criteria to the characteristics of each region and each disaster, including slowly evolving disasters such as drought, paying particular attention to production sectors, the most vulnerable areas and the populations affected, and enabling mobilisation to be more flexible and timely; considers that the eligible operations listed in Article 4 of the European Union Solidarity Fund (EUSF) are too restrictive; takes the view that, when setting eligibility thresholds, consideration of the regional dimension is vital, as otherwise regions facing very serious disasters can find themselves excluded because the threshold set for the whole Member State is not reached;

17. Stresses the need to create a suitable financial framework for disaster prevention, with adequate financial resources for preventing and combating disasters, that will strengthen and link existing instruments such as cohesion policy, rural development policy, regional policy, the Solidarity Fund, the Seventh Framework Programme and the Life+ programmes; asks that, in this context, prevention should be taken into account in the 2014-2020 Financial Perspective; calls on the European Commission to assess the possibility of proposing a more systematic pooling of available resources in order to strengthen the effectiveness of prevention mechanisms across the EU;

18. Urges the Commission to ensure that the current budgetary pressures arising from the crisis do not lead to a reduction in the resources allocated to existing disaster prevention policies and, as part of the current budget review, to carefully assess any gaps in the field of prevention and ascertain whether each type of disaster is covered by the instruments available;

19. Points out that cohesion policy is an essential tool in natural disaster risk prevention; considers that it must be possible for the various funds and instruments to operate flexibly and in a coordinated manner in order to improve the functioning and effectiveness of that policy; stresses that risk prevention must also dovetail with other policies pursued in the field of prevention, in order to prevent the fragmentation of measures and increase their effectiveness and added value;

20. Reaffirms the need to verify that EU funds have been used in an adequate manner, and for any misused funds to be repaid;

21. Emphasises that responsibility for disaster prevention lies primarily with the Member States and that the principle of subsidiarity in this area should continue to be considered;

22. Calls on the Member States who are responsible for land management to introduce criteria and legislation in order to prevent catastrophes in areas at risk of flood and landslides and other geological risks, taking into account the problems created by indiscriminate deforestation, and furthermore to prevent construction in these areas;

23. Invites the Member States to assess the possibility of improving the inclusion of disaster prevention in national operational programming of EU funding, as well as in national, regional and local operational programmes; considers that all public actors involved in environmental protection should be engaged and participate effectively in this process; urges the Commission to support the need to reformulate the operational programmes identified by Member States in this area; with a view to exchanging experience, asks the Commission to invite Member States to supply details of their operational programmes in place for dealing with natural and man-made disasters;

24. Considers that, inter alia, the following prevention measures should be the subject of priority support from the EU to the Member States:

a) drafting and revising building safety and land use legislation;

b) action to remedy situations conducive to future risks: renaturalising river beds; restoring and protecting river basins, wetlands and related eco-systems; monitoring erosion and sedimentation in water courses; increasing the through-flow capacity of bridges and water pipelines; clearing up and reordering forests; reforestation; and protecting and defending the coastline;

c) protecting and refurbishing inhabited areas, especially urban areas, that are particularly vulnerable to certain types of disasters, with the involvement of residents;

d) maintaining and inspecting the safety of existing major infrastructures, with particular emphasis on dams, fuel pipelines, road and rail bridges, energy, water supply, sanitation, communications and telecommunications facilities;

e) sustaining the agricultural activity in areas affected by depopulation and subject to the risk of natural disasters, and contributing to the reintegration of human activity by creating infrastructures to enable those who live in such areas to remain on the territory;

25. Calls on the Commission to support Member States in promoting awareness-raising campaigns for prevention and in adopting best practices, providing relevant updated information and training to the general public through channels that are easily accessible to all citizens on identified risks and procedures to be adopted when faced with natural or man-made disaster situations; urges that, in training schemes for populations, particular attention be paid to young people from school age on and to rural communities; in the context of public awareness-raising, stresses also the role of the European single emergency telephone line '112' and the need to make it better known;

26. Recalls that water is often involved in natural disasters, not only in floods – often due to inadequate planning – frost, hail and contamination of river basins, but also through its scarcity, which can wreak significant change, such as the desertification of large areas of southern Europe and south-eastern Europe;

27. Highlights the fact that persistent droughts have in recent years encouraged the proliferation of forest fires in Europe, at the same time worsening the desertification of a large number of regions;

28. In view of the interconnections between drought, forest fires and desertification, calls on the Commission to present a proposal for a directive, similar to the directive on floods, to promote the adoption of an EU policy on water scarcity, drought and adaptation to climate change;

29. Reiterates its call on the Commission to promote the entry into operation of the European Drought and Desertification Observatory which would be responsible for studying, mitigating and monitoring the effects of droughts and desertification, aiming to enhance sound, strategic decision-making and better coordination between Member States; considers that the interconnections between drought, forest fires, desertification and climate change adaptation should be taken into consideration and that serious and solidarity-based objectives should be set in the context of drought risk prevention and management policy;

30. Since forests are important for the production of wood, maintaining biodiversity, the prevention of floods, avalanches and erosion, management of groundwater resources and carbon capture, the fact that they are threatened by fire should be an issue of concern to all Member States; therefore calls on the Commission to present and to carry out, together with the Member States, legislative proposals and initiatives in the area of forest protection and fire prevention; considers that forestation and reforestation projects should be supported, with preference given to native species and mixed forests, to encourage biodiversity and greater resistance to fire, storms and disease, as well as the sustained collection and use of residual forest biomass - a renewable energy source; considers that, within the framework of a genuine cooperation in this domain, the regular collection of data, preparation of risk maps, preparation of fire risk management plans, identification of the resources needed and those available in the 27 Member States and coordination at different levels should be carried on;

31. Given that the starting of fires and the increase in their frequency are by nature environmental offences, calls on the Commission to study and propose to the Council and the European Parliament ways of implementing coercive measures which will discourage negligence and deliberate action in the starting of fires;

32. Highlights the importance of viewing prevention from a cross-cutting perspective, incorporating it in the relevant sectoral policies to promote balanced land occupation and cohesive economic and social development that is in tune with nature;

33. Recognises that some sectoral policies have led to certain regions being more exposed to risk by encouraging abandonment of the countryside and excessive concentration of the population in urban areas;

34. Considers that agricultural and forestry production are vulnerable to climatic phenomena such as drought, frost, ice, hail, forest fires, storms, floods, torrential rainfall and storms, to health risks such as pest infestations, animal diseases, epidemics, and epizootics, to destruction due to wild animals, and to consequences of human activities like climate change, pollution, acid rain and unintentional and deliberate genetic contamination, to landslides because of problems related to urban and regional planning, to technological and transport-related hazards, to the desertification of mountain areas and to forest fires primarily due to absence of forest maintenance and criminal behaviour, and to contamination of rivers due to chemical discharges from factories, nutrient leakage and the negligence of forest visitors;

35. Calls on the Commission and the Member States to encourage the implementation of good agricultural practices, which in some Member States has made it possible to halve infiltration of nitrogen-based fertilisers without reducing crop yields;

36. Advocates, as an essential element in the effective prevention of natural disasters, an environmentally and socially balanced agricultural policy that takes into account the need to support and stimulate sustainable agricultural production and rural development in the various countries and regions; advocates effectively strengthening incentives for agro-environmental and agro-rural jobs, encouraging people to settle in rural areas, as a key factor in conserving ecosystems, tackling the current trend of depopulation and impoverishment of these locations and relieving the pressure on urban areas; furthermore, highlights the role played by farmers as custodians of the countryside and regrets the insufficiency of key elements concerning the agricultural sector in the Commission communication;

37. Advocates the creation of an European agricultural public insurance scheme; urges the Commission to come forward with a proposal for an European public insurance system to better address the risk and income instability of farmers related to natural and man-made disasters; stresses that it must be more ambitious than the present model in order to avoid a multiplicity of different insurance schemes in the EU, creating huge imbalances between farmers' incomes; considers it urgent for a minimum compensation scheme for natural or man-made disasters to also be accessible to farmers across all Member States;

38. Calls on the Commission and Member States to include in the calculation of agri-environmental premiums the additional costs borne by farmers in order to take measures designed to prevent fires (such as cleaning of firebreaks, removal of dead arboreal plants, working of the soil along the perimeter of land parcels, etc.) and to dispose of water (cleaning of collecting ditches and canals);

39. Points out the importance of studying rural and urban adaptation measures, given the increased frequency and magnitude of extreme weather events in various geographical areas; considers that foreseeable negative effects of climate change will represent an additional constraint for agricultural activity and food security and sovereignty, and stresses the need to respond to this and to other challenges in the context of adapting to climate change and reducing its negative effects;

40. Emphasises the importance of public research and development (R&D) in preventing and managing disasters and calls for increased coordination and cooperation between the R&D institutions of Member States, especially those facing similar risks; calls for enhanced early warning systems in Member States and the creation and strengthening of links between the various early warning systems; recommends to the Commission that it should take due note of these needs and ensure appropriate funding;

41. Stresses the need to prepare the healthcare systems of the Member States from the point of view of human resource structure, good practice and risk awareness so that they are able to cope with disaster situations;

42. Underlines that it is important to have a comprehensive collection of data and information on the risks and costs of disasters and to share them at EU level, with a view to carrying out comparative studies and determining the likely cross-border impact of the disasters, thus making it possible for Member States to pool information on national civil capabilities and medical resources, and that we should use and develop already existing structures such as the Monitoring and Information Centre (MIC) rather than build up new ones;

43. Regrets the fact that the Commission has still not carried out a study on hazard and risk mapping practices in the Member States, as provided for in its Communication of 23 February 2009 on 'A Community approach on the prevention of natural and man-made disasters'; urges the Commission to make good on this commitment in an effective way during the first half of 2010;

44. Considers that a common methodology and minimum requirements for hazard and risk mapping need to be established at EU level;

45. Underlines the importance of drawing up standards to analyse and express the socio-economic impact of disasters on communities;

46. Recommends that issues relating to disaster prevention should be more fully included in the revision of the EIA Directive, particularly with regard to the assessment, communication and publicising of risks;

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

Poverty reduction and job creation in developing countries: the way forward

P7_TA(2010)0327

European Parliament resolution of 21 September 2010 on poverty reduction and job creation in developing countries: the way forward (2009/2171(INI))

(2012/C 50 E/05)

The European Parliament,

— having regard to the United Nations Millennium Declaration of 8 September 2000, which sets out the Millennium Development Goals (MDGs) as criteria collectively established by the international community for the elimination of poverty,

Tuesday 21 September 2010

— having regard to the commitments on aid volume, aid to Sub-Saharan Africa, and aid quality made by the G8 at the 2005 Gleneagles Summit,

— having regard to the Paris Declaration on aid effectiveness of 2 March 2005 and the conclusions of the high-level forum which met in Accra between 2 and 4 September 2008 concerning the follow-up to that Declaration,

— having regard to the Commission Communication entitled 'EU aid: delivering more, better and faster' (COM(2006)0087),

— having regard to the UN report 'Rethinking Poverty: Report on the World Social Situation 2010',

— having regard to the annual reports by the Secretary-General of the United Nations on the implementation of the Millennium Declaration,

— having regard to the joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy: 'The European Consensus' ([1]), signed on 20 December 2005,

— having regard to Regulation (EC) No 1905/2006 of the European Parliament and of the Council of 18 December 2006 establishing a financing instrument for development cooperation ([2]) (the 'Development Cooperation Instrument' (DCI)),

— having regard to the Abuja Declaration by African Heads of State and Government on HIV/AIDS, Tuberculosis and other related Infectious Diseases of 27 April 2001,

— having regard to Regulation (EC) No 1889/2006 of the European Parliament and of the Council of 20 December 2006 on establishing a financing instrument for the promotion of democracy and human rights worldwide ([3]),

— having regard to the Council Conclusions of 21 June 2007 'Promoting Employment through EU Development Cooperation',

— having regard to the Commission Communication entitled 'The European Union's role in promoting human rights and democratisation in third countries' (COM(2001)0252),

— having regard to the Commission Communication entitled 'Education and training in the context of poverty reduction in developing countries' (COM(2002)0116),

— having regard to the ACP-EU Joint Parliamentary Assembly resolution of 3 December 2009 on global governance and the reform of international institutions,

— having regard to the ILO Decent Work Agenda and to the ILO Global Jobs Pact, adopted by global consensus on 19 June 2009 at the International Labour Conference,

— having regard to the ILO report entitled 'World of Work Report 2009: The Global Jobs Crisis and Beyond', published in December 2009,

— having regard to its resolution of 24 March 2009 on MDG contracts ([4]),

([1]) OJ C 46, 24.2.2006, p. 1.
([2]) OJ L 378, 27.12.2006, p. 41.
([3]) OJ L 386, 29.12.2006, p. 1.
([4]) OJ C 117 E, 6.5.2010, p. 15.

— having regard to its resolution of 6 April 2006 on aid effectiveness and corruption in developing countries ([1]),

— having regard to its resolution of 23 May 2007 on promoting decent work for all ([2]),

— having regard to its resolution of 12 March 2009 on an approach to EC development assistance to health services in sub-Saharan Africa ([3]),

— having regard to the current reforms of the Common Agriculture Policy and the Common Fisheries Policy,

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on Development and the opinion of the Committee on Employment and Social Affairs (A7-0192/2010),

A. whereas strong and sustainable economic growth within a stable, business-friendly environment helps create wealth and jobs and is therefore the surest and most sustainable route out of poverty,

B. whereas a secure, corruption-free legal environment is essential for business to flourish,

C. whereas EU15 states are committed to spending 0,7 % of their GNI on ODA by 2015; whereas current ODA levels are around 0,4 %,

D. whereas poverty reduction and policy coherence for development are now EU Treaty obligations,

E. whereas developing countries should be supported in their desire to achieve maximum added value in their own countries, which calls for an industrial development strategy that must nevertheless continue to be compatible with sustainable development requirements, with particular reference to conservation of the environment,

F. whereas both EU donors and developing country governments are failing to meet their spending benchmarks for health and education,

G. whereas the developing world faces an urgent shortage of qualified health personnel; whereas the lack of qualified health personnel in developed countries constitutes one of the factors which aggravates the fragile health system in developing countries, and whereas many skilled workers, in health and other sectors, are not returning home to benefit their own communities, due to a number of reasons,

H. whereas the recent food-price crisis highlighted the ongoing importance of agriculture and food security for poor countries,

I. whereas 90 % of EU citizens are in favour of development cooperation, although the downturn threatens to weaken this support,

J. whereas the G20 has promised to crack down on tax havens,

K. whereas tax evasion and illicit capital flights from developing countries represent several times the value of development aid,

L. whereas remittances represent more capital inflows for developing countries than ODA,

([1]) OJ C 293 E, 2.12.2006, p. 316.
([2]) OJ C 102 E, 24.4.2008, p. 321.
([3]) OJ C 87 E, 1.4.2010, p. 162.

M. whereas 2,7 billion people currently have no access to credit,

N. whereas, to reduce poverty, it is necessary not only to generate employment but to create quality jobs,

O. whereas the poorest countries are severely underrepresented in international institutions and global fora,

P. whereas social protection systems have been proven as powerful instruments for poverty reduction and social cohesion and the majority of the global population has no adequate social protection coverage,

Challenges for developing countries

On the economy

1. Urges governments in developing countries to diversify their economy through the development of their manufacturing sector and to avoid overburdening businesses – especially SMEs, motors of jobs and growth – with excessive red tape;

2. Calls on all developing countries to sign up to the ILO's Decent Work Agenda and the UN Social Protection Floor initiative in order to guarantee satisfactory labour standards, high levels of comprehensive social protection coverage that reaches the poorest and most marginalised groups, genuine social dialogue and, in particular, involvement in the Employment Intensive Investment Programme;

3. Underlines the importance of signing up to and implementing the various ILO conventions on international labour standards and recommends employing the provisions of the ILO resolution 'Recovering from the crisis: A Global Jobs Pact';

4. Calls for the implementation of the right to freedom from forced labour and especially from child labour without exception, as without education children are condemned to a life in poverty;

5. Calls for particular emphasis to be placed on combating child labour, with a view to creating jobs for adults instead and enabling children to receive a suitable education;

6. Urges governments to prioritise action to help meet basic social needs and to promote the protection of children and vulnerable women who have been severely affected by the crisis, as well as young people at risk, unqualified, migrant and low-paid workers, rural workers and differently-abled persons;

7. Recalls that small and micro enterprises, especially in the agricultural sector, need adequate financing to preserve existing jobs and create new ones; encourages developing countries to promote saving and credit access, via micro-credit, micro-insurance and innovative credit agents, such as rural post offices or m-banking;

8. Calls on the EU to recognise the contribution of the social economy (e.g. cooperatives) to job creation and the promotion of decent work in developing countries, and to include the social economy in EU development programmes and cooperation strategies;

9. Invites developing countries to extend land ownership among the poor and dispossessed, for instance by giving squatters in shanty towns the titles to the land they live on;

10. Encourages developing countries to diversify their economies to the maximum, so as no longer to be exclusively dependent on a very limited number of products, particularly agricultural products for export;

11. Reminds developing countries to respect local traditions of common land use for agriculture in order to facilitate and to protect existing small farming;

12. Calls on the developing countries to treat the development of the agricultural sector and of food security as a priority when drawing up Country Strategy Papers and National Indicative Programmes;

13. Recalls that governance is included in the idea of a 'just state', that is, a state which guarantees democracy and civil rights and – at the same time as performing its executive functions such as ensuring access to justice, health care, education and administrative services – promotes and protects human rights and fundamental freedoms;

On citizenship and governance

14. Calls on all developing countries to sign the UN Convention against Corruption urgently and to implement its provisions effectively; also urges EU Member States, and EU companies, to respect the UN Convention;

15. Believes that EU Member States should act as role models for developing countries in terms of budgetary discipline, tax collection and good governance;

16. Believes that anti-corruption action should also target the private sector, as well as enhancing international cooperation, for instance through information exchange and asset-recovery programmes;

17. Urges all developing countries to foster independent parliaments, able to contribute effectively to deepening democracy by freely exercising their legislative, budgetary and scrutiny functions; at the same time, draws attention to the enormous importance of a judicial system which operates independently and is properly developed;

18. Encourages governments in developing countries to maximise involvement by civil society organisations in formulating and monitoring public policy;

19. Stresses that the social partners play an important role in economic development and can strengthen social cohesion, and consequently that the setting-up and consolidation of the relevant representative organisations should be encouraged;

20. Calls for the implementation of the freedom of association for trade unions and the right to bargain collectively without exemption in order to enforce, improve and defend decent work conditions;

21. Exhorts all states which have introduced laws restricting the freedom of civil society organisations to repeal such legislation;

22. Calls for the implementation of the right to freedom from discrimination, i.e. the right to work and be treated equally regardless of gender, ethnic origin, age, disability or sexual orientation, as a core principle in the fight against poverty;

23. Calls for the legal and social position of women to be significantly strengthened so as to prevent discrimination and make use of women's potential contribution to economic and social development;

24. Supports developing countries in their efforts to strengthen and deepen regional integration, through free-trade areas, regional economic communities, regional development banks, etc.;

Shared challenges

25. Reiterates its call for developing countries' national budgets and EU development aid to allocate at least 20 % of their spending to health and basic education;

26. Calls for a rethinking of privatisation policies, especially concerning utilities like water, sanitation and services of general interest, and for the social role of states in development governance, including the role of state-owned enterprises as employers and social service providers, to be reconsidered;

27. Draws attention to the crucial role of social protection systems as mentioned in the ILO Global Jobs Pact and the United Nations Social Protection Floor Initiative; calls, therefore, for a stronger emphasis on social protection systems to prevent increased poverty and address social hardship, while helping to stabilise the economy and maintain and promote employability;

28. Asks for free and full access for all to educational systems, i.e. basic and higher as well as vocational education, so that the local population can become qualified skilled workers;

29. Insists that both donor and developing countries have to fulfil their commitments to achieve the Millennium Development Goals by 2015;

30. Supports measures, such as salary subsidies and job and training opportunities, that encourage local scientists as well as other skilled workers to remain and practise within their communities and that strengthen medical systems which are accessible for everybody;

31. Supports the creation of new job positions within the developing countries;

32. Supports measures that invest in and build up public services in general in order to create jobs and strengthen state capacities, facilities and social cohesion as mentioned in the UN Report 'Rethinking poverty';

33. Calls for more emphasis to be placed on practical healthcare and awareness raising among the population about the merits of medical treatments, e.g. distributing blood analysers and training local people to use them;

34. Highlights that the development of human resources is indispensable in all development strategies and crucial to job creation; calls on the EU and developing countries to analyse employment needs and the labour market, make forecasts and anticipate the major challenges involved in adapting vocational training to employment;

35. Believes all development strategies should pay special attention to the most vulnerable and marginalised, especially women, children, older people and people with disabilities;

36. Considers it indispensable to meet basic needs, and therefore assigns particularly high priority to measures promoting food security and access to drinking water;

37. Highlights the problem of child labour and recognizes that it is one of the major obstacles to achieving universal primary education completion and reducing poverty and hampers the healthy upbringing and necessary education of these children; thus calls for the promotion of inter-agency coordination and alignment in education aid and child labour policy through strengthening existing mechanisms, including the Global Task Force for Child Labour and Education; finally, calls on the international community, all states concerned and the EU to commit themselves to doing their utmost to eradicate child labour as a matter of urgency and dedicated action;

38. Points out the importance of gender equality for the economic success of states, and calls therefore for greater efforts to also ensure gender equality in the economy;

39. Insists that donors and partner countries should ensure that agriculture, particularly smallholder farming and small and medium-sized eco-friendly agro-industries, move up the development agenda;

40. Emphasises that small farming based on decentralised, green and sustainable means of production facilitates job creation and sustainable development, since per hectare they employ more people than large farms, with the farmers and employees spending pro rata more on employment-intensive rural non-farm products;

41. Calls for jobs and employment creation to be given more effective support by coordinating employment and macro-economic policies, bearing in mind that the latter should not be restricted to controlling inflation and trade and fiscal deficits but also focus on the stability of real output, incomes and employment;

42. Supports investment in 'green jobs' and in green industry, for example by developing renewable energy and energy efficiency systems in poor countries, including solar power for the benefit of local communities, as a way to provide sustainable sources of energy and, at the same time, to create jobs while protecting the environment;

43. Calls for an increase in equal access to, and opportunities for, skills development, quality training and education; calls for improvements to be made as regards access to credit (including micro-finance) to encourage job creation;

44. Looks forward to increased cooperation between Parliament and its regional counterparts in developing countries;

45. Stresses the importance of promoting alternative indicators to GDP to measure social progress in developing countries, particularly in light of the suggestions made by the Commission on the Measurement of Economic Performance and Social Progress chaired by Joseph Stiglitz;

46. Calls for responses to the global economic crisis to be devised by country and region and to include the measures mentioned in the International Labour Organisation's (ILO) policy instrument 'A Global Jobs Pact' in order to facilitate investment in employment-intensive and environment-friendly sectors and social protection systems;

Challenges for donors

On aid

47. Urges all rich countries, especially EU states, to keep their spending promises as regards aid, i.e. at least 0,7 % of GNI by 2015;

48. Calls for a common definition of poverty among the Member States to identify the relevant working fields and the beneficiaries entitled to EU development aid;

49. Believes that policy coherence can bring fruitful results in terms of job creation in developing countries; calls therefore for a change in EU external polices as these have a direct impact on developing countries' economies and should be designed to support their sustainable needs in order to fight poverty, guarantee a decent income and livelihood and fulfil basic human rights, including social and economic rights and environmental protection;

50. Calls for substantial additional funding in order to combat the effects of climate change and the global economic crisis in developing countries;

51. Calls for basic education and public health to form the basis of development policies and insists that the current situation cannot justify any reduction in national spending and international aid to these sectors;

52. Calls on the EU to honour its aid-for-trade commitments;

53. Emphasises that the EU has to revise its subsidy policies, especially in the agricultural sector and in line with the needs of small and medium farmers in the EU, in order to facilitate fair trade conditions regarding developing countries;

54. Asks all donors, once again, to adhere more faithfully to the aid effectiveness agenda, especially as regards donor coordination and accountability;

55. Insists that the Commission make sure that the external dimension of the current reform of the Common Fisheries Policies will be mainstreamed with EU development policy as these are directly linked to the livelihood of the population in developing countries;

56. Emphasises that the fisheries sector in many countries is crucial for employment and food security and therefore all developing countries should be eligible for EU sector support to develop their own sustainable fisheries industry, research, control and enforcement to combat Illegal Unreported and Unregulated fisheries, independent of any fisheries access agreement with the European Union;

57. Underlines that EU sector support to the fisheries industry in third countries is aimed at equipping harbours in these countries with the proper infrastructure to facilitate the local landing and processing of fish in order to create new jobs; calls on the Commission to monitor and verify that these goals are achieved, and to provide financial and technical support to improve the ability of the third country to monitor fishing activities in its waters and to apprehend vessels seen to be committing infractions;

58. Insists that the EU should simplify its aid architecture and related procedures;

59. Calls for reinforced development policy coordination between the Commission and the EU Member States to prevent different policy actions having a negative impact on the achievement of the MDGs;

60. Expects that, since policy coherence for development is now a Treaty requirement, EU policies in areas such as farming, trade, migration and fisheries will not in any way undermine development efforts; intends to monitor closely how the EU fulfils this obligation;

61. Invites donors to invest intelligently in development education for their citizens;

62. Encourages donor countries to use this crisis to further explore existing possibilities in terms of additional and innovative sources of financing for development and to identify new ones to allow developing countries to diversify their sources of revenue and implement effective, concrete and operational spending programmes;

63. Calls on the Commission and the EU Member States to promote sustainable enterprises with decent jobs creation as a specific sector of development cooperation in line with the 2005 European Consensus on Development, and to foster its integration in more traditional sectors of development cooperation such as infrastructure, rural development, governance and trade-related assistance;

On new sources of funding

64. Urges G20 nations to carry through on pledges to stamp out tax havens, to tighten up supervision of financial markets and to usher in tax information exchange; furthermore, the G20 should instruct the International Accounting Standards Board to adopt a new standard that includes country-by-country reporting;

65. Calls on the G20 and EU states to take steps to make remittances cheaper and easier;

66. Calls on the Commission and the Member States to enhance public financial support to small and micro enterprises and farmers in the developing countries, including the informal sector, as called for in the ILO Global Jobs Pact, in order to combat poverty and unemployment;

On capacity building and global governance

67. Urges the EU to target its aid towards promoting capacity building in areas that will directly benefit the partner countries' economic fabric and create jobs, i.e. developing their productive capacity, building efficient tax systems, fighting corruption, strengthening institutions and civil society, facilitating access to microcredit and other sources of finance, etc.;

68. Calls for all EU development policies with an impact on job creation and poverty reduction to focus on measures which require governments, civil society, companies, foundations and local communities to achieve the UN Millennium Development Goals (MDGs) by 2015;

69. Calls on the EU to target its aid also towards building up social protection systems in developing countries as an important and effective means to reduce poverty;

70. Calls for priority to be given to education, follow-up assistance to school-leavers, vocational training, technology education, skills training, lifelong learning, access to finance, setting up high-quality training courses which improve the prospects of those who take them, health and safety, and encouraging entrepreneurial initiative schemes primarily for small and micro enterprises to create a sustainable workforce, thereby focusing especially on young, elderly, disabled and displaced people, women and any other marginalised groups;

71. Believes that the EU should take account of human rights and governance criteria when drawing up trade agreements with developing countries and should not hesitate to apply sanctions when states fail to respect their governance obligations; recalls that conditionality criteria apply to both the European Development Fund (EDF) and the Financing Instrument for Development Cooperation (DCI);

72. Asks the EU authorities to ensure scrupulous respect for the principle of conditionality, as stipulated in the Cotonou Agreement;

73. Emphasises that the same conditionality criteria apply to the provision of support under both the European Development Fund (EDF) and the Financing Instrument for Development Cooperation (DCI);

74. Calls on the Commission to promote appropriate methods and timetables for monitoring the production chains of European undertakings operating abroad in order to verify the elimination of child labour and compliance with the labour standards promoted by ILO Conventions, and to promote access to education, which is a crucial factor in combating poverty;

75. Urges the establishment of a reliable network for close relations among major governmental and non-governmental institutions and organisations dealing with poverty reduction in all developing countries in order to share views and experiences with EU assistance in formulation, implementation and monitoring;

76. Supports the establishment of databases at national and EU levels in order to collect and compare basic data relevant to poverty in developing countries as a way of facilitating and increasing efforts towards poverty reduction;

77. Stresses the need to strengthen existing coordination among international and regional organisation as an additional effort in providing technical support to the implementation and monitoring of an EU Action Plan on Poverty Alleviation;

78. Notes the need to establish 'Advisory Groups' on specific issues as a concrete step and reliable way of providing technical support in order to implement the objectives set out in an EU Action Plan on Poverty Alleviation in developing countries;

79. Accepts the use of budget support only where there are watertight guarantees that funds will reach their intended destination and satisfy their original purpose and where recipients fulfil human rights and democratic governance criteria; looks forward to more effective assessment and auditing of budget support

to analyse if the intended goal is achieved and if governments in the recipient countries comply with the abovementioned criteria; calls on the Commission to establish an IT-based scoreboard under the scrutiny of the European Parliament to assess the efficiency of Community aid in the field of poverty reduction, education and job creation, with this scoreboard being based on the degree of compliance with the expected financial ratios and aims;

80. Calls on the Commission to present to the European Parliament a coherent and credible proposal on EU post-election policy, which respects the free choice of the population in a given country, and fears that the current absence of a coherent post-election policy undermines the credibility of the EU Election Observation Missions;

81. Supports more democratic representation of developing countries in global institutions;

82. Invites the international financial institutions to review their loan policies in order to support democratic and sustainable economic development choices by developing countries;

83. Calls on the EU and the G-20 to take concrete action to eradicate abuses of tax havens, tax evasion and illicit financial flights from developing countries and to promote these resources to be invested in developing countries;

84. Calls for a new binding global financial agreement on the automatic disclosure by transnational corporate companies of the profits they made and the taxes they paid on a country-by-country basis;

85. Calls on the EU to support the UN Social Floor Initiative to extend or implement sustainable social protection systems in developing countries by ensuring greater coherence in external relations policies and developing a Communication on Social Protection in development cooperation, as suggested in the Council Conclusions on Promoting Employment through EU Development Cooperation;

On education

86. Agrees with the Commission that having a job is the best way to avoid poverty and social exclusion; believes that tackling the education gap in developing countries is one of the most effective strategies for breaking the cycle of poverty and unemployment;

87. Welcomes the Education For All - Fast Track Initiative (FTI) and the Commission's support of it in principle; urges the Commission to clarify what funds it currently makes available to the countries covered by this initiative, and for which purposes, particularly in the field of:

— early childhood care and learning,

— free and compulsory primary education for all,

— learning and life skills for young people and adults,

— adult literacy,

— gender equality,

— quality of education;

88. Urges the EU to introduce assistance programmes for parents in various fields where poverty leads to a lack of knowledge with regard to bringing up children to ensure that children in developing countries have real opportunities;

89. Notes that the quality of mental and physical health is not just a question of education, training and new information technologies, but also of access to water, food and medicine, so the EU should pay more attention to clustering free teaching materials, free meals, free school buses and free examinations into comprehensive aid projects; deems it imperative to call for a clear interrelation between EU-funded school-based projects and food and health programmes in developing countries;

90. Calls on the EU to concentrate its efforts on identifying branches where developing countries have a competitive advantage, whereby the establishment of work-based apprenticeships in these sectors shall be one of the main priorities of EU development aid;

91. Calls on the EU to provide more education opportunities for developing-world students but to encourage them to return home after their studies to benefit their own communities;

Access to the market

92. Points out that developing countries are advised that their products must compete in the open market while the same principle is often not applied to the developed world;

93. Calls on the Commission and the Member States to develop a coherent approach which respects the fundamentals of the free market and which guarantees reciprocity in the field of trade;

94. Stresses that many developing countries, particularly with regard to the agricultural sector, are characterised by subsistence economies and these economies are often the only source of income and living;

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

Wednesday 22 September 2010

Enforcement of intellectual property rights in the internal market

P7_TA(2010)0340

European Parliament resolution of 22 September 2010 on enforcement of intellectual property rights in the internal market (2009/2178(INI))

(2012/C 50 E/06)

The European Parliament,

— having regard to the communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee of 11 September 2009 on enhancing the enforcement of intellectual property rights in the internal market (COM(2009)0467),

— having regard to the resolution of the Competitiveness Council of 25 September 2008 on a comprehensive European anti-counterfeiting and piracy plan,

— having regard to Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) ([1]),

— having regard to Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society ([2]),

— having regard to Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights ([3]),

— having regard to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights ([4]),

— having regard to Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs ([5]),

— having regard to its position of 25 April 2007 on the amended proposal for a directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights ([6]),

— having regard to the Commission Strategy for the Enforcement of Intellectual Property Rights in Third Countries of 2005 and to the Commission Staff Working Document 'IPR Enforcement Report 2009',

— having regard to its recommendation of 26 March 2009 to the Council on strengthening security and fundamental freedoms on the Internet ([7]),

— having regard to the European Convention for the Protection of Human rights and Fundamental Freedoms,

([1]) OJ L 178, 17.7.2000, p. 1.
([2]) OJ L 167, 22.6.2001, p. 10.
([3]) OJ L 196, 2.8.2003, p. 7.
([4]) OJ L 195, 2.6.2004, p. 16.
([5]) OJ L 111, 5.5.2009, p 16.
([6]) OJ C 74 E, 20.3.2008, p. 526.
([7]) OJ C 117 E, 6.5.2010, p. 206.

— having regard to the legally binding character of the Charter of Fundamental Rights,

— having regard to its resolution of 10 April 2008 on cultural industries in Europe [1],

— having regard to the communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions of 25 June 2008 on the Small Business Act for Europe establishing the 'Think Small First' principle for an ambitious policy agenda for SMEs,

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on Legal Affairs and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0175/2010),

A. whereas infringements of intellectual property rights (IPR) constitute a genuine threat not only to consumer health and safety but also to our economies and societies,

B. whereas scientific and technical innovation, patents and the cultural industries make a decisive contribution to the competitiveness of the European economy, both through the number and diversity of the job openings they provide and through the wealth created; whereas the cultural economy, from creation through to distribution, must be supported,

C. whereas the European Union, as a member of the World Trade Organisation, is bound by the Agreement on Trade Related Intellectual Property Rights (TRIPS); whereas EU Member States are thereby committed to the adoption and implementation of effective measures against all infringements of IPRs,

D. whereas knowledge sharing and dissemination of innovation are strong traditions in the European Union; whereas access by the greatest possible number to technological progress and cultural products continues to be the foundation of education and development policy,

E. whereas in order properly to address the question of IPR enforcement in the internal market, it is important to take into consideration not only EU territory but also the situation at the EU's external borders and in third countries, in order to ensure compatibility between the protection of content of Community origin and the holders of rights thereto and consumer access to non-Community content,

F. whereas data concerning the scale of IPR infringements are inconsistent, incomplete, insufficient and dispersed, and whereas an objective, independent impact assessment is needed for any additional legislative proposal,

G. whereas innovation and creativity have considerable added value for the European economy and, taking account of the economic context, they should be preserved and developed,

H. whereas the violation of IPRs is a problem across the board which affects all sectors of industry, particularly the creative and innovative industries and sport,

I. whereas ongoing infringements of IPRs will lead to a fade-out of innovation in the EU,

[1] OJ C 247 E, 15.10.2009, p. 25.

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J. whereas the phenomenon of on-line IPR infringements has assumed worrying proportions, particularly for the creative content industries, and whereas it has not been established yet whether the existing legal framework is capable of effectively protecting rights holders on the Internet while guaranteeing a balance between all the interests at stake, including those of consumers,

K. whereas efforts to tackle infringement of copyright must enjoy public support in order not to risk eroding support for intellectual property rights amongst the citizens,

L. whereas the unauthorised uploading of copyrighted material to the Internet is a clear infringement of intellectual property rights and is prohibited by the World Intellectual Property Organisation (WIPO) treaties on copyright (WCT) and performances and phonograms (WPPT), to which the European Union is a contracting party,

M. whereas the creative sector should continue to develop models enabling access to creative content online which offer improved and cost-effective choices to consumers, including access to unlimited subscription services; whereas the development of these legal services is inhibited by the growth of unlawfully uploaded content online,

N. whereas, in order to maintain and increase the attractiveness of what they can offer their public, producers of audiovisual media must be in a position to use all the new means of distribution; whereas the current system of granting licences must be improved in such a way that the Member States have a flexible system available to them which can be adapted to the new technologies,

O. whereas, with the exception of legislation on penalties under the criminal law, a Community legal framework already exists with regard to the phenomenon of counterfeiting and piracy of physical goods, but whereas lacunae persist with regard to online IPR infringements,

P. whereas the measures provided for by Directive 2004/48/EC on the enforcement of intellectual property rights on the internal market have not yet been assessed, from the point of view of the protection of rights or from the point of view of its effects on consumers' rights,

Q. whereas the telecoms regulatory framework has recently been amended, includes provisions for standardised public interest notices which can address, among other things, copyright and infringement thereof without jeopardising data protection and privacy rights and stresses the need to respect fundamental rights in matters relating to Internet access,

R. whereas the possibility should be created in the European legal framework of proceeding against infringers of copyright, since international treaties are barely able to address IPR infringements,

S. whereas, in the case of patents, their protection is crucial in order to efficiently fight patent violations; whereas the question of the unified patent system at EU level has yet to be resolved,

T. whereas there are proven connections between various forms of organised crime and IPR infringements,

U. whereas the co-decision role of the European Parliament in commercial matters and its access to negotiation documents is guaranteed by the Lisbon Treaty,

V. whereas it is desirable that, alongside measures to prevent offences in this area, protection should be provided for consumers who legally make use of products that are covered by protection of intellectual property,

W. whereas current Community law constitutes no impediment to the development of multi-territory licensing systems,

X. whereas in various areas, including the text- and image-based sector, there are business models and channels and licensing schemes that provide broad access to works in a wide range of forms and formats, both within and across national borders,

1. Welcomes the communication of 11 September 2009 from the Commission concerning additional non-legislative measures; regrets however that the communication does not deal with the matter of completing the legislative framework by introducing a set of measures to combat intellectual property right infringements in an effective manner; welcomes the progress made in the EU in harmonising the fight against counterfeiting; encourages the Commission to step up its efforts in areas that are sensitive in terms of health and safety, including that of medicines;

2. Recalls that an exception to IPRs exists in the cultural area: the 'private copy';

3. Calls on the Commission to urgently present, by the end of 2010, a comprehensive IPR strategy addressing all aspects of IPRs, including their enforcement as well as their promotion, in particular the role of copyright as an enabler and not an obstacle, helping creators earn a living and disseminating their works;

4. Calls on the Commission to propose a comprehensive strategy on IPRs which will remove obstacles to creating a single market in the online environment and adapt the European legislative framework in the field of IPRs to current trends in society as well as to technical developments;

5. Stresses that any measures taken to enforce IPRs must respect the Charter of Fundamental Rights of the European Union, in particular Article 7 and Article 8, and the European Convention for the Protection of Human Rights and Fundamental Freedoms, in particular Article 6, Article 8, and Article 10, and be necessary, proportionate, and appropriate within a democratic society; recalls in this connection that Article 17 of the Charter of Fundamental Rights of the European Union provides for the protection of intellectual property;

6. Considers that the Commission should take IPR aspects into account in all relevant policies or legislative initiatives and consider these aspects in all processes relating to impact assessments where a proposal would have an impact on intellectual property;

7. Takes the view that the Commission should take into account the specific problems encountered by SMEs when it comes to reinforcing the intellectual property rights corresponding to the principle of 'Think Small First' established by the Small Business Act for Europe, inter alia by applying the principle of non-discrimination for SMEs;

8. In the light of the experiences undergone by rights-holders in some Member States, does not share the Commission's certitude that the current civil enforcement framework in the EU is effective and harmonised to the extent necessary for the proper functioning of the internal market and reminds the Commission that the report on the application of Directive 2004/48/EC is essential to confirm those claims;

9. Is of the opinion that the possibility of proceeding against infringers of intellectual property rights should be created in the European legal framework and reminds the Commission that the report on the application of Directive 2004/48/EC is essential to confirm those claims;

10. Calls on the Commission to draw up a report on the application of Directive 2004/48/EC, including an assessment of the effectiveness of the measures taken, as well as an evaluation of its impact on innovation and the development of the information society, in accordance with Article 18(1) of that Directive and, if necessary, to propose amendments; calls for that report also to include an assessment of the ways to strengthen and upgrade the legal framework with respect to the Internet;

11. Take account of the existence of particular formats making works accessible for those with disabilities and adopt the necessary measures to promote the distribution thereof;

12. Does not share the Commission's view that the principal body of laws with respect to IPR enforcement is already in place; points out in this respect that negotiations on the directive on criminal sanctions have not been successfully concluded;

13. Calls on the Commission to ensure that the measures aimed at strengthening the application of intellectual property rights in the internal market do not impinge on the legitimate right to interoperability, this being essential to healthy competition on the digital works distribution market, inter alia for the authors and users of free software;

14. Calls on the Commission to put forward appropriate legislative proposals based on Article 118 of the TFEU which will address the issue of an effective EU patent system and welcomes in this respect the Council conclusions of 4 December 2009 on an enhanced patent system in Europe as a significant positive development;

European Observatory on Counterfeiting and Piracy ('the Observatory')

15. Recognises the importance of comprehensive and reliable information and data on all types of IPR infringements for the development of evidence-based and result-oriented policy making;

16. Welcomes the establishment of the Observatory as a tool for the centralisation of statistics and data which will serve as a basis for proposals to be implemented to combat effectively the phenomena of counterfeiting and online IPR infringements; urges the Commission to produce a report on how best to use Europol and existing structures for cooperation between customs authorities in this field to combat criminal IPR infringements effectively;

17. Wishes the Observatory to become a tool for collecting and exchanging data and information on all forms of all IPR infringements, including compiling scientific research on counterfeiting and IPR regulation;

18. Calls on the Commission to clarify the tasks which are to be entrusted to the Observatory and stresses that the success of the Observatory largely depends on the involvement and cooperation of all stakeholders, including the national authorities, rights holders, consumers' organisations and the industries concerned, in order to increase transparency and avoid duplication of effort;

19. Calls on the Commission to inform Parliament and the Council fully and comprehensively about the results of the Observatory's activities through annual reports in which the Commission draws conclusions and proposes solutions necessary to improve IPR law;

Cultivating consumer awareness

20. Calls on the Commission and the Member States in association with the stake holders to organise a campaign to raise awareness at European, national and local level of the risks to consumer health and safety arising from counterfeit products and also the adverse impact of counterfeiting and on-line IPR infringement on the economy and society; emphasises the need to increase awareness, especially among young European consumers, of the need to respect IPR;

21. Calls on all parties concerned, including Internet service providers, online sales platforms, rights holders and consumers' organisations, with regard to IPR infringements and the sale of counterfeit products online, to adopt practical measures to alert and educate people on the value of copyright and the impact of IPR infringements and counterfeiting on jobs and growth, such as brief, visible and relevant educational and warning messages;

22. Stresses the need to educate young people to enable them to understand what is at stake in intellectual property and to identify clearly what is legal and what is not, by means of targeted public awareness campaigns, particularly against online IPR infringement;

23. Calls on the Commission therefore to put pressure on the industry to devise even more payment facilities, in order to make it easier for European consumers to buy legally-offered content, so as to increase legal downloading in the EU;

Tackling on-line infringement and protecting IPRs on the Internet

24. Agrees with the Commission that additional non-legislative measures such as discussions on possible improvements to the digital market in Europe through voluntary harmonisation of procedures and standards amongst stakeholders can be useful to improve the application of IPRs, particularly measures arising from in-depth dialogue among stakeholders;

25. Stresses that the enormous growth of unauthorised file sharing of copyrighted works and recorded performances is an increasing problem for the European economy in terms of job opportunities and revenues for the industry as well as for government;

26. Stresses that a number of factors have allowed this phenomenon to develop, particularly technological advances and the lack of legal offers; recalls however that this phenomenon constitutes a violation of IPRs to which appropriate, urgent solutions need to be found, geared to the sector concerned and in compliance with fundamental rights;

27. Stresses that support for and development of the provision of a diversified, attractive, high-profile, legal range of goods and services for consumers may help to tackle the phenomenon of online infringement, and recognises in this respect that the lack of a functioning internal European digital market constitutes an important obstacle to the development of legal online offers and that the EU runs the risk of condemning to failure efforts to develop the legitimate online market if it does not recognise that fact and make urgent proposals to address it;

28. Asks, therefore, the Commission to pressure the industry to come up with new payment facilities, in order to make it easier for European consumers to buy legally-offered content, thereby ensuring that legal downloading will increase in the EU;

29. Calls for specific legislation ensuring that private consumers who have legitimately received, for their own private use, reproductions of original products which are covered by protection under intellectual property rights are not required to demonstrate the legitimacy of those reproductions, but that it should be up to interested parties to prove any violation of rules under the protection of intellectual property rights;

30. Stresses that all parties concerned, including Internet service providers, must join in the dialogue with stakeholders in order to find appropriate solutions; calls on the Commission, failing this, to submit a legislative proposal or to amend existing legislation, particularly Directive 2004/48/EC, so as to upgrade the Community legal framework in this field on the basis of national experiences;

31. Calls on the Commission to think broadly about methods of facilitating industry access to the digital market without geographical borders, taking account of the particular features of each sector, by addressing urgently the issue of multi-territory licences, where there is substantial demand from consumers, and the lack of harmonised legislation with regard to copyright as well as an effective and transparent system for rights management, which would complement this existing growth in services which are legal and which meet consumer demand for easier ubiquitous, instant and customised access to content;

32. Stresses that the system for granting licences should be improved on the basis of technical neutrality, in such a way that the Member States have available to them a flexible, effective and transparent system which can be adapted to the new technologies;

33. Calls on the Commission to review the issue of cross-border management of rights and change the current situation of legal uncertainty created by Commission Recommendation 2005/737/EC of 18 October 2005 on collective cross-border management of copyrights, taking into account the fact that copyright is inherently territorial for cultural, traditional and linguistic reasons and ensuring a pan-European licensing system providing consumers with access to the widest possible choice of content and not at the expense of European local repertoire;

34. Draws attention, furthermore, to the growing problem of Internet-based industrial espionage and theft of data constituting industrial property, in particular technical documentation and source code;

35. Proposes that the Observatory should carry out a detailed analysis of the problem of data theft and put forward proposals for combating the problem;

36. Calls on the Commission to identify the particular problems and needs of SMEs, to develop specific measures to assist SMEs in the fight against infringements of intellectual property rights and to enable SMEs to better protect themselves both in the EU and in third countries;

37. Supports steps taken by the Commission with a view to identifying the best ways to further improve the EU Customs Regulation, which allows the detention of goods suspected of infringing IPRs and is, as such, one of the pillars of the Union's legal framework designed to enforce IPRs;

38. Calls on the Commission to pursue innovative and upgraded cooperation between administrative departments and the various sectors of industry concerned;

39. Calls on the Member States and the Commission to extend the cooperation between the Office for Harmonisation in the Internal Market and national intellectual property offices to also cover the fight against infringements of intellectual property rights;

40. Recognises the need for the use of existing institutional structures in the Member States in the fight against counterfeited goods, and therefore calls on the national patent and other intellectual property offices to provide greater support and training to small and medium-sized enterprises and to the public;

The international dimension and impact on the internal market

41. Calls on the Commission to step up its cooperation with priority third countries with regard to intellectual property and promote a balanced approach in the context of the negotiations on intellectual property under the auspices of the World Trade Organisation concerning intellectual property, particularly in the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);

42. Calls on the Commission to ensure that its efforts to further the negotiations on the multilateral Anti-Counterfeiting Trade Agreement (ACTA) with a view to improving the effectiveness of the IPR enforcement system against counterfeiting are continued with full account being taken of the Parliament's position, in particular as expressed in its resolution of 18 December 2008 on the impact of counterfeiting on international trade, and calls on it to fully inform Parliament on the progress and outcome of the negotiations and to ensure that the provisions of ACTA fully comply with the acquis communautaire on IPR and fundamental rights;

43. Supports the continuation and enhancement by the Commission of bilateral cooperation initiatives, including 'IP dialogues' with third countries and technical assistance projects;

44. Notes that the biggest challenge for the internal market lies in combating infringements of intellectual property rights at the EU's external borders and in third countries; in this respect, calls on the Commission to create more intellectual property helpdesks in third countries (notably in India and Russia) in order to help European entrepreneurs with the more active enforcement of their intellectual property rights and in combating infringements of intellectual property rights in third countries and the entry into the Internal Market of counterfeited goods manufactured in such third countries;

Organised crime

45. Stresses the importance of fighting organised crime in the area of IPRs, in particular counterfeiting and online IPR infringement; points out in this context the need for appropriate EU legislation on proportional and fair sanctions and supports close strategic and operational cooperation between all the interested parties within the EU, in particular Europol, national authorities and the private sector, as well as with non-EU states and international organisations;

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46. Instructs its President to forward this resolution to the Council, the Commission, the European Economic and Social Committee and the parliaments and governments of the Member States.

European strategy for the economic and social development of mountain regions, islands and sparsely populated areas

P7_TA(2010)0341

European Parliament resolution of 22 September 2010 on the European strategy for the economic and social development of mountain regions, islands and sparsely populated areas

(2012/C 50 E/07)

The European Parliament,

— having regard to Part III, Title XVIII of the Treaty on the Functioning of the European Union and in particular to Article 174 thereof,

— having regard to the regulations governing the Structural Funds for the period 2007-2013,

— having regard to the Council Decision 2006/702/EC of 6 October 2006 on Community strategic guidelines on cohesion ([1]),

— having regard to its resolution of 2 September 2003 on structurally disadvantaged regions (islands, mountain regions, regions with low population density) in the context of cohesion policy, and their institutional prospects ([2]),

— having regard to the opinion of the Committee of the Regions of 7 July 2005 on the revision of the guidelines for regional State aids ([3]),

— having regard to its resolution of 15 March 2007 on the islands and natural and economic constraints in the context of the regional policy ([4]),

— having regard to the Commission communication of 6 October 2008 entitled 'Green Paper on Territorial Cohesion - Turning territorial diversity into strength' (COM(2008)0616),

— having regard to the Commission staff working document entitled 'Regions 2020 - an assessment of future challenges for EU regions' (SEC(2008)2868),

([1]) OJ L 291, 21.10.2006, p. 11.
([2]) OJ C 76 E, 25.3.2004, p. 111.
([3]) OJ C 31, 7.2.2006, p. 25.
([4]) OJ C 301 E, 13.12.2007, p. 244.

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— having regard to its resolution of 24 March 2009 on the Green Paper on Territorial Cohesion and the state of the debate on the future reform of cohesion policy ([1]),

— having regard to the Commission communication of 25 June 2009 on the Sixth Progress Report on Economic and Social Cohesion (COM(2009)0295),

— having regard to the Commission communication of 31 March 2010 entitled 'Cohesion policy: Strategic Report 2010 on the implementation of the programmes 2007-2013' (COM(2010)0110),

— having regard to Rule 110(4) of its Rules of Procedure,

A. whereas the principle of territorial cohesion was consolidated in the regulations on the Structural Funds 2007-2013 and is one of the new key objectives established for the European Union by the Treaty of Lisbon, aimed at securing the harmonious development of the EU by reducing regional disparities and removing obstacles to development, including obstacles linked to natural and geographical handicaps,

B. whereas it is important to clarify the impact of the Lisbon Treaty on the status of regions deserving particular measures in the framework of regional policy,

C. whereas, in keeping with Article 174 of the Treaty on the Functioning of the European Union, particular attention shall be paid to regions which suffer from severe and permanent natural or demographic handicaps, such as the northernmost regions with very low population density and island, cross-border and mountain regions,

D. whereas mountain regions, islands and sparsely populated areas are exposed to particular challenges linked to demographic changes, poor accessibility, climate change, migratory phenomena, energy supply and regional integration,

1. Welcomes the inclusion of territorial cohesion as a new objective of the Union, as well as new Article 174; believes that the provisions of Article 174 should be translated into specific development strategies and concrete measures aimed at overcoming the handicaps and exploiting the potentials of these regions;

2. Considers that mountain regions, islands and sparsely populated areas constitute homogeneous groups of regions and that they share some important common features which differentiate them from other regions; believes that they deserve specific regional development programmes; stresses, in this context, the special situation of the island Member States located on the periphery of the Union;

3. Is of the opinion that GDP must remain the main criterion for determining eligibility for regional policy assistance; calls nevertheless on the Commission and the Member States to work towards more pertinent and territorialised statistical indicators, in order to provide a more comprehensive picture of the development level of these disadvantaged regions; stresses that indicators other than GDP (total population, unemployment/employment rates, education levels, population density) can already be used by the Member States in redistributing funds among regions, within their allocated envelopes, taking into account the specific attributes of each region;

4. Calls for the establishment of a specific European integrated and flexible policy framework for dealing with mountain regions, islands and sparsely populated areas on the basis of their shared features, while also taking proper account of different situations and showing due regard for the principle of proportionality; is of the opinion that cohesion policy should address the situation of the islands not just through regional policy measures, but also using other EU policies that have a significant territorial impact on the development of these regions; believes that a European policy framework for mountain regions, islands and sparsely populated areas may have the added value required in order to overcome the permanent handicaps of these regions and adapt their development model in such a way as to make good use of their assets;

([1]) OJ C 117 E, 6.5.2010, p. 65.

5. Calls on Member States and regional and local authorities to play a major role in the development strategies of mountain regions, islands and sparsely populated areas, because a vertical approach involving all levels of government, in accordance with the principle of subsidiarity, is required in order to place these regions on the right path towards sustainable development, taking into consideration other important sectors in each region; stresses that the potential within these regions, many of which have very substantial natural resources, can make a positive contribution towards achieving the goals, especially in the fields of energy policy and R&D, set out in the EU2020 strategy;

6. Stresses that the objective of economic and social development in these handicapped regions can be achieved only through carefully devised EU programmes and actions specifically adapted to each region and aimed at achieving a structural adjustment of these regions and making them more competitive and capable of coping with the main challenges facing them, and also through efficient coordination and implementation of the four Structural Funds, the Cohesion Fund and other financial instruments, such as those provided by the European Investment Bank;

7. Calls on the Commission and the Member States to ensure that mountain regions, islands and sparsely populated areas will continue to benefit from specific provisions under the new multiannual financial framework and during the next programming period;

8. Welcomes European Groupings of Territorial Cooperation (EGTCs) as an instrument aimed at overcoming the obstacles to territorial cooperation; encourages mountain regions, islands and sparsely populated areas to make use of EGTCs for the management of territorial cooperation projects with other regions that are cofinanced by the EU, as a way of bringing them closer to their surrounding economic areas;

9. Encourages the Member States to make full use of the European Neighbourhood Policy instruments in mountain areas, sparsely populated areas and islands, so as to enable them to benefit from the resources available across borders;

10. Calls for the dropping of the distance-related criterion (150 km) used for the purpose of classifying islands as border regions eligible for financing under cross-border cooperation programmes coming under the cohesion policy Territorial Cooperation Objective or the European Neighbourhood Policy; believes that, if it is necessary to establish some kind of limit, it would be more appropriate, in the case of island regions, for the cross-border territory condition to be applied at maritime basin level;

11. Instructs its President to forward this resolution to the Commission, the Council, the national, regional and local governments of the Member States and the economic and social partners.

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III

(Preparatory acts)

EUROPEAN PARLIAMENT

Draft amending budget No 5/2010: OLAF and the review of own resources

P7_TA(2010)0319

European Parliament resolution of 21 September 2010 on Council's position on Draft amending budget No 5/2010 of the European Union for the financial year 2010, Section III – Commission (13473/2010 – C7-0260/2010 – 2010/2091(BUD))

(2012/C 50 E/08)

The European Parliament,

— having regard to the Treaty on the Functioning of the European Union and in particular Article 314 thereof and to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

— having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1], and particularly Articles 37 and 38 thereof,

— having regard to the general budget of the European Union for the financial year 2010, as finally adopted on 17 December 2009 [2],

— having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [3],

— having regard to Draft amending budget No 5/2010 of the European Union for the financial year 2010, which the Commission presented on 15 June 2010 (COM(2010)0320),

— having regard to Council's position on Draft amending budget No 5/2010, which the Council established on 13 September 2010 (13473/2010 – C7-0260/2010),

— having regard to Rule 75b and 75e of its Rules of Procedure,

— having regard to the report of the Committee on Budgets (A7-0249/2010),

A. whereas the Council's position on Draft amending budget No 5/2010 covers modifications to the establishment plan of OLAF, without additional financial provisions, as well as the revision of the forecast of Traditional Own Resources (TOR, i.e. customs duties and sugar sector levies), VAT and GNI bases, the budgeting of the relevant UK corrections as well as their financing and revision of financing of GNI reductions in favour of the Netherlands and Sweden in 2010, resulting in a change in the distribution between Member States of their own-resources contributions to the EU budget,

[1] OJ L 248, 16.9.2002, p. 1.
[2] OJ L 64, 12.3.2010.
[3] OJ C 139, 14.6.2006, p. 1.

B. whereas the purpose of Draft amending budget No 5/2010 is to formally enter this budgetary adjustment into the 2010 budget,

C. whereas the Council adopted its position on 13 September 2010,

1. Takes note of Draft amending budget No 5/2010;

2. Approves Council's position on Draft amending budget No 5/2010 unamended and instructs its President to declare that Amending budget No 4/2010 has been definitively adopted and to arrange for its publication in the *Official Journal of the European Union*;

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

Investigation and prevention of accidents and incidents in civil aviation ***I

P7_TA(2010)0321

European Parliament legislative resolution of 21 September 2010 on the proposal for a regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation (COM(2009)0611 – C7-0259/2009 – 2009/0170(COD))

(2012/C 50 E/09)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and Council (COM(2009)0611),

— having regard to Article 251(2) and Article 80(2) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0259/2009),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 100(2) of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Economic and Social Committee of 27 May 2010 [1],

— after consulting the Committee of the Regions,

— having regard to the opinion of the European Data Protection Supervisor of 4 February 2010 [2],

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[1] Not yet published in the Official Journal.
[2] OJ C 132, 21.5.2010, p. 1.

— having regard to the undertaking given by the Council representative by letter of 30 June 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Transport and Tourism (A7-0195/2010),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the parliaments of the Member States.

P7_TC1-COD(2009)0170

Position of the European Parliament adopted at first reading on 21 September 2010 with a view to the adoption of a Regulation (EU) No …/2010 of the European Parliament and of the Council on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 996/2010)

Security of gas supply ***I

P7_TA(2010)0322

European Parliament legislative resolution of 21 September 2010 on the proposal for a regulation of the European Parliament and of the Council concerning measures to safeguard security of gas supply and repealing Directive 2004/67/EC (COM(2009)0363 – C7-0097/2009 – 2009/0108(COD))

(2012/C 50 E/10)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2009)0363),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0097/2009),

— having regard to the Communication from the Commission to the European Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 194(2) of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the Economic and Social Committee of 20 January 2010 ([1]),

— after consulting the Committee of the Regions,

— having regard to the undertaking given by the Council representative by letter of 25 June 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Industry, Research and Energy and the opinions of the Committee on Foreign Affairs, of the Committee on Economic and Monetary Affairs, the Committee on the Environment, Public Health and Food Safety and of the Committee on the Internal Market and Consumer Protection (A7-0112/2010),

1. Adopts its position at first reading hereinafter set out;

2. Takes note of the Commission statements annexed to this resolution;

3. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

([1]) Not yet published in the Official Journal.

P7_TC1-COD(2009)0108

Position of the European Parliament adopted at first reading on 21 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council concerning measures to safeguard security of gas supply and repealing Council Directive 2004/67/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 994/2010)

ANNEX

Commission Statement on long term security of supply measures including diversification of gas supply sources and routes, regional cooperation and international cooperation in energy efficiency

The Commission underlines that the diversification of gas supply sources and routes for the Union is essential to improve the security of gas supply of the individual Member States and the Union as a whole.

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Recognizing the need to develop a long term security of supply strategy, the Commission will adopt by end of 2010 a comprehensive Energy Infrastructure Package assessing the priorities for the development of gas infrastructures in the coming decades and the progress achieved on the priorities identified in the Second Strategic Energy Review. The Energy Infrastructure Package will identify the instruments and measures to provide incentives for investments in gas infrastructures, in particular including the diversification of supply routes, integration of 'gas islands', facilities for liquefied natural gas (LNG), as well as storage capacities.

The Commission also supports the close cooperation of all stakeholders at all levels – the Member States, the independent Regulators, the gas industry and the consumers – within the regional initiatives. In 2010 the Commission will issue a Communication on the regional initiatives to provide guidance how to best achieve the progress and further develop existing regional cooperation initiatives. Close regional cooperation is crucial to achieve fully functioning internal energy market. The Communication on regional initiatives will make proposals as to common goals and best practices.

Finally, the Commission recognises that energy efficiency plays an important role in ensuring long term energy security. The Commission will continue to develop a close cooperation with third countries to promote energy efficiency through the exchange of information on the energy savings strategies, research on energy efficient technologies and sharing the best practices, through the International Partnership for Energy Efficiency Cooperation and through bilateral arrangements.

Commission Statement on competition with respect to recital 45

The Commission considers that the reference in recital 45 to distortions of competition covers all forms of restriction of competition, including in particular restrictive clauses of contracts, for example destination clauses.

The Commission also confirms that the application of article 101 of the TFEU to the conditions referred in recital 45 will be carried out where appropriate by the Commission or by one or more of the competent competition authorities of the Member States, in line with the provisions of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [1].

[1] OJ L 1, 4.1.2003, p. 1.

Agreement between the EC and Pakistan on readmission ***

P7_TA(2010)0323

European Parliament legislative resolution of 21 September 2010 on the draft Council decision on the conclusion of the Agreement between the European Union and the Islamic Republic of Pakistan on the readmission of persons residing without authorisation (05942/2010 – C7-0264/2009 – 2009/0036(NLE))

(2012/C 50 E/11)

(Consent)

The European Parliament,

— having regard to the draft agreement between the European Community and the Islamic Republic of Pakistan on the readmission of persons residing without authorisation (08793/2009),

— having regard to the proposal for a Council decision (COM(2009)0106),

— having regard to Article 63, first paragraph, point 3, point (b) and Article 300(2), first subparagraph, first sentence and Article 300(3), first subparagraph, of the EC Treaty, pursuant to which the Council consulted Parliament (C7-0264/2009),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to the draft Council decision (05942/2010),

— having regard to Article 79(3) and Article 218(6), second subparagraph, point (a), point (v) of the Treaty on the Functioning of the European Union,

— having regard to Rules 81 and 90(8) of its Rules of Procedure,

— having regard to the recommendation of the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on Foreign Affairs (A7-0231/2010),

1. Consents to conclusion of the agreement;

2. Takes note of the Commission declaration annexed to this resolution;

3. Instructs its President to forward its position to the Council, the Commission, and the governments and parliaments of the Member States and of the Islamic Republic of Pakistan.

ANNEX

COMMISSION DECLARATION

The Commission recalls that EU law requires Member States to ensure that third country nationals present on the territory of the Member States may apply for international protection if they so wish and that in particular the Treaty, the Asylum Qualification and the Return Directive make it clear that Member States must respect the principle of *non-refoulement* in accordance with their international obligations.

The Commission also recalls that EU Member States are in particular obliged to ensure, in all cases, that no return is effected in violation of Article 3 of the European Human Rights Convention and Article 19 of the EU Charter of Fundamental Rights, which oblige States to ensure that a person should not be returned if he or she would be likely to suffer serious harm on his or her return to a country of origin or transit.

Pakistan has given refuge to at times more than 3 million refugees from the conflict in Afghanistan, and in so doing has contributed more than many other UN members to the reception of refugees. While the Commission recognizes Pakistan's achievements in this sphere, it is ready to continue to call on Pakistan to ratify the Geneva Convention on Refugees (UN Convention relating to the Status of Refugees of 1951 and its Protocol of 1967).

The Commission is committed to regularly inform the European Parliament about all the concluded EU readmission agreements. In particular, the Commission:

— will report every 6 months to the EP about the implementation of the EU readmission agreements, with particular reference to the ongoing work of the Joint Readmission Committees,

— will establish contacts with relevant international organizations active in Pakistan in order to gather to the extent possible the available information about the situation of persons readmitted to Pakistan (both Pakistani and where applicable third country nationals) under the EU agreement.

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Multiannual financial framework for 2007-2013

P7_TA(2010)0328

European Parliament resolution of 22 September 2010 on the proposal for a Council regulation laying down the multiannual financial framework for the years 2007-2013 (COM(2010)0072 – 2010/0048(APP))

(2012/C 50 E/12)

The European Parliament,

— having regard to the proposal for a Council Regulation laying down the multiannual financial framework for the years 2007-2013 (COM(2010)0072) ('proposal for a MFF Regulation'),

— having regard to the request for consent which the Council is to submit pursuant to Article 312(2) of the Treaty on the Functioning of the European Union (TFEU),

— having regard to Articles 311 and 312 TFEU,

— having regard to the Interinstitutional Agreement of 17 May 2006 on budgetary discipline and sound financial management [1] ('current IIA'),

— having regard to the joint declaration of the European Parliament, the Council and the Commission of 12 November 2009 on transitional measures applicable to the budgetary procedure after the entry into force of the Lisbon Treaty, reproduced in annex V of its resolution of 17 December 2009 on the draft general budget of the European Union for the financial year 2010 [2],

— having regard to its resolution of 12 November 2009 on transitional procedural guidelines on budgetary matters in view of the entry into force of the Lisbon Treaty [3],

— having regard to the Commission's proposal of 3 March 2010 for a Regulation of the European Parliament and of the Council amending Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities (COM(2010)0071),

— having regard to the Commission's proposal of 3 March 2010 for an Interinstitutional Agreement between the European Parliament, the Council and the Commission on cooperation in budgetary matters (COM(2010)0073),

— having regard to the Council conclusions of 16 March 2010 on the 2011 EU budget,

— having regard to the Commission report of 27 April 2010 to the European Parliament and the Council on the functioning of the Interinstitutional Agreement on budgetary discipline and sound financial management (COM(2010)0185),

[1] OJ C 139, 14.6.2006, p. 1.
[2] Texts adopted, P7_TA(2009)0115.
[3] Texts adopted, P7_TA(2009)0067.

— having regard to Council Regulation (EU) No 407/2010 of 11 May 2010 establishing a European financial stabilisation mechanism ([1]),

— having regard to the questions of 20 May 2010 on the review of the Multiannual Financial Framework 2007-2013 to the Council (O-0074/2010 - B7-0310/2010) and to the Commission (B7-0311/2010 - O-0075/2010),

— having regard to Rule 81(3) of its Rules of Procedure,

— having regard to the interim report of the Committee on Budgets (A7-0248/2010),

A. whereas Article 312 TFEU states that Council shall adopt a regulation laying down the multiannual financial framework (MFF),

B. whereas the Joint Declaration of 12 November 2009 on the transitional rules applicable to the budgetary procedure after the entry into force of the Lisbon Treaty agreed by the European Parliament, the Council and the Commission sets out the measures needed to ensure continuity of EU action and a smooth transition to the new legal framework for the budgetary procedure deriving from the entry into force of the Lisbon Treaty,

C. whereas the abovementioned proposal for a MFF Regulation, which cannot be adopted by Council without the consent of the European Parliament, aims to align the provisions of the current IIA with the requirements of the Lisbon Treaty,

D. whereas Article 312(5) TFEU calls on the European Parliament, the Council and the Commission to take any measure necessary to facilitate the adoption of the financial framework,

E. whereas the Lisbon Treaty gives to the European Union significant new prerogatives, for example in the fields of external action (Article 27(3) of the Treaty on European Union), sport (Article 165 TFEU), space (Article 189 TFEU), climate change (Article 191 TFEU), energy (Article 194 TFEU), tourism (Article 195 TFEU) and civil protection (Article 196 TFEU),

F. whereas Article 311 TFEU requires the Union to provide itself with the means necessary to attain its objectives and carry out its policies,

G. whereas Point 4 of the current IIA provides for an adjustment of the MFF - IIA in case of the entry into force of a new Treaty with budgetary implications,

H. whereas even without the new prerogatives given to the European Union by the Treaty of Lisbon, the ceilings of the current MFF were reached or exceeded between 2007 and 2009 confirming the need for more flexibility if the European Union is to react effectively to urgent and unforeseen events,

I. whereas, according to the European Commission's latest financial programming for 2012-2013 (SEC(2010)0473) - which does not take account of the various elements of unprogrammed expenditure that remain to be financed within the headings - the margin available under heading 1a will be less than EUR 50 million per year and the global margin available under all headings will be limited to EUR 436 million for 2012 and EUR 435 million for 2013,

J. whereas the European Financial Stabilisation Mechanism has potentially significant budgetary implications,

([1]) OJ L 118, 12.5.2010, p. 1.

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1. Requests the Council and the Commission to take into account the following recommendations:

   i. work with European Parliament to allow swift adoption of the new instruments needed to implement the budgetary provisions of the Lisbon Treaty and revise the current MFF in order to provide for the extra resources necessary to deliver initiatives not foreseen when the current MFF was adopted;

   ii. fully comply with Article 312(3) TFEU which requires the financial framework to lay down any provisions required for the annual budgetary procedure to run smoothly and with Article 312(5) which states that 'throughout the procedure leading to the adoption of the financial framework, the European Parliament, the Council and the Commission shall take any measure necessary to facilitate its adoption';

   iii. fully comply with Article 311 TFEU which requires the Union to provide itself with the means necessary to attain its objectives and carry out its policies, taking into account the new areas of action given by the Lisbon Treaty, including in the fields of external action, sport, space, climate change, energy, tourism and civil protection;

   iv. draw all necessary conclusions from the fact that even before the addition of these new Lisbon-related needs, over the last four years of the current MFF, the annual budgets could only be agreed either through using up the existing margins or through recourse to the instruments foreseen by the current IIA to finance EU priorities such as Galileo, the food facility or the European Recovery Plan, and that remaining margins under the ceilings of the current financial framework are estimated to be negligible for the remainder of the period;

   v. abide by point 4 of the current IIA which states that 'should a Treaty revision with budgetary implications occur during the multiannual financial framework 2007 to 2013 (hereinafter referred to as "the financial framework"), the necessary adjustments will be made accordingly';

   vi. acknowledge that the current economic climate might lead the budgetary authority to make some efforts towards reprioritisation within the budget in order to ensure the adequate funding of priorities while bearing in mind, however, the European added value of the EU budget, since it is an expression of solidarity and efficiency by pooling together financial resources otherwise dispersed at national, regional and local level; emphasise as well that an overwhelming part of the EU budget expenditures support long-term investments necessary to stimulate EU economic growth;

   vii. recognise that new needs cannot be met through redeployment or reprioritisation and that a revision of the MFF and the flexibility mechanisms included in the IIA is necessary, contrary to the Council's position as set out in its conclusions of 16 March 2010 on the budget guidelines for 2011 and reaffirmed by the Presidency-in-office in its statements during the 15 June 2010 debate on oral question B7-0310/2010 O-0074/2010; recall furthermore that new needs stemming from the entry into force of the Treaty of Lisbon should logically entail savings at national and regional level;

   viii. respond to declaration 3 of the current IIA calling for a full, wide-ranging review by 2008/2009 covering all aspects of EU spending and resources, and stop attempting to deal with the challenges/competences given to the EU by the new Treaty through a very narrow review of the functioning of the current IIA lacking any political dimension;

   ix. recognise that the position of the Council and the Commission on the revision of the MFF until now is contradictory with the fact that they are constantly coming up with new proposals calling for new resources such as the 'Bananas Agreement' and ITER;

x. express its concern considering the trend developed by Member States towards launching European policies financed outside of the EU budget; measure the risk of a lack of democratic control and legitimacy over those policies as well as a breach of the principle of universality of the EU budget and the negative impact this trend might imply with regard to the principle of solidarity;

xi. take all necessary steps for a revision of the MFF providing the extra resources necessary to deliver the European External Action Service and other Lisbon-Treaty-related policy priorities, as well as other initiatives, particularly under Heading 1a 'Competitiveness Growth and Employment' and Heading 4 'External Relations', providing EU added value allowing the EU to meet its commitments and its citizens' expectations;

xii. take note of the fact that without this revision the Parliament will not be able to adopt any proposals for new agencies or any further Council initiatives unless accompanied by proposals for fresh resources;

xiii. pursue efforts to provide more flexibility as indicated in the abovementioned Commission's report on the functioning of the Interinstitutional Agreement on budgetary discipline and sound financial management;

xiv. recognise the importance of flexibility to create reserves and margins allowing the EU to respond to current and future needs, both within the financial framework, within and between headings and in negotiations over its establishment and revision;

xv. take note of the fact that Parliament insists on a stronger and increased degree of flexibility and the creation of sufficient reserves for each category, as well as higher amounts available through the Flexibility Instrument and on a simplification of the procedure for shifting resources between the different headings of the MFF;

xvi. take note that Parliament is not prepared to enter into negotiations over any proposal that does not include at least the current degree of flexibility over revisions to the financial framework of up to 0,03 % of EU GNI (referred to in Article 8(3) of the proposal for a MFF Regulation);

xvii. understand that a purely technical approach to the implementation of the Lisbon Treaty in the budgetary field is insufficient and that, for the Parliament to be able to give its consent, entering without delay a real, political negotiation at an appropriately high, and if necessary at the highest, level, is a must;

xviii. given its possible far-reaching budgetary consequences, give further thought to the European Financial Stabilisation Mechanism ahead of the adoption of the MFF regulation; accept that both arms of the budgetary authority be involved in decisions concerning the impact this mechanism could have on the EU budget; agree that any possible budgetary needs linked to this mechanism should be financed through an ad-hoc revision of the MFF to ensure that sufficient involvement of the budgetary authority is guaranteed on time;

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

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Draft amending budget No 7/2010: guarantee provided by the European Union in accordance with the provisions of Article 122 of the TFEU – financial assistance to Member States

P7_TA(2010)0329

European Parliament resolution of 22 September 2010 on Council's position on Draft amending budget No 7/2010 of the European Union for the financial year 2010, Section III- Commission (13476/2010 – C7-0261/2010 – 2010/2120(BUD))

(2012/C 50 E/13)

The European Parliament,

— having regard to the Treaty on the Functioning of the European Union and in particular Article 314 thereof and to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

— having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1], and particularly Articles 37 and 38 thereof,

— having regard to the general budget of the European Union for the financial year 2010, as finally adopted on 17 December 2009 [2],

— having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [3],

— having regard to Draft amending budget No 7/2010 of the European Union for the financial year 2010, which the Commission presented on 12 July 2010 (COM(2010)0383),

— having regard to Council's position on Draft amending budget No 7/2010, which the Council established on 13 September 2010 (13476/2010 – C7-0261/2010),

— having regard to Rule 75b and 75e of its Rules of Procedure,

— having regard to the report of the Committee on Budgets (A7-0250/2010),

A. whereas the Council's position on Draft amending budget No 7/2010 covers the necessary modifications concerning the creation of a new budget item 01 04 01 03 for the guarantee provided by the European Union in accordance with the provisions of Article 122(2) of the Treaty on the Functioning of the European Union and, correspondingly, a new Article 8 0 2 on the revenue side,

B. whereas the purpose of Draft amending budget No 7/2010 is to formally enter this budgetary adjustment into the 2010 budget,

C. whereas the Council adopted its position on 13 September 2010,

1. Takes note of Draft amending budget No 7/2010;

[1] OJ L 248, 16.9.2002, p. 1.
[2] OJ L 64, 12.3.2010.
[3] OJ C 139, 14.6.2006, p. 1.

2. Approves Council's position on Draft amending budget No 7/2010 unamended and instructs its President to declare that Amending budget No 5/2010 has been definitively adopted and to arrange for its publication in the *Official Journal of the European Union*;

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

Refund of value added tax *

P7_TA(2010)0330

European Parliament legislative resolution of 22 September 2010 on the proposal for a Council directive amending Directive 2008/9/EC laying down detailed rules for the refund of value added tax, provided for in Directive 2006/112/EC, to taxable persons not established in the Member State of refund but established in another Member State (COM(2010)0381 – C7-0201/2010 – 2010/0205(CNS))

(2012/C 50 E/14)

(Special legislative procedure – consultation)

The European Parliament,

— having regard to the Commission proposal to the Council (COM(2010)0381),

— having regard to Article 113 of the Treaty on the Functioning of the European Union pursuant to which the Council consulted Parliament (C7-0201/2010),

— having regard to the opinion of the European Economic and Social Committee of 15 September 2010 [1],

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs (A7-0247/2010),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 293(2) of the Treaty on the Functioning of the European Union;

3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;

4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;

5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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[1] Not yet published in the Official Journal.

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TEXT PROPOSED BY THE COMMISSION	AMENDMENT

Amendment 1

Proposal for a directive – amending act
Recital 6

(6) ***The measures necessary*** for the implementation of the detailed rules, including common forms where necessary, on the electronic submissions and notifications referred to in Directive 2008/9/EC ***should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission***.	(6) ***Uniform conditions should be ensured*** for the implementation of the detailed rules, including common forms where necessary, on the electronic submissions and notifications referred to in Directive 2008/9/EC. ***Article 291 of the Treaty on the Functioning of the European Union provides that rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of its implementing powers be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of such a regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]) continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable within the framework of this Directive.***

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([1]) OJ L 184, 17.7.1999, p. 23.

Pharmacovigilance of medicinal products (amendment of Regulation (EC) No 726/2004) ***I

P7_TA(2010)0331

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2008)0664 – C6-0515/2008 – 2008/0257(COD))

(2012/C 50 E/15)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0664),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0515/2008),

— having regard to the Communication from the Commission to the European Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Economic and Social Committee of 10 June 2009 ([1]),

— having regard to the opinion of the Committee of the Regions of 7 October 2009 ([2]),

— having regard to the undertaking given by the Council representative by letter of 23 June 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0153/2010),

1. Adopts its position at first reading hereinafter set out;

2. Takes note of the Commission statement annexed to this resolution;

3. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

([1]) OJ C 306, 16.12.2009, p. 22.
([2]) OJ C 79, 27.3.2010, p. 50.

P7_TC1-COD(2008)0257

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1235/2010.)

ANNEX

Statement by the Commission

Following the request made by the European Parliament and the Council on the grading of the head of the European Medicines Agency, the Commission in order not to delay the adoption of this important proposal undertakes to re-publish the vacancy notice for the next head of the European Medicines Agency with the grade AD15 instead of AD14.

The Commission considers that the right place to deal with the issue is the ongoing horizontal discussion on the role of EU agencies within the Inter-institutional working group on agencies. The discussion on this aspect is open in the inter-institutional working group, and if this discussion leads to different conclusions on the appropriate publication level, then this grading could be reconsidered for future publications.

Pharmacovigilance (amendment of Directive 2001/83/EC) ***I

P7_TA(2010)0332

European Parliament legislative resolution of 22 September 2010 on the proposal for a directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2008)0665 – C6-0514/2008 – 2008/0260(COD))

(2012/C 50 E/16)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0665),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0514/2008),

— having regard to the Communication from the Commission to the European Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Economic and Social Committee of 10 June 2009 [1],

— having regard to the opinion of the Committee of the Regions of 7 October 2009 [2],

— having regard to the undertaking given by the Council representative by letter of 23 June 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0159/2010),

1. Adopts its position at first reading hereinafter set out;

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[1] OJ C 306, 16.12.2009, p. 28.
[2] OJ C 79, 27.3.2010, p. 50.

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2008)0260

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Directive 2010/…/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2010/84/EU.)

Placing on the market and use of biocidal products ***I

P7_TA(2010)0333

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products (COM(2009)0267 – C7-0036/2009 – 2009/0076(COD))

(2012/C 50 E/17)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2009)0267),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0036/2009),

— having regard to the communication from the Commission to the European Parliament and the Council entitled: 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

— having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the EU,

— having regard to the opinion of the European Economic and Social Committee of 17 February 2010 [1],

— having regard to Rules 55 and 37 of its Rules of Procedure,

[1] Not yet published in the Official Journal.

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Industry, Research and Energy (A7-0239/2010),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2009)0076

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council concerning the placing on the market and use of biocidal products and repealing Directive 98/8/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

(2) Biocidal products should not be placed on the market or used unless they comply with the authorisation granted in accordance with this Regulation.

(3) The purpose of this Regulation is to increase the free movement of biocidal products within the Union ***and to ensure a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The provisions of this Regulation should be underpinned by the precautionary principle in order to ensure that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*** In order to remove as far as possible obstacles to trade in biocidal products ▌, rules should be laid down for the approval of active substances and the placing on the market and use of biocidal products, including the rules on the mutual recognition of authorisations and on parallel trade.

[1] Opinion of 17 February 2010 (not yet published in the Official Journal).
[2] Position of the European Parliament of 22 September 2010.

(4) Rules concerning the placing on the market of biocidal products in the Community were initially adopted in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1]. It is necessary to adapt that system on the basis of the report from the Commission to the Council and the European Parliament entitled 'Evaluation of the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (submitted in accordance with Article 18(5) of the Directive) and progress Report on the work programme referred to in Article 16(2) of the same Directive' on the first seven years of its implementation, which analyses the problems and weaknesses of that Directive.

(5) Taking into account the main adaptations which are introduced in the existing regulatory system, a Regulation is the appropriate legal instrument to replace Directive 98/8/EC as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.

(6) A difference should be made between existing active substances which were on the market in biocidal products on 14 May 2000 and new active substances which were not yet on the market in biocidal products by that date. That date was initially set in Directive 98/8/EC as the date by which that Directive had to be transposed into national legislation. A distinction was drawn between substances which were on the market on that date and those which were not. A work programme is being carried out for the review of all existing substances with view to their inclusion in Annex I to Directive 98/8/EC. During that review, biocidal products containing existing substances can continue to be placed on the market in order to prevent a situation where no biocidal products would be available on the market. New active substances should be reviewed before biocidal products containing them can be placed on the market so as to ensure that only safe new products can be placed on the market.

(7) During the work programme, and at most up until the decision on inclusion of the active substance in Annex I to Directive 98/8/EC, Member States may temporarily authorise biocidal products that do not comply with the provisions of this Regulation under certain conditions. Following the decision on inclusion, Member States should grant, cancel or modify authorisations in accordance with this Regulation.

(8) In order to ensure legal certainty, it is necessary to establish a Union list of active substances permitted for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in the Union list. The information that interested parties should submit in support of an inclusion of an active substance in the Union list should be specified.

(9) The risks associated with the production, use and disposal of a chemically active substance and materials and articles treated with it are to be assessed and managed in a similar way as they are in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency [2].

(10) With a view to achieving a high level of environmental and human health protection, active substances with the worst hazard profiles should not be approved for use in biocidal products except in specific situations. These should include situations when the approval is justified because of a negligible exposure of humans to the substance, public health reasons or disproportionate negative impacts of a possible non-inclusion provided no alternatives exist.

(11) In order to prevent the use of active substances with the worst hazard profiles, in particular when their use is not authorised under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market [3], it is appropriate to restrict their approval to situations when the exposure of humans to the substance is negligible or the substance is necessary for public health reasons.

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[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 396, 30.12.2006, p. 1.
[3] OJ L 309, 24.11.2009, p. 1.

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(12) The active substances in the Union list should be regularly examined to take account of developments in science and technology. Where there are serious indications that an active substance used in biocidal products may pose a higher risk than previously thought, the Commission should be able to review the inclusion of the active substance.

(13) Active substances can, on basis of their intrinsic hazardous properties, be designated as candidates for substitution with other active substances, whenever such substances considered as effective towards the targeted harmful organisms become available in sufficient variety to avoid the development of resistance amongst harmful organisms. In order to allow for a regular examination of substances identified as candidates for substitution, the inclusion period for these substances should not, even in the case of renewal, exceed ***seven years***. Furthermore, the identification of substances which are considered as candidates for substitution should be considered as a first step of a comparative assessment.

(14) In the course of the authorisation or renewal of biocidal product authorisations, it should be possible to compare two or more biocidal products with regard to risks posed by them and benefits accrued through their use. As a result of such a comparative assessment, authorised biocidal products containing active substances indicated as candidates for substitution could be replaced with others that present significantly less risk to health or to the environment and where there are no significant adverse economic or practical impacts. Appropriate phase-out periods should be provided for in such cases.

(15) In order to avoid unnecessary administrative and financial burden for the industry as well as competent authorities, a full in-depth evaluation of an application to renew the inclusion of an active substance in the Union list or the authorisation should be carried out only if the competent authority that was responsible for the initial evaluation decides so on the basis of the available information.

(16) There is a need to ensure effective coordination and management of the technical, scientific and administrative aspects of this Regulation at Union level. The European Chemicals Agency set up under Regulation (EC) No 1907/2006 (hereinafter the 'Agency') should carry out specified tasks with regard to the evaluation of active substances as well as the authorisation of certain categories of biocidal products and related tasks in the Union territory. Consequently, a Biocidal Products Committee should be established within the Agency to carry out the tasks attributed to the Agency by this Regulation.

(17) It is recognised that biocidal products intended to be used not only for purposes of this Regulation but also in connection with medical devices, such as disinfectants used for the disinfection of surfaces in hospitals as well as medical devices, may pose risks different from those covered by this Regulation. Therefore, such biocidal products should be required to comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([1]), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([2]) or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ([3]).

(18) As the costs of the application of this Regulation to food or feedingstuffs used for biocidal purposes would be disproportionate to the benefits thereof, food and feedingstuffs used for biocidal purposes should not be covered by this Regulation. Furthermore, the safety of food and feedingstuffs is subject to Union legislation, in particular Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([4]).

([1]) OJ L 189, 20.7.1990, p. 17.
([2]) OJ L 169, 12.7.1993, p. 1.
([3]) OJ L 331, 7.12.1998, p. 1.
([4]) OJ L 31, 1.2.2002, p. 1.

(19) Processing aids are covered by existing Union legislation, in particular Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption [1] and 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]. Therefore, it is appropriate to exclude them from the scope of this Regulation.

(20) As products used for the preservation of food or feedstocks by the control of harmful organisms, which were previously covered by product type 20, are now covered by Directive 89/107/EEC and Regulation (EC) No 1831/2003, it is not appropriate to maintain this product type.

(21) As the International Convention for the Control and Management of Ships' Ballast Water and Sediments provides for an effective assessment of the risks posed by ballast water management systems, the final approval and subsequent type approval of such systems should be considered equivalent to the product authorisation required under this Regulation.

(22) In order to take account of the specific nature of some biocidal products and the low level of risk associated with their proposed use, and to encourage the development of biocidal products containing new active substances, it is appropriate to provide for a Union authorisation of those products.

(23) In order to ensure that only biocidal products that comply with the relevant provisions of this Regulation are placed on the market, biocidal products should be subject to authorisation either by competent authorities for placing on the market or use in the territory of a Member State, or a part of it, or by the Commission for placing on the market or use in the Union.

(24) In order to facilitate access to the internal market and to avoid the additional costs and time involved in obtaining separate national authorisations in separate Member States, ▌the scope of the Union authorisation procedure ***should be extended to all categories of biocidal products with the exception of biocidal products that contain certain active substances***.

(25) In order to ensure a harmonised application of the low-risk criteria by competent authorities, it is necessary to specify those criteria in the Regulation as far as possible. The criteria should be based on the hazard characteristics of the biocidal products and the exposure to the product associated with its use. The use of low-risk biocidal products should not lead to a high risk of developing resistance in target organisms.

▌

(26) In view of the provisions on low-risk biocidal products in this Regulation, it seems appropriate to exempt active substances contained in those products from the registration obligations under Regulation (EC) No 1907/2006. This is, in particular, necessary because these substances do not fulfil the conditions in Article 15(2) of that Regulation.

(27) It is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by competent authorities.

(28) In order to evaluate the risks that would arise from the proposed uses of biocidal products, it is appropriate that the applicants submit dossiers which contain the necessary information. Defining a data set for active substances and for biocidal products in which they are contained is necessary so as to assist both the applicants seeking authorisation and competent authorities carrying out the evaluation in deciding on the authorisation.

[1] OJ L 40, 11.2.1989, p. 27.
[2] OJ L 268, 18.10.2003, p. 29.

(29) In the light of the diversity of both the active substances and the biocidal products, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should be able to request adaptations of the data requirements, as appropriate, including the waiving of data requirements which are unnecessary or impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide the appropriate technical and scientific justification to support their requests.

(30) In order to ensure that the applicant can effectively exercise his right to request an adaptation of the data requirements, the competent authorities should inform the applicant about this possibility and the grounds on which such request could be made. Furthermore, in order to facilitate the preparation of the request, in particular by small- and medium-sized enterprises (SMEs), the competent authority should assist the applicant, where possible, in preparing such a request.

(31) In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States should establish national helpdesks. These should be in addition to the operational guidance documents provided by the Agency.

(32) In order to facilitate access to the market of biocidal products belonging to one group of products, it should be possible to authorise such groups of biocidal products with similar uses and allow limited variations with regard to the reference biocidal product provided that those variations do not affect the level of the risk and the efficacy of the products.

(33) When biocidal products are being authorised, it is necessary to ensure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance, and, in the case of vertebrate animals, unnecessary suffering and pain, and have, in the light of current scientific and technical knowledge, no unacceptable effect on the environment and on human or animal health. When deciding whether a biocidal product should be authorised, due consideration should be given to the benefits resulting from its use.

(34) Infestation with harmful organisms should be avoided by means of suitable deterrents to banish or repel such organisms. In addition, other precautionary steps should be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if such measures have no effect should further steps be taken. Biocidal products that pose lower risks for humans, animals and the environment should always be used in preference to other products where those lower risk products provide an effective remedy in particular situations. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used as a last resort.

(35) In order to avoid duplication of the evaluation procedures and to ensure free movement of biocidal products, as well as of materials and articles treated with them, within the Union, procedures should be established to ensure that authorisations of products granted in one Member State are recognised in all other Member States.

(36) Specific provisions should lay down procedures to ensure the smooth operation of mutual recognition of authorisations granted by Member States, and in particular the resolution of any disagreements without undue delay.

(37) In order to enable Member States to co-operate in the evaluation of biocidal products and to facilitate the access of biocidal products to the market, it should be possible to launch the process of mutual recognition together with the application for the first authorisation.

(38) There is a need to provide for a dispute settlement mechanism at Union level to ensure the effective functioning of mutual recognition. If a competent authority refuses to mutually recognise an authorisation or proposes to restrict it, the Commission should be empowered to take a decision. In the event of technical or scientific questions, the Commission may consult the Agency before preparing the decision.

(39) While envisaging harmonised provisions for all biocidal product types, including those intended to control vertebrates, the actual use of such product types might give rise to concern. Therefore, Member States should be allowed to derogate from the principle of mutual recognition for biocidal products that fall under certain particular types of biocides when intended to control particular kinds of vertebrates, in so far as such derogations are justified and do not jeopardise the purpose of this Regulation regarding an appropriate level of protection of the internal market.

(40) In order to facilitate the functioning of the authorisation and mutual recognition procedures, it is appropriate to establish a system for the mutual exchange of information, and Member States, the Commission and the Agency should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products.

(41) If the use of a biocidal product is in the interest of a Member State, but there is no applicant interested in the placing on the market of such product in the Member State, pest control bodies and other professional organisations should be allowed to apply for an authorisation. In the event that they are granted an authorisation, they should possess the same rights and obligations as any other authorisation holder.

(42) In order to take account of the scientific and technical developments as well as the needs of the authorisation holders, it should be specified under what conditions authorisations can be cancelled, reviewed or amended. Provisions on the notification and exchange of information which may affect the authorisations should be set out so as to enable the competent authorities and the Commission to take appropriate action.

(43) In the event of an unforeseen danger threatening public health or the environment which cannot be contained by other means, it should be possible for Member States to authorise, for a limited period of time, biocidal products which do not comply with the requirements laid down in this Regulation.

(44) In order to encourage the development of new active substances, the procedure for the evaluation of a newly developed active substance should not prevent Member States or the Union from authorising, for a limited period of time, biocidal products containing that active substance before the active substance is entered in Annex I, provided that a dossier meeting all requirements has been submitted and it is believed that the active substance and the biocidal product satisfy the conditions set for them.

(45) In order to encourage research and development in active substances and biocidal products, it is necessary to establish rules under which unauthorised biocidal products or active substances may be placed on the market for the purposes of research and development.

(46) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade of ▌identical biocidal products that are authorised in different Member States.

(47) For the purposes of ensuring the protection of human and animal health and of the environment, and non-discrimination between articles or materials originating in the Union and articles or materials imported from third countries, all treated articles or materials placed on the internal market should contain only authorised biocidal products.

(48) For the purposes of enabling consumers to make informed choices and facilitating the enforcement of this Regulation by competent authorities, articles or materials treated with biocidal products should be appropriately labelled.

(49) Applicants that have invested in supporting the inclusion of an active substance in Annex I or in the authorisation of a biocidal product in accordance with the provisions of this Regulation ***or in accordance with Directive 98/8/EC*** should be able to recover part of their investment by receiving equitable compensation whenever use is made of proprietary information that they submitted in support of such inclusions or authorisations for the benefit of subsequent applicants.

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(50) With a view to ensuring that all proprietary information submitted in support of the inclusion of an active substance in Annex I or an authorisation of a biocidal product is protected from the moment of its submission, and to prevent situations where some information is without protection, the provision on information protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.

(51) In order to encourage the development of new active substances and biocidal products containing them, it is necessary to provide for a period of protection with respect to the proprietary information submitted in support of the inclusion of active substances or authorisations of products which is longer than the period of protection for information concerning existing active substances and products containing them.

(52) It is essential to minimise the number of tests on animals and to ensure that testing ***with biocidal products or active substances contained in biocidal products*** should be made dependent on the purpose and use of a product. Applicants should share, and not duplicate, vertebrate animal studies in exchange for equitable compensation. In the absence of an agreement on sharing vertebrate animal studies between the data owner and the prospective applicant, the Agency should allow the use of the studies by the prospective applicant without prejudice to the decision on the compensation made by national courts. A Union register listing the contact details of the owners of such studies should be established and put at the disposal of all authorities to inform prospective applicants.

(53) The generation of information by alternative means that do not involve tests on animals and that are equivalent to prescribed tests and test methods should also be encouraged. In addition, the adaptation of data requirements should be used to prevent unnecessary costs related to testing.

(54) In order to ensure that the requirements laid down in respect of authorised biocidal products are satisfied when they are placed on the market, the Member States should take measures for appropriate control and inspection arrangements.

(55) It is necessary to provide for the effective communication of information on risks resulting from biocidal products and risk management measures as it forms an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful for the commercial interests of the person concerned***, except where it is necessary for the protection of human health and the environment***.

(56) In order to increase the effectiveness of monitoring and control, and to provide information relevant for addressing the risks of biocidal products, producers, importers and professional users should be required to keep records of the products they produce, place on the market or use. The Commission should adopt implementing rules on data collection, transmission and processing.

(57) In order to facilitate the exchange of information between competent authorities, the Agency and the Commission, a Union Register for Biocidal Products should be established.

(58) It is necessary to specify that provisions concerning the Agency laid down in Regulation (EC) No 1907/2006 should apply accordingly in the context of biocidal active substances and products. Where separate provisions need to be made with respect to the tasks and functioning of the Agency under this Regulation, it should be specified in the provisions of this Regulation.

(59) The costs of the procedures associated with the operation of this Regulation need to be recovered from those who seek to place or do place biocidal products on the market and from those supporting the inclusion of active substances in Annex I. In order to promote the smooth operation of the internal market, the Commission should adopt measures to harmonise the structure of fee systems established by the Member States and the Agency taking into account the special needs of SMEs.

(60) It is necessary to provide for the possibility of an appeal against certain decisions of the Agency. The Board of Appeal set up within the Agency by Regulation (EC) No 1907/2006 should also guarantee the processing of appeals against decisions adopted by the Agency under this Regulation.

I

(61) There is scientific uncertainty about the safety of nanomaterials for human health and the environment and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials. SCENIHR has furthermore found a general lack of high-quality exposure data for both humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised. More and more biocidal products contain nanosilver. The use of nanomaterials in biocidal products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly. At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety, the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies which take into account the specific characteristics of nanomaterials. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(62) In view of the environmental impact that anti-fouling products can have in water, the Commission should take steps at international level to ensure that the AFS Convention (International Convention on the Control of Harmful Anti-Fouling Systems on Ships) is ratified worldwide and adapted to this Regulation.

(63) According to Article 291 of the Treaty on the Functioning of the European Union, rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, and given the necessity to adopt as soon as possible this Regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]) continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable. References to provisions of that Decision should nevertheless be replaced with references to the rules and principles set out in the new regulation as soon as that regulation enters into force.

(64) It is appropriate to provide for a deferred application of this Regulation so as to facilitate the smooth transition to the new system applying to the inclusion of active substances in Annex I and authorisation of biocidal products.

(65) Due to the limited number of new submissions of applications for inclusion of active substances in Annex I, the Agency should take over the co-ordination and facilitation tasks for new submissions as of the date of applicability of this Regulation. However, in view of the high number of historical dossiers and in order to allow some time for the Agency to prepare for the new role, it should take over the tasks related to dossiers submitted under Directive 98/8/EC as of 1 January 2014.

(66) In order to respect the legitimate expectations of companies with respect to the placing on the market and use of low-risk biocidal products covered by Directive 98/8/EC, those companies should be allowed to place such products on the market if they comply with the rules on the registration of low-risk biocidal products under that Directive. However, this Regulation should apply after the expiry of the first registration.

([1]) ***OJ L 184, 17.7.1999, p. 23.***

(67) Taking into consideration that some products were not previously covered by the Union legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules concerning *in situ* generated active substances ***and*** treated articles and materials ▌.

(68) In order to ensure an equal treatment of persons placing on the market biocidal products containing one or more existing active substances, they should be required to hold a dossier or have a letter of access to a dossier, or to each component of the dossier, for each of the active substances contained in the product. Those persons who do not comply with this obligation by 1 January 2014 should no longer be allowed to place their products on the market. Appropriate phase-out periods for disposal, storage and use of existing stocks of biocidal products should be laid down in such cases.

(69) This Regulation should take account, as appropriate, of other work programmes concerned with the review or authorisation of substances and products, or relevant international conventions,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules for:

(1) the placing on the market and use of biocidal products within the Member States or the Union;

(2) the mutual recognition of authorisations within the Union;

(3) the establishment at Union level of a list of active substances which may be used in biocidal products.

The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, in order to ensure that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.

Article 2

Scope

1. This Regulation shall apply to biocidal products as defined in point (a) of Article 3(1).

A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

2. This Regulation shall not apply to biocidal products that are within the scope of the following instruments:

(a) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ([1]);

(b) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([2]);

([1]) OJ L 262, 27.9.1976, p. 169.
([2]) OJ L 213, 21.7.1982, p. 8.

(c) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([1]);

(d) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ([2]);

(e) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community ([3]);

(f) Directive 90/385/EEC;

(g) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([4]);

(h) Directive 93/42/EEC;

(i) European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners ([5]);

(j) Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials ([6]);

(k) Directive 98/79/EC;

(l) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ([7]);

(m) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ([8]);

(n) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([9]);

(o) Regulation (EC) No 1831/2003;

(p) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([10]);

(q) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([11]);

(r) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food ([12]).

([1]) OJ L 184, 15.7.1988, p. 61.
([2]) OJ L 354, 31.12.2008, p. 16.
([3]) OJ L 92, 7.4.1990, p. 42.
([4]) OJ L 230, 19.8.1991, p. 1.
([5]) OJ L 61, 18.3.1995, p. 1.
([6]) OJ L 125, 23.5.1996, p. 35.
([7]) ***OJ L 330, 5.12.1998, p. 32.***
([8]) OJ L 311, 28.11.2001, p. 1.
([9]) OJ L 311, 28.11.2001, p. 67.
([10]) OJ L 139, 30.4.2004, p. 1.
([11]) OJ L 139, 30.4.2004, p. 55.
([12]) ***OJ L 338, 13.11.2004, p. 4.***

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3. Subject to any explicit provision to the contrary, this Regulation shall be without prejudice to the following instruments:

(a) Council Directive 67/548/EEC 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]);

(b) Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances ([2]);

(c) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([3]);

(d) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ([4]);

(e) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ([5]);

(f) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) ([6]);

(g) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([7]);

(h) Regulation (EC) No 1907/2006;

(i) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising ([8]);

(j) Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals ([9]);

(k) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides ([10]);

(l) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ([11]).

4. Article 58 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

5. This Regulation shall not apply to food or feedingstuffs that are used for biocidal purposes.

([1]) OJ 196, 16.8.1967, p. 1.
([2]) OJ L 33, 8.2.1979, p. 36.
([3]) OJ L 183, 29.6.1989, p. 1.
([4]) OJ L 131, 5.5.1998, p. 11.
([5]) OJ L 200, 30.7.1999, p. 1.
([6]) OJ L 262, 17.10.2000, p. 21.
([7]) ***OJ L 327, 22.12.2000, p. 1.***
([8]) OJ L 376, 27.12.2006, p. 21.
([9]) OJ L 204, 31.7.2008, p. 1.
([10]) OJ L 309, 24.11.2009, p. 71.
([11]) OJ L 353, 31.12.2008, p. 1.

6. This Regulation shall not apply to processing aids that are used for biocidal purposes.

7. Where a biocidal product is intended by its manufacturer to be used for the purpose of exerting a controlling effect on any harmful organism present on medical devices and for other purposes covered by this Regulation, the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC shall also be fulfilled.

8. Biocidal products which obtained the final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VII of this Regulation. Articles 38 and 57 shall apply accordingly.

Article 3

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'biocidal products' means

active substances or mixtures containing one or more active substances, put up in the form in which they are supplied to the user, ***primarily*** intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

All substances, mixtures and devices placed on the market with the intention to generate active substances shall also be considered biocidal products;

(b) 'micro-organism' means

any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;

(c) 'active substance' means

a substance or a micro-organism with an action against harmful organisms;

(d) 'existing active substance' means

a substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product- and process-orientated research and development;

(e) 'new active substance' means

a substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product- and process-orientated research and development;

(f) 'substance of concern' means

any substance, other than an active substance, which has an inherent capacity to cause an adverse effect***, immediately or in the more distant future,*** on humans, ***especially children,*** animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present a risk of causing such an effect.

Such a substance would, unless there are other grounds for concern, normally be a substance classified as dangerous according to Directive 67/548/EEC and be present in the biocidal product at a concentration leading to the product being regarded as dangerous within the meaning of Directive 1999/45/EC or Regulation (EC) No 1272/2008;

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(g) 'harmful organism' means

organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect***, immediately or in the more distant future,*** on humans, ***especially children, human*** activities or the products they use or produce, or on animals or the environment;

(h) 'residues' means

substances present in or on plants or products of plant origin, edible animal products, ***water resources,*** drinking water or elsewhere in the environment and resulting from the use of a biocidal product, including their metabolites, breakdown or reaction products;

(i) 'placing on the market' means

the ▌supply of a biocidal product ***to third parties***, whether in return for payment or free of charge, ***or the making available of a biocidal product to third parties. Importation shall be deemed to be placing on the market. No supply to third parties is involved when*** in the course of a commercial activity ***treated materials or products are individually manufactured and then incorporated by the manufacturer***;

(j) 'use' means

all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with view to exporting the biocidal product outside the Union;

(k) 'treated material or article' means

any substance, mixture, material or article which was treated with or incorporates one or more biocidal products ▌;

(l) 'external biocidal effect' means

the effect of applications whereby the incorporated biocidal product is intended to be released under normal or reasonably foreseeable conditions of use;

(m) 'national authorisation' means

an administrative act by which the competent authority of a Member State authorises the placing on the market and the use of a biocidal product in its territory or in a part thereof;

(n) 'Union authorisation' means

an administrative act by which the Commission authorises the placing on the market and the use of a biocidal product in the territory of the Union or in a part thereof;

(o) 'authorisation' means

national authorisation or Union authorisation;

(p) 'unique product formulation' means

a biocidal product with no variations as to the percentage of the active substance, the percentage composition of the non-active substances, or the perfumes, dyes or pigments it contains;

(q) 'frame formulation' means

a group of biocidal products that have similar uses and that present limited variations in their composition with regard to a reference biocidal product belonging to that group which contains the same active substances of the same specifications, where such permitted variations do not adversely affect the level of risk or the efficacy of these products;

(r) 'letter of access' means

an original document, signed by the owner or owners of information ***or their authorised representative***, which states that the information may be used by the ***designated*** competent ***authority***, the Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation ***for the benefit of a third party***;

(s) 'food and feedingstuff' means

food as defined in Article 2 of Regulation (EC) No 178/2002 and feedingstuff as defined in Article 3(4) of that Regulation.

(t) 'food contact materials' means

any material or article, intended to come into contact with food, that is covered by Regulation (EC) No 1935/2004;

(u) 'processing aid' means

any substance which:

(i) is not consumed as a food or feedingstuff by itself;

(ii) is intentionally used in the processing of raw materials, foods or feedingstuff or their ingredients to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives, provided they do not present any health risk and do not have any technological effect on the final product;

(v) 'administrative change' means

a modification of an existing authorisation of a purely administrative nature, which does not involve a re-assessment of the risk for public health or the environment or the efficacy of the product;

(w) 'minor change' means

a modification of an existing authorisation which cannot be deemed to be an administrative change as it involves a limited re-assessment of the risk for public health or the environment or of the efficacy of the product, and does not adversely affect the level of risk for public health or the environment and the efficacy of the product;

(x) 'major change' means

a modification of an existing authorisation which cannot be deemed to be an administrative change or a minor change;

(y) 'technical equivalence' means

similarity as regards the chemical composition and hazard profile of a substance produced from a new manufacturing source, compared to the substance of the reference source with respect to which the initial risk assessment was carried out;

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(z) 'nanomaterial' means

any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

(i) those related to the large specific surface area of the materials considered; and/or

(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material;

(za) 'manufacturer' means

(i) in the case of an active substance produced within the Union and placed on the market, the manufacturer of that active substance or a person established within the Union designated by the manufacturer as his sole representative for the purposes of this Regulation,

(ii) in the case of an active substance produced outside the Union, the person established within the Union and designated by the manufacturer of that active substance as his sole representative for the purposes of this Regulation or, where no such person has been so designated, the importer into the Union of that active substance,

(iii) in the case of a biocidal product produced outside the Union, the person established within the Union and designated by the manufacturer of that biocidal product as his sole representative for the purposes of this Regulation or, where no such person has been so designated, the importer into the Union of that biocidal product;

(zb) 'professional user' means

any natural or legal person who uses biocidal products in the framework of his professional activity;

(zc) 'vulnerable groups' means

persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high biocide exposure over the long term;

(zd) 'SMEs' means

small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ([1]).

2. For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:

(a) substance;

(b) mixture;

(c) article;

(d) product and process-orientated research and development;

(e) scientific research and development.

([1]) ***OJ L 124, 20.5.2003, p. 36.***

CHAPTER II

INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

Article 4

Conditions for inclusion

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if ***at least one of*** the biocidal products containing that active substance ***fulfils*** the conditions laid down in point (b) of Article 16(1). ***An active substance referred to in Article 5 may be included in Annex I only for an initial period of 5 years.***

2. The inclusion in Annex I of an active substance shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 6.

3. Active substances, as such or in biocidal products, may be placed on the market in the Union for use in biocidal products only if they have been included in Annex I in accordance with the provisions of this Regulation.

4. Unless otherwise provided in this Regulation, all manufacturers of an active substance, as such or in a biocidal product, shall submit to the Agency an application for inclusion in Annex I.

5. An active substance ***and the definition of the reference source for the active substance for the purposes of determining technical equivalence*** shall, where appropriate, be included in Annex I together with conditions relating to any of the following:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) the product type as outlined in Annex V;

(d) manner and area of use;

(e) designation of categories of users;

(f) characterisation of the chemical identity with regard to stereoisomers;

(g) other particular conditions based on the evaluation of the information related to that active substance.

6. Where appropriate, maximum residue limits shall be established with respect to active substances included in Annex I in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [1] and Regulation (EC) No 470/2009 of the European Parliament and the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin [2].

Article 5

Exclusion criteria

1. ***Without prejudice to paragraph 2, the following*** active substances ▌shall ***not*** be included in Annex I ▌:

[1] OJ L 70, 16.3.2005, p. 1.
[2] OJ L 152, 16.6.2009, p. 11.

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(a) ***active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;***

(b) ***active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;***

(c) ***active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;***

(d) active substances which, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine-disrupting properties.

Not later than 13 December 2013, the Commission shall adopt, by means of delegated acts in accordance with Articles 73 and subject to the conditions of Articles 74 and 75, measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of those criteria, substances that are, or are to be, classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties. In addition, substances such as those that are, or are to be, classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered as having such endocrine-disrupting properties;

(e) active substances that are persistent, bio-accumulative and toxic;

(f) active substances that are very persistent and very bio-accumulative;

(g) persistent organic pollutants (POP) under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants ([1]).

2. The ▌active substances ***referred to in paragraph 1 may*** be included in Annex I ***only if*** at least one of the ***following*** conditions ▌is met:

(a) ***the exposure of humans or the environment to the active substance in question in a biocidal product, under normal conditions of use, is negligible, meaning that the product is used in closed systems or under other conditions excluding contact with humans;***

(b) ***it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment, to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available.***

The use of any biocidal product containing active substances included in Annex I pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.

A Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this paragraph shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods that are as effective as the biocidal product concerned, and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.

([1]) ***OJ L 158, 30.4.2004, p. 7.***

Article 6

Data requirements for an application

1. An application to include an active substance in Annex I shall contain at least the following elements:

(a) a dossier***, or a letter of access to a dossier,*** for the active substance satisfying the requirements set out in Annex II;

(b) a dossier***, or a letter of access to a dossier,*** for at least one representative biocidal product that contains the active substance satisfying the requirements set out in Annex III.

The application shall be accompanied by the fees payable under Article 71.

2. Notwithstanding paragraph 1, the applicant need not provide data required under that paragraph if any of the following grounds applies:

(a) the information is not necessary ***as all relevant*** exposure ***can be ruled out under*** the proposed uses;

(b) it is not scientifically necessary to supply the information;

(c) it is not technically possible to supply the information.

3. An applicant may propose to adapt the data required under paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

The competent authority shall inform the applicant about the possibility of proposing the adaptation of data requirements, the grounds on which such an adaptation can be requested and, where possible, shall provide assistance in preparing such a proposal.

4. ***In order to define*** what constitutes adequate justification to adapt the data required under paragraph 1 on the ground referred to in paragraph 2(a), ***the Commission shall adapt the criteria by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***.

Article 7

Submission and validation of applications

1. The applicant shall submit an application for inclusion of an active substance in Annex I, or for subsequent amendments to the conditions of inclusion of an active substance, to the Agency. ***The Agency shall indicate*** the name of the competent authority of the Member State that ***it has chosen*** to evaluate ***the*** application. That competent authority (hereinafter the 'evaluating competent authority') shall be responsible for the evaluation of the application.

2. The Agency shall provide a submission number to be used in all correspondence relating to the application until the active substance is included in Annex I, and a submission date, which shall be the date on which the application is received by the Agency.

3. The Agency shall, within one month from the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

4. Within ***three weeks*** after receipt of an application, the Agency shall validate the application if it complies with the following requirements:

(a) dossiers referred to in points (a) and (b) of Article 6(1) have been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

5. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a ▌ time limit ***of up to two months*** for the submission of that information.

The Agency shall, within ***three weeks*** after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to submit the requested information by the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

Within two months of receiving the application, the Agency shall assign a unique identification code to all the information in the dossier.

6. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 5.

7. If the Agency, on the basis of the validation made pursuant to paragraph 4, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 8

Evaluation of applications

1. The evaluating competent authority shall, within 12 months after the validation, evaluate the dossiers in accordance with Article 4, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3).

The evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the conclusions of the evaluation within two months. The evaluating competent authority shall take due account of these comments when finalising its evaluation.

The evaluating competent authority shall send the conclusions of the evaluation to the Agency.

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit ***that shall not exceed six months. In exceptional circumstances and following proper justification, the time limit may be extended by up to a further six months. The evaluating competent authority*** shall inform the Agency ***about its request to the applicant and the extension of the time limit. Where such additional information includes animal testing, the applicant shall be advised by experts from the Agency or competent authorities regarding suitable alternative methods and testing strategies to replace, reduce or refine the use of vertebrate animals.***

The 12-month period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.

3. If the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance***, or different substances with similar or common effects on the same endpoints, whether by the same or different mechanism of action,*** it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

4. Within nine months after receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the inclusion of the active substance in Annex ***I, having regard to the conclusions of the evaluating competent authority.***

5. ***In order to keep the list of authorised active substances updated,*** on receipt of the opinion of the Agency, the Commission shall adopt***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75,*** a decision ▌to include the active substance in Annex I. ▌

6. Notwithstanding Article 7(1), the evaluation of the application may be carried out by the competent authority other than the one which has received the copy of the application.

The competent authority that has been notified of the application for the evaluation may submit a duly substantiated request to appoint another evaluating competent authority to the Commission within one month after receipt of the notification referred to in Article 7(3). The Commission shall take the decision in accordance with the procedure referred to in Article 76(2). The 12-month period referred to in paragraph 1 shall commence on the date when this decision is taken.

Article 9

Active substances which are candidates for substitution

1. An active substance that fulfils at least one of the following criteria shall be considered a candidate for substitution in accordance with the procedure referred to in paragraph 2:

(a) its acceptable daily intake, acute reference dose or acceptable operator exposure level is significantly lower than those of the majority of the active substances included in Annex I for the same product type;

(b) it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;

(c) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, ***such as high potential of risk to groundwater,*** even with very restrictive risk management measures;

(d) it is very persistent and very bioaccumulative according to the criteria set out in Annex XIII to Regulation (EC) No 1907/2006;

(e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as ***respiratory sensitisers,*** carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B;

(f) it is considered to have endocrine-disrupting properties that may cause adverse effect on humans ***or the environment*** on the basis of the assessment of Union or internationally agreed test guidelines or other available data.

2. When preparing an opinion on the inclusion, or renewal of the inclusion, of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and shall address the matter in its opinion.

3. Prior to submitting the opinion on the inclusion, or renewal of the inclusion, of an active substance in Annex I to the Commission, the Agency shall make publicly available information on potential candidates for substitution with a reasonable period during which relevant information, including information on available substitutes, may be submitted by interested third parties. The Agency shall take due account of the information received when finalising its opinion.

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4. By way of derogation from ***Articles 4(1) and*** 10(3), the inclusion of an active substance in Annex I that is considered as a candidate for substitution shall be ***granted or*** renewed for a period not exceeding ***seven years***.

5. Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in Annex I.

CHAPTER III

RENEWAL AND REVIEW OF INCLUSION OF AN ACTIVE SUBSTANCE

Article 10

Conditions for renewal

1. The Commission shall renew the inclusion of an active substance in Annex I if the active substance still complies with the requirements referred to in Articles 4 ***and 5***.

2. Based on new elements examined or adaptations to technical progress, the renewal of the inclusion may be accompanied, as appropriate, by conditions and restrictions.

3. Unless ***more strictly*** specified in the decision to renew the inclusion of an active substance in Annex I, the renewal ***may*** be ***renewed*** for ***a*** period ***not exceeding 10 years***.

Article 11

Submission and validation of applications

1. The applicant shall submit the application for renewal of the inclusion of an active substance in Annex I to the Agency at least 18 months before the expiry of the inclusion in Annex I for a given product-type.

The application shall be accompanied by the fees payable under Article 71.

When applying for renewal, the applicant shall submit a list of all data relating to the active substance that have been generated since the inclusion of the active substance in Annex I and a justification as to whether the conclusions of the initial assessment of the active substance are still valid. The evaluating competent authority may require the applicant to submit the data referred to in this list at any time.

2. The Agency shall, within one month after receipt of the application, notify the evaluating competent authority that carried out the initial evaluation of the application for inclusion in Annex I that the application is available in the Agency database.

3. Within two months after receipt of an application, the Agency shall validate the application if it complies with the following requirements:

(a) information referred to paragraph 1 has been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

4. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a ▌ time limit ***of up to two months*** for the submission of that information.

The Agency shall, within two months after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

5. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 4.

6. If the Agency considers, on basis of the validation made pursuant to paragraph 3, that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 12

Evaluation of applications for renewal

1. On the basis of the available information and the need to review the conclusions of the initial evaluation of the application for inclusion in Annex I, the evaluating competent authority that carried out the initial evaluation shall, within one month after the validation referred to in Article 11, decide whether a full evaluation of the application for renewal is necessary.

If the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 to 4 of Article 8. The decision on the application shall be adopted in accordance with paragraphs 5, 6 and 7 of this Article.

2. If the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within six months, prepare and submit to the Agency a recommendation on the renewal of the inclusion of the active substance in Annex I.

Prior to submitting the recommendation to the Agency, the evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the recommendation within one month. The evaluating competent authority shall take due account of these comments when finalising its recommendation.

3. On receipt of the recommendation from the evaluating competent authority, the Agency shall make it available to the Commission, the competent authorities of other Member States and the applicant and allow a period of three months during which they may submit written comments to it.

4. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a competent authority objecting to the recommendation referred to in paragraph 2. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.

5. ***In order to keep the list of authorised active substances updated,*** at the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75,*** a decision concerning the renewal of the inclusion of the active substance in Annex I. ▌

6. Where, for reasons beyond the control of the applicant, the inclusion of the active substance in Annex I is likely to expire before a decision has been taken on its renewal, the Commission shall, in accordance with the procedure referred to in Article 76(2), adopt a decision postponing the expiry date of inclusion for a period sufficient to enable it to examine the application.

7. Where the Commission decides not to renew the inclusion of an active substance in Annex I, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks of biocidal products containing that active substance.

The period of grace shall not exceed six months for the placing on the market and an additional maximum of twelve months for the disposal, storage, and use of existing stocks of the biocidal products containing that active substance.

Article 13

Review of inclusion of an active substance in Annex I

1. ***In order to keep the list of authorised active substances updated,*** the Commission may review the inclusion of an active substance in Annex I at any time where there are ▌indications that ***any of*** the requirements ▌in ***Articles*** 4 ***and 5*** are no longer complied with. ***It shall review the inclusion also in cases where there are indications that the objectives of Article 4(1)(a)(iv), Article 4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.*** Where those indications are confirmed, the Commission shall adopt***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75,*** a decision amending the entry of an active substance in Annex I or removing it from that Annex.

▌

2. The Commission may consult the Agency on any questions of a scientific or technical nature relating to the review of the inclusion of an active substance in Annex I. The Agency shall, within nine months of the request, prepare an opinion and submit it to the Commission.

3. Where the Commission removes the entry of an active substance from Annex I, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks of biocidal products containing that active substance.

The period of grace shall not exceed six months for the placing on the market and an additional maximum of twelve months for the disposal, storage, and use of existing stocks of the biocidal products containing that active substance.

Article 14

Detailed procedures for renewal and review

In order to ensure the smooth functioning of the renewal and review procedures, the Commission may adopt ***further*** detailed measures ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***.

▌

CHAPTER IV

GENERAL PRINCIPLES OF AUTHORISATION OF BIOCIDAL PRODUCTS

Article 15

Placing on the market and use of biocidal products

1. No biocidal product may be placed on the market or used unless an authorisation has been issued for that biocidal product in accordance with this Regulation.

2. Application for authorisation shall be made by, or on behalf of, the person who ***will*** be ***the authorisation holder. The person may be, but is not necessarily, the person*** responsible for the placing on the market of a biocidal product in a particular Member State or in the Union.

▌

Application for ▌authorisation shall be submitted to the Agency. ***When an applicant submits an application for national authorisation, that applicant shall, with the agreement of the Member State concerned on whose territory the national authorisation would be applicable, identify in the application itself, as laid down in Article 22, the competent authority of the Member State of his choice which shall be responsible for the evaluation of, and decision on, the application (hereinafter the 'receiving competent authority').***

Authorisation holders shall have a permanent office within the Union.

A single application for authorisation may be made by the applicant for a group of products intended to be authorised under a frame formulation.

3. An authorisation may be granted for a unique product formulation or for a frame formulation.

4. An authorisation shall be granted for a maximum period of 10 years.

5. Biocidal products shall be used properly. Proper use shall include compliance with the conditions for granting an authorisation established in Article 16 and labelling requirements laid down in Article 58.

Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary.

Infestation with harmful organisms shall be avoided by suitable measures of deterrence to banish or repel such organisms. In addition, other precautionary steps shall be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if those measures show no effect shall further steps be taken. Biocidal products that pose low risks for humans, animals and the environment shall always be used in preference to others. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress shall be applied only as a last resort.

Mandatory measures shall be established through a framework directive for Union action and thereafter implemented in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk-reduction measures and the promotion of alternatives.

By … (*), the Commission shall submit a proposal for such a framework directive to the European Parliament and the Council.

Article 16

Conditions for granting an authorisation

1. A biocidal product shall be authorised only if the following conditions are met:

(a) the active substances included therein are listed in Annex I and any conditions included in that Annex together with those active substances are complied with;

(*) ***Two years after entry into force of this Regulation.***

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(b) it is established according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2, complies with the following criteria:

(i) it is sufficiently effective;

(ii) it has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) it has no ***immediate or delayed harmful effect*** itself or as a result of its residues ***on groundwater or on human health, including the health of vulnerable groups***, or animal health***, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Agency to assess such effects are available***;

(iv) it has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment;

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil***, taking into account locations distant from its use following long-range environmental transportation***;

— its impact on non-target organisms;

— its impact on biodiversity and the ecosystem;

(c) the ***chemical identity***, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and non-active substances, and its ***metabolites and*** residues of toxicological or environmental significance, which result from uses that are to be authorised, can be determined according to the relevant requirements in Annexes II and III;

(d) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use, storage and transport of the product;

(e) where nanomaterials are used in the product, the risk to the environment and to health has been assessed separately.

2. The evaluation of the compliance of the biocidal product with the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

(a) all normal conditions under which the biocidal product may be used;

(b) how any material or article treated with it or containing it may be used;

(c) the consequences of its use and disposal;

(d) cumulative or synergistic effects.

3. When evaluating whether the criteria in point (b) of paragraph 1 have been fulfilled, information should whenever possible be derived from information already available on the substance of concern contained in the biocidal product, in order to keep tests on animals to a minimum. In particular, the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 should wherever possible be applied for the purpose of ascertaining the adverse effects of the biocidal product and for the subsequent risk assessment.

4. The evaluation of the compliance of the biocidal product with the criteria set out in points (b) and (c) of paragraph 1 shall not take into account a substance contained in the biocidal product if it is present in a preparation at a concentration lower than any of the following:

(a) the applicable concentrations laid down in Article 3(3) of Directive 1999/45/EC;

(b) the concentration limit values laid down in Annex I to Directive 67/548/EEC;

(c) the concentration limit values laid down in Part B of Annex II to Directive 1999/45/EC;

(d) the concentration limit values laid down in Part B of Annex III to Directive 1999/45/EC;

(e) the concentration limit values laid down in an agreed entry in the classification and labelling inventory established under Title V of Regulation (EC) No 1272/2008;

(f) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to Regulation (EC) No 1907/2006.

5. An authorisation to place a low-risk biocidal product on the market ***may be granted only if the active substances are evaluated as low-risk active substances and included in Annex I in accordance with Articles 4 and 5. The authorisation*** shall be subject to compliance with the requirements of points ***(a)*** to (d) of paragraph 1.

6. A biocidal product shall be authorised only for uses for which relevant information has been submitted in accordance with Article 18.

7. A biocidal product shall not be authorised for placing on the market to, or use by, the general public if it fulfils any of the following criteria for classification:

(a) it is toxic, very toxic or a category 1 or 2 carcinogen, or a category 1 or 2 mutagen or toxic for reproduction category 1 or 2 according to Directive 1999/45/EC;

(b) it is toxic, very toxic or a category 1A or 1B carcinogen, or a category 1A or 1B mutagen or toxic for reproduction category 1A or 1B according to Regulation (EC) No 1272/2008;

(c) it is considered to have endocrine-disrupting properties;

(d) it has developmental neurotoxic or immunotoxic effects.

8. In the case of a frame formulation, ***the following variations in composition with regard to a*** reference biocidal product ***are possible:***

(a) elimination of an active substance in a reference biocidal product with at least two active substances;

(b) a reduction in the percentage of the active substances;

(c) elimination of one or more non-active substances;

(d) an alteration in percentage composition of one or more non-active substances***;***

(e) the replacement of one or more non-active substances by others presenting the same or lower risk.

9. The Commission should, in accordance with the procedure set out in Article 76(2), provide technical and scientific guidance for product authorisation, with particular regard to harmonised data requirements, evaluation procedures and decisions by the Member States.

10. In order to facilitate the harmonisation of authorisation practices throughout the Union and to reduce the administrative burden on companies and competent authorities, the Commission shall adopt, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, measures specifying the conditions, criteria and procedures for regulating the authorisation and placing on the market of the same product for the same use, under different trade names and by different companies. The criteria and the procedures for such measures shall be based on, but not limited to, the following principles:

(a) no additional evaluation will be performed as it concerns an already authorised product;

(b) authorisation decisions shall be taken within a short timeframe;

(c) authorisation fees shall be low in accordance with the limited administrative work required.

Article 17

Criteria for low-risk biocidal products

1. A biocidal product shall be considered a low-risk biocidal product ***if the active substances therein are included in Annex I and*** if ***all of*** the following conditions are fulfilled:

(a) for any given environmental compartment, the ratio of the predicted environmental concentration (PEC) to predicted no-effect concentration (PNEC) may be derived and does not exceed 0.1;

(b) for any effect to human health, the margin of exposure (the ratio of no observed adverse effect level (NOAEL) and exposure concentration) is higher than 1 000;

(c) the cumulative effects of both active substances and non-active substances are taken into consideration and defined as low-risk.

However, a biocidal product shall not be considered a low-risk biocidal product if at least one of the following conditions is met:

(a) it contains one or more ▌substances which fulfil the criteria for being ***a persistent organic pollutant under Regulation (EC) No 850/2004, for being*** persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;

(b) it contains one or more active substances qualified as endocrine disrupters;

(c) it contains one or more active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as or which meet the criteria to be classified as one of the following:

(i) carcinogenic;

(ii) mutagenic;

(iii) neurotoxic;

(iv) immunotoxic;

(v) toxic to reproduction;

(vi) sensitising;

(vii) corrosive;

(viii) very toxic or toxic.

(d) it contains a nanomaterial;

(e) it is explosive;

(f) it contains any substance of concern;

(g) it is highly flammable;

(h) it is self-igniting at application temperature.

▌

2. For a low-risk biocidal product it shall be demonstrated that the potential for the development of resistance in target organisms due to the use of the biocidal product is low.

3. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in low-risk biocidal products that are authorised for placing on the market in accordance with Article 15 shall be regarded as being registered, and the registration as completed, for manufacture or import for use in a low-risk biocidal product, and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of that Regulation.

Article 18

Data requirements for an application for authorisation

1. The applicant for an authorisation shall submit the following documents together with the application:

(a) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;

(b) a proposal for a summary of the biocidal product characteristics that includes the information referred to in points (a), (b) and (e) to (m) of Article 20(2);

(c) for biocidal products other than low-risk biocidal products, a dossier or a letter of access to a dossier satisfying the requirements set out in Annex II for each active substance in the biocidal product;

(d) for low-risk biocidal products, any relevant information in support of the conclusion that the biocidal product is to be considered a low-risk biocidal product;

(e) if the active substance contained in a low-risk biocidal product has been included in Annex I, a letter of access if the appropriate protection period for information according to Article 49 has not expired.

2. The application for authorisation shall be accompanied by the fees payable under Article 71.

3. The ***Agency*** may require applications for a national authorisation to be submitted in ***an*** official ***language*** of the Member State in which ***the receiving*** competent authority is situated.

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4. If the application concerns a biocidal product that is intended by its manufacturer to be used inter alia for the purposes referred to in Article 2(7), it shall be accompanied by a declaration of conformity regarding the compliance with the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC.

5. The Commission shall, in accordance with the procedure referred to in Article 76(2), draw up technical notes for guidance to facilitate the implementation of point (d) of paragraph 1. ***The Commission shall, in accordance with the procedure set out in Article 76(2), provide technical and scientific guidance and tools, in particular to support applications for authorisation under Articles 18, 19 and 20, above all for SMEs.***

The technical notes shall be published in the 'C' series of the *Official Journal of the European Union*.

Article 19

Waiving of data requirements

1. Notwithstanding Article 18, the applicant need not provide data required under that Article if any of the following grounds applies:

(a) the information is not necessary owing to the exposure associated with the proposed uses;

(b) it is not scientifically necessary to supply the information;

(c) it is not technically possible to supply the information.

2. The applicant may propose to adapt the data required under Article 18 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

The competent authority shall inform the applicant about the possibility of proposing the adaptation of data requirements, the grounds on which such an adaptation can be requested and, where possible, shall provide assistance in preparing such a proposal.

3. ***In order to define*** what constitutes adequate justification to adapt the data required under Article 18 on the grounds referred to in point (a) of paragraph 1***, the Commission shall adapt the criteria by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***.

▌

Article 20

Content of authorisation

1. An authorisation shall stipulate the terms and the conditions relating to the placing on the market and use of the biocidal product.

2. An authorisation shall include the summary of the biocidal product characteristics listing the following information:

(a) trade name of the biocidal product;

(b) name and address of the authorisation holder;

(c) date of the authorisation and its date of expiry;

(d) authorisation number;

(e) ***where required for proper use of the biocidal product, the*** qualitative and quantitative composition in terms of the active substances and non-active substances, ***taking account of the concentration limits in Article 16(4)***;

(f) manufacturers of the biocidal product (names and addresses including location of manufacturing sites);

(g) manufacturers of the active substances (names and addresses including location of manufacturing sites);

(h) physical state and nature of the biocidal product;

(i) hazard and precautionary statements;

(j) the product-type in accordance with Annex V and the target harmful organisms;

(k) application doses and instructions for use;

(l) categories of users;

(m) particulars of likely direct or indirect adverse effects and first aid instructions;

(n) instructions for safe disposal of the product and its packaging;

(o) in the case of a biocidal product that is intended by its manufacturer to be used inter alia for the purposes referred to in Article 2(7), any specific conditions of use and a statement that the biocidal product is in conformity with the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC;

(p) for toxicologically and ecotoxicologically relevant components of biocidal products and residues thereof, analytical methods including recovery rates and the limits of determination (LOD).

3. In addition to paragraph 2, in the case of a frame formulation, the authorisation shall indicate, as appropriate, the following information:

(a) the reference biocidal product within the group of products comprising the frame formulation ▌;

(b) the permitted alteration of the composition of this reference biocidal product expressed ***as a reduction in the*** percentage of the ***active substances or as an alteration in the percentage of the*** non-active substances contained in the biocidal products which are considered to belong to that frame formulation;

(c) the non-active substances that may be substituted in the authorised biocidal products belonging to that frame formulation.

4. In the case of a frame formulation, one single authorisation number shall be provided for all biocidal products which belong to that frame formulation.

Article 21

Comparative assessment of biocidal products

1. The receiving competent authority or, in the case of evaluation of an application for a Union authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for an authorisation or a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1). ***The comparative assessment shall be carried out in relation to all biocidal products that have the same purpose, when sufficient experience has been gained in their use and they have been in use for at least five years.***

2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission.

3. The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:

(a) for the uses specified in the application, ***other*** authorised biocidal ***products*** already ***exist*** which ***present*** significantly lower risk for human or animal health or the environment ***and which prove equally effective and involve no significant increase in the risks for any other parameter***;

(b) the biocidal product or non-chemical control or prevention method referred to in point (a) does not present significant economic or practical disadvantages;

(c) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

4. The Commission shall, on the basis of paragraph 3, adopt measures laying down the procedure necessary for the definition of an application for comparative assessment of biocidal products. Those measures shall define the criteria and algorithms to be used in a comparative assessment to ensure that there is uniform application throughout the Union.

5. Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt its decision in accordance with Article 76(3).

In order to specify the procedures relating to comparative assessments involving questions of Union interest, ***the Commission shall adapt the criteria by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***.

6. Notwithstanding Article 15(4), an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for ***periods*** not exceeding five years.

Member States shall establish and implement a substitution plan in order to ensure that the application of the relevant biocidal product is phased out within the authorisation period and that the relevant active substance or product can be replaced with sound chemical or non-chemical alternatives.

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or modification of the authorisation shall take effect ***three years*** after the decision or at the end of the inclusion period of the candidate for substitution, whichever is the earlier.

CHAPTER V

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 22

Submission and validation of application

1. ***The person responsible for the placing of a biocidal product on the market, or his representative, shall submit*** an application for a national ***or Union*** authorisation ***to the Agency and inform the Agency of the name of the receiving competent authority. The Agency shall, within three weeks after receipt of the application, notify the receiving competent authority or, in the case of an application for a Union authorisation, the evaluating competent authority, that the application is available in the Agency database.***

2. ***Within three weeks after receipt of an application, the Agency shall validate the application if it complies with the following requirements:***

(a) the documents referred to in Article 18 have been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

3. ***If the Agency*** considers that the application is ***incomplete***, it shall ▌ inform the applicant ***what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information***.

The Agency shall, within three weeks after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant does not submit the required additional information on time, and shall notify the applicant and the receiving competent authority of the rejection.

In such cases, part of the fees payable to the Agency under Article 71 shall be reimbursed.

4. An applicant may, in accordance with Article 68, submit an appeal against the decision of the Agency under the third subparagraph of paragraph 3.

5. If the Agency considers, on the basis of the validation made pursuant to paragraph 2, that the application is complete, it shall without delay inform the applicant and the receiving competent authority to that effect.

Article 23

Evaluation of application

1. The receiving competent authority shall, within ***six months*** of the validation referred to in Article 22, decide on the application in accordance with Article 16.

2. If an application relating to the same biocidal product is being examined by the competent authority of another Member State or if the competent authority of another Member State has already authorised the same biocidal product, the receiving competent authority shall decline to assess the application and inform the applicant thereof.

However, the applicant may request that his application be assessed in accordance with Article 25 or Article 28.

3. If it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall request the applicant to submit such information. The ***six-month*** period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.

4. The receiving competent authority shall draft a report summarising the conclusions of its assessment and the reasons for authorising a biocidal product or for refusing to grant an authorisation. The receiving competent authority shall send the draft assessment report to the applicant who shall be provided with the opportunity to submit oral or written comments within one month. The receiving competent authority shall take due account of these comments when finalising its assessment.

The receiving competent authority shall approve the summary of the biocidal product characteristics referred to in Article 20(2). It shall forward the applicant a copy of the final assessment report.

5. As soon as the receiving competent authority has taken a decision on an application, it shall enter the following information in the Union Register of Biocidal Products:

(a) the summary of biocidal product characteristics;

(b) the report summarising the conclusions of the assessment of the biocidal product and the reasons for authorising, or refusing to authorise, the biocidal product;

(c) the administrative decisions taken by the receiving competent authority concerning the application.

Article 24

Renewal of a national authorisation

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least ***12 months*** before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 71.

2. The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 16 are still satisfied.

3. When applying for renewal, the applicant shall submit a list of all data relating to the biocidal product that have been generated since the previous authorisation and a justification as to whether the conclusions of the initial assessment of the biocidal product are still valid.

The receiving competent authority may require the applicant to submit the data referred to in the list at any time.

4. Within one month after receipt of an application for a renewal of a national authorisation, the receiving competent authority shall validate the application if it complies with the following requirements:

(a) the information referred to in paragraph 3 has been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

5. If the receiving competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.

The receiving competent authority shall, within one month of receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The receiving competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and inform the applicant thereof.

If the receiving competent authority considers, on basis of the validation made pursuant to paragraph 4, that the application is complete, it shall without delay inform the applicant thereof.

6. The decision on the application for renewal of the national authorisation shall be taken within six months of the validation.

7. If, when the application for renewal is evaluated, it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall ask the applicant to submit such information. The six-month period referred to in paragraph 6 shall be suspended from the date of the request until the date the information is received.

8. Where, for reasons beyond the control of the holder of the national authorisation, no decision is taken on the renewal of the national authorisation before its expiry, the receiving competent authority shall grant the renewal of the national authorisation for the period necessary to complete the evaluation.

9. As soon as the competent authority has taken a decision concerning the renewal of a national authorisation, it shall enter the information referred to in Article 23(5) in the Union Register of Biocidal Products.

CHAPTER VI

MUTUAL RECOGNITION PROCEDURES

Article 25

Mutual recognition of national authorisations in sequence

1. The holder of a national authorisation for a biocidal product granted by a competent authority in accordance with Article 15 (hereinafter the 'reference competent authority') may apply for a national authorisation of the biocidal product in another Member State under the procedure for mutual recognition in sequence.

2. The application for mutual recognition shall be accompanied by:

(a) a reference to the national authorisation granted by the reference competent authority;

(b) an electronic summary of the dossier satisfying the requirements set out in Annex III;

(c) a reference to the report of the reference competent authority summarising the conclusions of its assessment and the reasons for authorising the biocidal product.

The application shall be accompanied by the fees payable under Article 71.

3. The receiving competent authority may require a translation of the national authorisation and application into one ▌of the official languages of the Member State where that competent authority is situated.

Applications for a national authorisation which involve a mutual recognition procedure, including the documents referred to in Article 18, may be submitted to the competent authority in English.

4. The receiving competent authority shall decide on the application within four months of receipt of the application.

5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference competent authority***, unless specific national circumstances justify a deviation according to Article 29***.

A single authorisation number shall be used in all the Member States involved.

6. The Commission shall adopt, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, measures specifying the criteria and procedures for assigning the single authorisation number referred to in paragraph 5.

7. As soon as the competent authorities have taken a decision on an application for mutual recognition of a national authorisation under this Article, they shall enter the information referred to in points (a) and (c) of Article 23(5) in the Union Register of Biocidal Products.

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Article 26

Application for mutual recognition by pest control bodies

1. Where no application for a national authorisation has been submitted in a Member State for a biocidal product that is already authorised in another Member State, official or scientific bodies involved in pest control activities or professional organisations may apply, with the consent of the authorisation holder in another Member State, for a national authorisation for the same biocidal product, the same use and under the same conditions for use in that Member State under the mutual recognition procedure provided for in Article 25.

The applicant shall demonstrate that the use of such a biocidal product is of general interest for that Member State.

The application shall be accompanied by the fees payable under Article 71.

2. By way of derogation from paragraph 1, where the authorisation holder does not give his consent, the applicant may indicate that in the application and the competent authority of the Member State concerned may accept the application on grounds of public interest.

3. If the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 16 and the conditions under this Article are complied with, the competent authority shall authorise the placing of the biocidal product on the market.

4. The official or scientific bodies involved in pest control activities or professional organisations shall have the rights and obligations of the authorisation holder.

Article 27

Objections regarding the conditions for a national authorisation

1. Where, within four months of receipt of the application for mutual recognition, the competent authority considers that a biocidal product, which has been authorised in another Member State, does not satisfy the requirements of Article 16, it shall without delay notify the Commission, the competent authorities of the other Member States and the applicant thereof, and shall provide them with an explanatory document identifying the biocidal product and its specifications and setting out the grounds on which it proposes to refuse to recognise or to restrict the national authorisation.

The Commission shall***, after consultation with the applicant,*** adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 76(3).

Within three months of receipt of the notification, the Commission shall make a proposal for a decision. Should the Commission ask the Agency for an opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.

2. If the Commission decision confirms the grounds presented for refusing or restricting the subsequent authorisation, the competent authority that had previously authorised the biocidal product shall without delay review its national authorisation to comply with that decision.

If the Commission decision confirms the initial national authorisation, the competent authority that proposed to refuse to recognise a national authorisation, or to recognise the national authorisation subject to certain conditions, shall without delay authorise the biocidal product concerned in accordance with the initial authorisation.

Article 28

Mutual recognition of national authorisations in parallel

1. If the applicant seeks to receive national authorisations for a biocidal product in more than one Member State in parallel, he shall submit to a reference competent authority of his choice an application containing:

(a) the documents referred to in Article 18;

(b) a list of all other Member States where a national authorisation is sought (hereinafter the 'other Member States concerned').

The application shall be accompanied by the fees payable under Article 71.

The reference competent authority shall be responsible for the evaluation of the application.

2. The applicant shall submit to the competent authorities of the other Member States concerned an application for mutual recognition of the authorisation for which it has applied to the reference competent authority. This application shall contain:

(a) an electronic summary of the dossier as required in Annex III;

(b) the names of the reference competent authority and of the other Member States concerned.

3. The reference competent authority shall, within one month after receipt of an application referred to in paragraph 1, validate the application if it complies with the following requirements:

(a) the information referred to in paragraph 1 has been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

4. If the reference competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. The reference competent authority shall also inform the other Member States concerned.

The reference competent authority shall, within one month after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The reference competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the other Member States concerned thereof.

5. If the reference competent authority considers, on the basis of the validation made pursuant to paragraph 3, that the application is complete, it shall without delay inform the applicant and the other Member States concerned.

6. The reference competent authority shall evaluate the information referred to in paragraph 1 and prepare a report summarising the conclusions of its assessment and a draft of the summary of the biocidal product characteristics within 12 months from the receipt of a valid application and shall communicate the report and the draft summary to the competent authorities of other Member States concerned and the applicant. The reference competent authority shall send the draft assessment report to the applicant who shall be provided with the opportunity to submit oral or written comments within one month. The reference competent authority shall take due account of these comments when finalising its assessment.

7. Within four months after receipt of the documents referred to in paragraph 6, the competent authorities of other Member States concerned shall approve the assessment report and the summary of the product characteristics, and shall inform the reference competent authority accordingly.

8. The reference competent authority and the competent authorities of the other Member States concerned shall authorise the biocidal product on the basis of the approved assessment report and the summary of the biocidal product characteristics within one month after the end of the period referred to in paragraph 7.

A single authorisation number shall be used in all the Member States involved.

The Commission shall adopt, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, measures specifying the criteria and procedures for assigning the single authorisation number.

9. If one or more competent authorities of other Member States concerned have not approved the assessment report and the summary of the biocidal product characteristics within four months after receipt of the documents referred to in paragraph 6, they shall notify the Commission, the applicant, the reference competent authority and the competent authorities of other Member States concerned and shall provide them with an explanatory document identifying the biocidal product and its specifications and setting out the grounds on which they propose to refuse to recognise, or to restrict, the national authorisation.

The Commission shall***, following consultation of the applicant,*** adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 76(3).

This decision shall be taken within three months of the notification by the competent authority referred to in the first subparagraph. If the Commission requests an opinion from the Agency pursuant to Article 30, the three-month period shall be suspended until the Agency submits its opinion.

If the Commission decision ***confirms*** the grounds presented for refusing or restricting the ***subsequent*** authorisation, the competent authority that ***had previously authorised the biocidal product*** shall without delay ***review its*** national authorisation ***to comply with that decision***.

If the Commission decision confirms the initial national authorisation, the competent authority that proposed to refuse to recognise a national authorisation, or to recognise the national authorisation subject to certain conditions, shall without delay authorise the biocidal product concerned in accordance with the initial authorisation.

10. As soon as the competent authorities have taken a decision on an application for a national authorisation in more than one Member State in parallel, they shall enter information referred to in Article 23(5), where applicable, in the Union Register of Biocidal Products.

Article 29

Adjustment to local circumstances

1. The competent authority that has received an application for mutual recognition in accordance with Articles 25 or 28 may, within two months from the receipt of the application, propose to the applicant that certain conditions referred to in points ***(e),*** (f), (g), (j), (l)***, (m)*** and (n) of Article 58(2) in the authorisation be adjusted to local circumstances, so that conditions for issue of an authorisation laid down in Article 16 are satisfied, and shall inform the Commission thereof, if it establishes that, in its territory, one of the following conditions is met:

(a) the target species is not present in harmful quantities;

(b) unacceptable tolerance or resistance of the target organism to the biocidal product is demonstrated;

(c) the relevant circumstances of use, in particular the climate or the breeding period of the target species, differ significantly from those in the Member State where the initial evaluation was carried out or the Member State where the initial national authorisation was issued ▌;

(d) an unchanged national authorisation presents harmful effects on human health or unacceptable effects on the environment.

The competent authorities shall communicate to the Commission all proposals concerning adjustment of conditions in national authorisations to local circumstances and the reasons for proposing adjustment.

2. Subject to Union law, appropriate conditions may be imposed with respect to the requirements referred to in Article 15 and other risk-mitigation measures deriving from specific conditions of use.

3. If, within 2 months, an agreement on the proposed adjustments is not reached between the applicant and the competent authority that has received an application for mutual recognition, that competent authority shall without delay inform the Commission thereof and provide an explanatory document on the proposed adjustments identifying the biocidal product and its specifications and setting out the grounds on which it proposes to adjust the conditions of the national authorisation.

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Article 30

Opinion of the Agency

1. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a Member State objecting to the mutual recognition of a national authorisation or seeking to adjust the authorisation to local circumstances. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.

2. Before issuing its opinion, the Agency shall provide the applicant or the authorisation holder with an opportunity to present written or oral explanations within a specified time limit not exceeding one month.

The Agency may suspend the time limit referred to in paragraph 1 to allow the applicant or the authorisation holder to prepare the explanations.

Article 31

Derogation regarding certain ***active substances or*** product-types

By way of derogation from ***Articles 25 to 29***, competent authorities of Member States may refuse mutual recognition of national authorisations granted for ***biocidal products containing active substances referred to in Articles 5 and 9 and for*** product types 15, 17 and 23 of Annex V, provided that such a refusal can be justified on grounds of the protection of health of humans, ***particularly the health of vulnerable groups, the protection of the health of*** animals or plants, the protection of ***the environment***, national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

Wednesday 22 September 2010

CHAPTER VII

UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

Section 1

Granting of Union authorisations

Article 32

Union authorisation

A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each of the Member States as an authorisation issued by the competent authority of that Member State.

Article 33

Biocidal products for which Union authorisation may be granted

1. ***From 2013,*** the Union authorisation may be granted to the following categories of biocidal products:

(a) biocidal products containing one or more new active substances;

(b) low-risk biocidal products.

2. ***From 2017, the Union authorisation may be granted to all categories of biocidal products with the exception of biocidal products that contain active substances that fall under Article 5.***

Article 34

Submission and validation of application

1. The person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a Union authorisation to the Agency and inform the Agency of the name of the competent authority of the Member State of his choice which shall be responsible for the evaluation of the application (hereinafter the 'evaluating competent authority').

The Agency shall, within one month after receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

2. Within two months after receipt of an application, the Agency shall validate the application if it complies with the following requirements:

(a) the documents referred to in Article 18 has been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

3. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.

The Agency shall, within two months from the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to complete the application within the deadline and shall inform the applicant and the evaluating competent authority thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

4. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 3 of this Article.

5. If the Agency considers, on the basis of the validation made pursuant to paragraph 2, that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 35

Evaluation of applications

1. The evaluating competent authority shall, within twelve months after the validation, evaluate the dossiers in accordance with Article 16 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 19(2).

The evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the conclusions of the evaluation within one month. The evaluating competent authority shall take due account of these comments when finalising its evaluation.

The evaluating competent authority shall send the conclusions of the assessment and the assessment report to the Agency.

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency thereof.

The twelve-month period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.

3. Within ***three*** months from receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least the following elements:

(a) a statement on whether the conditions of points (b), (c) and (d) of Article 16(1) are fulfilled, and a draft summary of the biocidal product characteristics, as referred to in Article 20(2);

(b) where relevant, details of any terms or conditions which should be imposed on the placing on the market or use of the biocidal product;

(c) the final assessment report on the biocidal product.

4. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the Union authorisation of the biocidal product in accordance with the procedure referred to in Article 76(3). As soon as the Commission has taken a decision to grant a Union authorisation, it shall enter the information referred to in Article 23(5) in the Union Register of Biocidal Products.

The ▌Member State ***shall notify the Commission where it restricts or prohibits*** the Union authorisation ▌ for a biocidal product of the product-types 15, 17 or 23 of Annex V ***in the territory of that Member State. Such restriction or prohibition must*** be justified on grounds of the protection of:

(a) human health, ***particularly the health of vulnerable groups,***

(b) the environment, particularly vulnerable ecosystems,

(c) animals***,***

(d) plants***,***

(e) national treasures possessing artistic, historic or archaeological value, or

(f) industrial and commercial property.

If a Member State decides that ▌the Union authorisation should be adjusted to the different local circumstances in that Member State in accordance with Article 29***, it shall inform the Commission thereof***.

5. If the decision referred to in the first subparagraph of paragraph 4 is to refuse to grant a Union authorisation to a biocidal product because it does not fulfil the criteria for a low-risk biocidal product in accordance with Article 17, the applicant may apply, if relevant, for a Union authorisation in accordance with point (a) of Article 33(1) or a national authorisation in accordance with Chapter V.

6. The competent authority that has been notified of the application for the evaluation as referred to in Article 34(1) may, within one month after receipt of the notification, submit a duly substantiated request to the Commission to appoint another evaluating competent authority. The Commission shall take a decision in accordance with the procedure referred to in Article 76(2).

Section 2

Renewal of Union authorisations

Article 36

Submission and validation of applications

1. The authorisation holder or his representative shall submit an application for renewal of a Union authorisation to the Agency at least ***12 months*** before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 71.

2. The Agency shall, within one month after receipt of the application, notify the evaluating competent authority that carried out the initial evaluation of the application for Union authorisation that the application is available in the Agency database.

3. The Commission shall renew a Union authorisation, provided that the conditions set out in Article 16 are still satisfied.

4. When applying for renewal, the applicant shall submit a list of all data relating to the biocidal product that have been generated since the previous authorisation and a justification as to whether the conclusions of the initial assessment of the biocidal product are still valid.

The evaluating competent authority that carried out the initial evaluation may require the applicant to submit the data referred to in the list at any time.

5. Within two months after receipt of an application, the Agency shall validate the application if it complies with the following requirements:

(a) the documents referred to paragraph 4 has been submitted;

(b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

6. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.

The Agency shall, within two months after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

7. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 6 of this Article.

8. If the Agency, on basis of the validation made pursuant to paragraph 5, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 37

Evaluation of applications for renewal

1. On the basis of the available information and a need to review the conclusions of the initial assessment of the application for Union authorisation, the evaluating competent authority that carried out the initial evaluation of the application for Union authorisation shall, within one month after the validation referred to in Article 36(5), decide whether a full evaluation of the application for renewal is necessary.

If the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 to 3 of Article 35. The decision on the application shall be adopted in accordance with paragraph 5 of this Article.

2. If the evaluating competent authority that carried out the initial evaluation of the application for Union authorisation decides that a full evaluation of the application is not necessary, it shall, within ***six months*** after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

Prior to submitting the recommendation to the Agency, the evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the recommendation within one month. The evaluating competent authority shall take due account of these comments when finalising its recommendation.

3. On receipt of the recommendation from the evaluating competent authority, the Agency shall make it available to the competent authorities of other Member States and the applicant and allow a period of three months during which they may submit written comments to it.

4. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a competent authority objecting to the recommendation referred to in paragraph 2. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.

5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision to renew, or to refuse to renew, the Union authorisation in accordance with the procedure referred to in Article 76(3). As soon as the Commission has taken a decision, it shall update the information referred to in Article 23(5) in the Union Register of Biocidal Products.

6. Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation in accordance with the procedure referred to in Article 76(2).

CHAPTER VIII

CANCELLATION, REVIEW AND MODIFICATIONS OF AUTHORISATIONS

Article 38

Obligation for notification of new information

1. If the authorisation holder becomes aware of information concerning the authorised biocidal product or the active substance(s) it contains which may affect the authorisation, he shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified:

(a) new knowledge or information on the effects of the active substance or biocidal product for humans***, especially for vulnerable groups,*** or the environment;

(b) data indicating the potential of the active substance for the development of resistance;

(c) new knowledge or information indicating that the biocidal product is not sufficiently effective;

(d) changes in the source or composition of the active substance.

2. The competent authority that granted the national authorisation or in the case of a Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 39.

3. The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such information it received.

Competent authorities of Member States that have issued national authorisations for the same biocidal product under the mutual recognition procedure shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 39.

Article 39

Cancellation or modification of an authorisation

1. The competent authority of a Member State or, in the case of a Union authorisation, the Commission, may at any time cancel or amend an authorisation it has granted in the following cases:

(a) ***where there is failure to comply with*** the requirements referred to in Article 16 ***or with Union standards for the protection of human health and the environment, particularly those laid down in Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive) ([1]), Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration ([2]), Directive 2000/60/EC, Directive 98/83/EC and Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control ([3]);***

(b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;

(c) a condition included in the authorisation has not been complied with;

(d) the authorisation holder fails to comply with his obligations resulting from this Regulation;

(e) there are indications that the objectives of Article 4(1)(a)(iv), Article 4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.

2. Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give him the opportunity to submit written or oral comments or additional information within a specified time limit. The evaluating competent authority shall take due account of these comments when finalising its decision.

3. Where the competent authority or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

Competent authorities which have issued authorisations for the same biocidal product under the mutual recognition procedure shall, within four months, cancel or amend the authorisations accordingly, taking into account local circumstances, and shall notify the Commission thereof.

In the case of disagreement between competent authorities of certain Member States, the points of disagreement shall be referred without delay to the Commission and the procedure laid down in Articles 27 and 30 shall apply mutatis mutandis.

4. As soon as the competent authority or the Commission in the case of a Union authorisation, has taken a decision to cancel or amend an authorisation, it shall update the information referred to in Article 23(5) relating to the biocidal product concerned in the Union Register of Biocidal Products.

Article 40

Cancellation of an authorisation at the request of the authorisation holder

The competent authority that has granted the national authorisation or, in case of Union authorisation, the Commission, shall cancel the authorisation at the request of its holder, who shall state the reasons for such request. If such a request concerns a Union authorisation, it shall be submitted to the Agency.

([1]) ***OJ L 164, 25.6.2008, p. 19***.
([2]) ***OJ L 372, 27.12.2006, p. 19***.
([3]) ***OJ L 24, 29.1.2008, p. 8***.

As soon as the competent authority or the Commission in the case of a Union authorisation, has taken a decision to cancel an authorisation, it shall update the information referred to in Article 23(5) information relating to the biocidal product concerned in the Union Register of Biocidal Products.

Article 41

Modification of an authorisation at the request of the authorisation holder

1. The terms and conditions of an authorisation shall not be changed unless the authorisation has been amended by the competent authority which has previously authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission.

2. An application by an authorisation holder to amend the terms and conditions of an authorisation shall be submitted to the competent authorities of all the Member States which have previously authorised the biocidal product concerned, or in the case of a Union authorisation, to the Agency.

The application shall be accompanied by the fees payable under Article 71.

3. A modification of an existing authorisation shall fall under one of the following categories of changes:

(a) administrative change;

(b) minor change;

(c) major change.

Article 42

Detailed procedures on cancellation and modifications

1. In order to ensure the smooth functioning of the cancellation and modification procedures, the Commission shall adopt ***further detailed*** measures specifying the criteria and procedures relating to a cancellation of an authorisation or modifications of the terms and conditions of an authorisation under Articles 39 to 41, including a dispute settlement mechanism***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***.

2. The criteria and the procedures referred to in paragraph 1 shall be based on, but not limited to, the following principles:

(a) a simplified notification procedure shall be applied for administrative changes to the authorisation;

(b) a reduced evaluation period shall be established for minor changes to the authorisation;

(c) in the case of major changes the evaluation period shall be proportionate to the extent of the proposed change.

Article 43

Period of grace

Notwithstanding Article 82, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the disposal, storage, placing on the market and use of existing stocks except in cases where continued placing on the market or use of the product would constitute an unacceptable risk to human health or the environment.

The period of grace shall not exceed six months for the placing on the market and an additional maximum period of twelve months for the disposal, storage, and use of existing stocks of the biocidal products concerned.

Article 44

Parallel trade

1. A competent authority of a Member State (hereinafter 'Member State of introduction') may grant a parallel trade permit for a biocidal product that is authorised in another Member State (hereinafter 'Member State of origin') to be placed on the market and used in the Member State of introduction, if it determines that the biocidal product is ▌identical in composition to a biocidal product already authorised in that Member State (hereinafter the 'reference product').

The applicant who intends to place the biocidal product on the market in the Member State of introduction shall submit the application for a parallel trade permit to the competent authority of the Member State of introduction.

The application shall be accompanied by all the information necessary to demonstrate that the biocidal product is ▌identical to the reference product as defined in paragraph 3.

2. A parallel trade permit shall be granted within two months from submission of an application. The competent authority of the Member State of introduction may request from the competent authority of the Member State of origin additional information necessary to determine whether the product is ▌identical to the reference product. The competent authority of the Member State of origin shall provide the requested information within one month of receiving the request.

3. A biocidal product shall be considered as ▌identical to the reference product if ***all*** of the following conditions ***are*** met:

(a) ***it has been manufactured by the same company or by an associated undertaking or under licence in accordance with*** the same ***manufacturing process***;

(b) it is ***identical*** with regard to the ***specification and content of the active*** substances ▌and ***in*** the type of formulation;

(c) it is either the same or equivalent ***with regard to the co-formulants present and the packaging size, material or form,*** in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

4. An application for a parallel trade permit shall include the following information and items:

(a) name and authorisation number of the biocidal product in the Member State of origin;

(b) the registration numbers of the active substances contained in the product and a letter of access in accordance with Article 50 from the applicant referred to in Article 7;

(c) the competent authority of the Member State of origin that authorised the reference product;

(d) name and address of the authorisation holder in the Member State of origin ***and a letter of access in accordance with Article 50 from the authorisation holder***;

(e) original label and instructions for use with which the biocidal product is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction;

(f) name and address of the applicant;

(g) name to be given to the biocidal product to be distributed in the Member State of introduction;

(h) a draft label for the product intended to be placed on the market in the Member State of introduction;

(i) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

(j) name and authorisation number of the reference product in the Member State of introduction.

The competent authority of the Member State of introduction may require a translation of the relevant parts of the original instructions for the use referred to in point (e).

5. The parallel trade permit shall prescribe the same conditions for placing on the market and use as the authorisation of the reference product.

6. The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.

If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 40 and the requirements of Article 16 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would have normally expired.

7. Without prejudice to specific provisions in this Article, Articles 38 to 41 and Chapter XIII shall apply mutatis mutandis to biocidal products placed on the market under a parallel trade permit.

8. The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.

9. Where a decision concerning the application for a parallel trade permit is taken in accordance with the provisions of this Article, the competent authorities of Member States which have taken such a decision shall enter the information referred to in Article 23(5) in the Union Register of Biocidal Products.

CHAPTER IX

DEROGATIONS

Article 45

Derogation from the requirements

1. By way of derogation from Articles 15 and 16, a competent authority may authorise, for a period not exceeding ***four months***, the placing on the market of a biocidal product not complying with the provisions of this Regulation for a limited and controlled use if ***all of the following conditions are met:***

(a) such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means;

(b) the active substances concerned are approved for inclusion in Annex I or evaluated according to Article 4 and a full dossier is provided;

(c) if the relevant active substances fall under Article 5 or are classified as candidates for substitution according to Article 9, a mandatory substitution plan has been established and implemented by the applicant or competent authority in order to replace the relevant substances with non-hazardous chemical or non-chemical alternatives within two years of the date of approval; and

(d) the application of the product is restricted to professional users who are certified pursuant to the requirements for integrated pest management and the use is appropriately monitored.

The competent authority referred to in the first subparagraph shall without delay inform the other competent authorities and the Commission of its action and the justification for it. The competent authority shall without delay inform the other competent authorities and the Commission of a revocation of such action.

The Commission shall without delay decide whether, and under what conditions, the action taken by the competent authority may be extended for a period not exceeding 18 months in accordance with the procedure referred to in Article 76(3).

▌

2. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in biocidal products which are authorised for placing on the market in accordance with this Article shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of Regulation (EC) No 1907/2006.

Article 46

Research and development

1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs of this paragraph.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

In the case of product and process-oriented research and development, the person who intends to carry out the experiment or the test shall, prior to the placing of the biocidal product or the active substance on the market, notify the information required in the second subparagraph to the competent authority of the Member State where the placing on the market occurs.

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a national authorisation for this purpose which limits the quantities to be used and the areas to be treated and which may impose further conditions. The competent authority shall without delay inform the Commission and other competent authorities about the issued national authorisation.

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall obtain experiment or test authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted.

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects***, whether immediate or delayed,*** on human ***health, in particular on the health of children,*** or animal health or any unacceptable adverse effect on the environment***, humans, or animals***, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.

4. ***In order to encourage research and development in active substances and biocidal products,*** the Commission shall adopt***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75,*** measures to specify the overall applicable maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted in accordance with paragraph 2 of this Article.

▌

CHAPTER X

TREATED ARTICLES OR MATERIALS

Article 47

Placing on the market of treated articles or materials

1. Treated materials or articles that incorporate one or more biocidal products shall not be placed on the market unless the ***active substances*** used for treating the materials or articles are ***included in Annex I.***

2. The person responsible for placing treated articles or materials on the market shall obtain a letter of certification by the authorisation holder in respect of all biocidal products which have been used in the treatment of those articles or materials or which have been inserted into the articles or materials.

3. Treated articles or materials shall be labelled with the following information:

(a) the ***words 'treated with biocidal products', followed by the*** name, ***using wherever possible common nomenclature (e.g. INCI),*** of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials***, where relevant, and of all active substances which are intended to be released under normal or foreseeable conditions of use from the treated article or material, unless at least equivalent labelling requirements or alternative means to meet information requirements already exist under sector-specific legislation, the names of all nanomaterials being followed by the word 'nano' in brackets***;

(b) ▌ the biocidal property attributed to treated articles or materials***, if the biocidal product contained therein will come into direct contact with people and the environment***;

▌

(c) any hazard statement or precautionary statement set out in the authorisation for the biocidal product ***if the biocidal product is intended to be released under normal or reasonably foreseeable conditions of use***.

The labelling shall be clearly visible, easily legible, appropriately durable ***and*** printed ***on the article or material,*** on the packaging, on the instructions for use or on the warranty of the treated article or material ***in the national language or languages of the Member State on whose market the treated article or material is to be placed***.

In the case of treated materials or articles which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

This paragraph shall not apply where such labelling requirements already exist under other Union legislation.

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CHAPTER XI

DATA PROTECTION AND DATA-SHARING

Article 48

Protection of information held by competent authorities or the Agency

1. Information submitted for the purposes of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except in one of the following cases:

(a) the subsequent applicant has written agreement in the form of a letter of access ***in accordance with Article 50*** that he can use that information,

(b) the relevant time limit for data protection has expired;

(c) the subsequent applicant is also an owner of the information.

2. When an applicant submits any information to a competent authority or to the Agency, he shall also provide a list of all the information submitted. In the list he shall specify whether he is the owner of the information or whether he only holds a letter of access to that information. In the latter case, the list shall contain the name and contact details of the owner. The applicant shall inform the competent authority or the Agency about any changes in the ownership of the information.

3. On receipt of the list referred to in paragraph 2, the competent authorities shall send it to the Agency.

4. ***Each item of information in*** the list referred to in paragraph 2 shall be ***identified by a unique code and*** entered by the Agency, ***with all relevant details and linked to the identity of the initial applicant and the information owner,*** in the Biocides Data Sharing Register.

5. The Commission, the Agency, the advisory scientific committees set up under Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment ([1]) and the competent authorities shall have access to the information referred to in paragraph 1.

Article 49

Information protection periods

1. Information submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for this information shall start when the information is submitted.

Information protected under Directive 98/8/EC ▌ for which the protection period expired under Directive 98/8/EC or ***information protected under this Article*** shall***, on application,*** be protected again.

An entry date shall be individually established for each document that has been given a unique code in accordance with Article 48(4).

2. The protection period for information submitted in view of the inclusion of an existing active substance in Annex I shall end 10 years after the date of the inclusion of the relevant active substance in Annex I for the particular product-type.

The protection period for information submitted in view of the inclusion of a new active substance in Annex I shall end 15 years after the date of the inclusion of the relevant active substance in Annex I for the particular product-type.

([1]) OJ L 66, 4.3.2004, p. 45.

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The protection period for information submitted in view of the renewal or review of the inclusion of an active substance in Annex I shall end 5 years after the date of the decision concerning the renewal or the review being taken.

3. The protection period for information submitted in view of the authorisation of a biocidal product containing only existing active substances shall end 10 years after the date of the first authorisation of the product.

The protection period for information submitted in view of the authorisation of a biocidal product containing a new active substance shall end 15 years after the date of the first authorisation of the product.

The protection period for information submitted in view of the renewal or modification of the authorisation of a biocidal product shall end 5 years after the date of the renewal or modification of the authorisation.

▌

Article 50

Letter of access

1. A letter of access shall contain at least the following information:

(a) name and contact details of the data owner and the beneficiary;

(b) date on which the letter of access takes effect and its expiry date;

(c) the submitted information to which the letter of access grants citation rights;

(d) the address of the manufacturing facility where the active substance or biocidal product is produced;

(e) the conditions under which it may be revoked.

2. Revocation of a letter of access prior to its expiry date shall not affect the validity of the authorisation issued on the basis of the letter of access in question.

Article 51

Mandatory information sharing

1. ***Given that*** animal testing ***should be avoided***, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort ***where no alternative solution can be employed without producing an impact on humans or animals***. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.

2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals (hereinafter the 'prospective applicant'), shall ask the competent authority or the Agency whether such tests or studies have already been submitted in connection with a previous application. The competent authority or the Agency shall verify if there is any data on such tests or studies in the Biocides Data Sharing Register.

Where those tests or studies have already been submitted in connection with a previous application, ***the competent authority or the Agency shall, without delay, assess technical equivalence in relation to the comparison source. If the technical equivalence assessment is positive,*** the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

Where the data acquired under those tests or studies are still protected under Article 49, and involve tests on vertebrate animals, the prospective applicant shall request from the owner of the information the right to refer to the tests or studies.

Where the data acquired under those tests or studies are still protected under Article 49, and do not involve tests on vertebrate animals, the prospective applicant may request from the owner of the information the right to refer to the tests or studies.

Article 52

Compensation for mandatory information sharing

1. Where a request has been made in accordance with Article 51(2), the prospective applicant and the owner of the information shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.

2. Where such agreement is reached, the owner of the information shall make available to the prospective applicant the information and shall give the prospective applicant permission to refer to the data owner's tests or studies.

3. Where no such agreement is reached two months after the request was made according to Article 51(2), the prospective applicant shall without delay inform the Agency and the owner of the information thereof. Within two months of being informed about the failure to reach an agreement, the Agency shall give the prospective applicant the right to refer to the tests or studies involving tests on vertebrate animals. National courts shall decide on the proportionate share of the cost that the prospective applicant shall pay to the data owner.

4. The costs of sharing the tests or studies shall be determined in a fair, transparent and non-discriminatory manner.

5. An appeal may be brought, in accordance with Article 68, against Agency decisions under paragraph 3 of this Article.

Article 53

Use of data for subsequent applications for authorisations

1. In the case of a biocidal product which has already been authorised in accordance with Articles 15, 25 or 28, and where all periods of protection of information according to Article 49 have expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant***, and if the periods of protection of information according to Article 49 have not expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant pursuant to Article 52, in both cases*** in so far as the subsequent applicant can provide evidence that the biocidal product is similar to, and its active substances technically equivalent to, the one formerly authorised, including in terms of degree of purity and nature of impurities.

An appeal may be brought, in accordance with Article 68, against Agency decisions under the first subparagraph of this paragraph.

2. Notwithstanding paragraph 1, subsequent applicants shall provide the following information accordingly to the receiving competent authority or the Agency:

(a) all data necessary for the identification of the biocidal product, including its composition;

(b) the information needed to identify the active substance and to establish technical equivalence of the active substance;

(c) all data necessary for the evaluation of substances of concern contained in the biocidal product;

(d) the data needed to demonstrate that the biocidal product has comparable efficacy to the biocidal product formerly authorised in accordance with Articles 15, 25 or 28.

CHAPTER XII

INFORMATION AND COMMUNICATION

Section 1

Monitoring and reporting

Article 54

Compliance with requirements

1. Competent authorities shall perform official controls in order to ensure that manufacturers of active substances which are placed on the market for use in biocidal products have submitted to the Commission the information about the active substances referred to in Annex II or are in the possession of a letter of access to a dossier which complies with the requirements of Annex II.

2. Competent authorities shall make the necessary arrangements for biocidal products which have been placed on the market on their own or incorporated in treated materials to be monitored to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [1] shall apply accordingly.

3. Competent authorities shall carry out official controls in order to enforce compliance with this Regulation.

4. Every ***year***, starting in 2013, competent authorities shall submit to the Commission a report on the implementation of this Regulation in their respective territories. ***The implementation reports shall be published annually on the relevant website of the Commission.*** The reports shall include:

(a) information on the results of official controls carried out in accordance with paragraph 3;

(b) information on any poisonings involving biocidal products***, especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases arising***;

(c) information on the impact on the environment.

5. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Union authorisation procedure and mutual recognition, by ***1 January 2019 and every three years thereafter***. The Commission shall submit the report to the European Parliament and the Council.

On the basis of the report, the Commission shall assess the desirability of proposing amendments to this Regulation.

6. Not later than … [2], the Commission shall submit to the European Parliament and Council a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them.

[1] OJ L 218, 13.8.2008, p. 30.
[2] ***Two years after the entry into force of this Regulation.***

7. Not later than … [1], the Commission shall draw up a report on the impact of the spread of biocidal products in the environment. The Commission shall submit the report to the European Parliament and the Council.

Article 55

Confidentiality

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2] and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.

2. Disclosure of the following information shall be deemed to undermine the protection of the commercial interests of the person concerned:

(a) details of the full composition of a biocidal product;

(b) the precise use, function or application of a substance or mixture;

(c) the precise tonnage of the substance or mixture manufactured or placed on the market;

(d) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;

(e) names and addresses of manufacturers of the active substances, including location of manufacturing sites;

(f) the location of a biocidal product's manufacturing site.

However, where urgent action is essential to protect human health, safety or the environment, the Agency or the competent authorities ***shall take the necessary measures to*** disclose the information referred to in this paragraph.

3. Any person who submits information related to an active substance ***or a biocidal product*** to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 56(2) not be made available including a justification as to why the disclosure of the information could be harmful for his or any other concerned party's commercial interests.

4. Information accepted as confidential by a competent authority or the Agency shall be treated as confidential by the other competent authorities, the Agency and the Commission.

Article 56

Electronic public access

1. The following information held by the competent authorities, the Agency or, as appropriate, the Commission on active substances shall be made, free of charge, publicly available ***in a single database, in a structured format, at least on the relevant website of the Commission***:

(a) without prejudice to point (f) of paragraph 2, the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature for active substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/ 2008:

(i) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

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[1] ***Five years after the entry into force of this Regulation.***
[2] OJ L 145, 31.5.2001, p. 43.

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(ii) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(iii) hazard class 4.1;

(iv) hazard class 5.1;

(b) if applicable, the name of the active substance as given in European Inventory of Existing Commercial Chemical Substances (EINECS);

(c) the classification and labelling of the active substance;

(d) physicochemical data concerning the active substance and data on pathways and environmental fate;

(e) where the active substance qualifies as persistent, bio-accumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006 or as an endocrine disrupter or where it has been classified in accordance with Regulation (EC) No 1272/2008 as carcinogenic, mutagenic, neurotoxic, immunotoxic, toxic to reproduction or sensitising, a clear reference to that effect;

(f) the result of each toxicological and ecotoxicological study;

(g) acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI to this Regulation;

(h) the guidance on safe use provided in accordance with Annex II and Annex III to this Regulation;

(i) analytical methods if requested in accordance with Annex II or III to this Regulation which make it possible to detect a dangerous substance when discharged into the environment***, including water resources and drinking water,*** as well as to determine the direct exposure of humans.

If the information listed in the first subparagraph concerns a new active substance, it shall be made publically available only after the date on which the inclusion of the new active substance in Annex I to this Regulation becomes effective.

2. The following information on active substances whether on their own, in mixtures or in materials or articles, or information on biocidal products shall be made publicly available, free of charge, except where a party submitting the information submits a justification in accordance with Article 55(3), accepted as valid by the competent authority, the Agency or, as appropriate, the Commission, as to why such publication is potentially harmful for the commercial interests of the applicant or any other party concerned:

(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;

(b) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);

(c) information, other than that listed in paragraph 1, contained in the safety data sheet;

(d) the trade name(s) of the substance;

(e) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for active substances referred to in point (a) of paragraph 1 that are only used as one or more of the following:

(i) in scientific research and development;

(ii) in product and process orientated research and development.

3. After the authorisation has been granted, confidentiality shall not in any case apply to:

(a) the name and address of the applicant;

(b) the name and address of the biocidal product manufacturer;

(c) the name and address of the active substance manufacturer;

(d) the content of the active substance or substances in the biocidal product and the name of the biocidal product;

(e) physical and chemical data concerning the biocidal product;

(f) any ways of rendering the active substance or biocidal product harmless;

(g) a summary of the results of the tests required pursuant to Article 18 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

(h) recommended methods and precautions to reduce dangers from handling, storage, transport and use as well as from fire or other hazards;

(i) safety data sheets;

(j) methods of analysis referred to in point (c) of Article 16(1);

(k) methods of disposal of the product and of its packaging;

(l) procedures to be followed and measures to be taken in the case of spillage or leakage;

(m) first aid and medical advice to be given in the case of injury to persons.

4. Public access shall be granted free of charge to an inventory containing details of biocidal products authorised pursuant to Article 16(5) and of the corresponding manufacturers.

Article 57

Record-keeping and reporting

1. Producers, importers and professional users of biocidal products shall keep records of the biocidal products they produce, place on the market or use for at least ***10 years***. They shall make available the relevant information contained in these records to the competent authority on request.

2. The Commission shall adopt implementing measures to specify the form and content of the information in the records, and to ensure the uniform application of paragraph 1 in accordance with the procedure referred to in Article 76(3).

Section 2

Information about biocidal products

Article 58

Classification, packaging and labelling of biocidal products

1. Biocidal products shall be classified, packaged and labelled in accordance with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008 and the approved summary of the biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 20(2).

In addition, products which may be mistaken for food, drink or feedingstuffs shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption.

2. Labels shall not be misleading and, in any case, shall not mention indications such as 'low-risk biocidal product', 'non-toxic' or 'harmless'. In addition, the label must show clearly and indelibly the following information:

(a) the identity of every active substance and its concentration in metric units;

(b) the authorisation number allocated to the biocidal product by the competent authority;

(c) whether the product contains nanomaterials and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets;

(d) the type of mixture;

(e) the uses for which the biocidal product is authorised;

(f) directions for use and the dose rate, expressed in metric units ***or in another manner which is meaningful and comprehensible to the user***, for each use provided for under the terms of the authorisation;

(g) particulars of likely direct or indirect adverse side effects and any directions for first aid;

(h) if accompanied by a leaflet, the sentence 'Read attached instructions before use';

(i) where applicable, warnings for vulnerable groups;

(j) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;

(k) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

(l) the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport;

(m) where applicable, the categories of users to which the biocidal product is restricted;

(n) where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;

(o) for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC.

By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (d), (f), (g), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3. ▌Biocidal products placed on the market of ***the*** territories ***of the Member States shall be*** labelled in ***the*** national language or languages ***of the country where they are marketed***.

Article 59

Safety Data Sheets

The safety-data sheets shall be prepared and made available in accordance with Annex II of Regulation (EC) No 1907/2006, for biocidal products classified as hazardous, and in accordance with the requirements of Article 31 of that Regulation, for active substances used exclusively in biocidal products.

Safety data sheets shall contain the following information:

(a) important categories of product whose active substance has been included in Annex I;

(b) the name of at least one Member State where the biocidal product has been authorised;

(c) the authorisation number of the biocidal product as such or present in a treated article or material.

Article 60

Union Register of Biocidal Products

1. A Union Register for Biocidal Products shall be established and maintained by the Commission.

2. The Union Register for Biocidal Products shall be used for the exchange of information between competent authorities, the Agency and the Commission.

3. Applicants shall use the Union Register for Biocidal Products to generate the application form for all procedures relating to the authorisation of biocidal products, the mutual recognition and the parallel trade permit.

4. Competent authorities shall update in the Union Register for Biocidal Products the information relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled. The Commission shall update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.

5. ***In order to ensure the proper functioning of the Union Register for Biocidal Products,*** the Commission may adopt***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75,*** detailed rules on the types of information to be entered in the ▌Register ▌and the procedures related to it ▌.

Article 61

Biocides Data Sharing Register

1. The Biocides Data Sharing Register shall be established and maintained by the Agency.

2. The Biocides Data Sharing Register shall contain information provided by competent authorities and the Agency in accordance with paragraphs 3 and 4 of Article 48.

The Register shall only be accessible to competent authorities, the Agency and the Commission. Competent authorities and the Agency shall respond to all enquiries by prospective applicants concerning information contained in the Biocides Data Sharing Register in order to facilitate sharing of information and shall on request provide the contact details of the owner of the information in question and a statement whether and for how long the information is subject to data protection under this Regulation.

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Article 62

Access to information

1. Member States shall ensure that all professional users, distributors and advisers have access to appropriate information on the benefits, risks and safe use of biocidal products.

2. Member States shall take the necessary measures to provide the public with information about the benefits and risks associated with biocidal products and ways of minimising the use of those products.

3. The Commission shall make available on the internet a list of all active substances available within the internal market.

The persons responsible for the placing on the market of biocidal products shall make a list of such products available on the internet. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.

Access to those websites shall not be subject to any restriction or condition and their content shall be kept up to date. The relevant website addresses shall be indicated on the labelling of the biocidal products in a visible manner.

Article 63

Advertising

1. Any advertisement for biocidal products shall be accompanied by the sentences 'Use biocides safely. Always read the label and product information before use'. The sentences shall be clearly distinguishable in relation to the whole advertisement.

2. Advertisers may replace the word 'biocides' in the prescribed sentences with a clear reference to the product-type as set out in Annex V being advertised.

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment. In any case, the advertising of a biocidal product shall not mention indications such as 'low-risk biocidal product', 'non-toxic' or 'harmless'.

Article 64

Poison control

1. Member States shall appoint a body or bodies responsible for receiving information on biocidal products which have been placed on the market, including information on the chemical composition of such products, and for making such information available in cases where suspected poisoning arises from biocidal products.

Member States may decide to appoint the body or bodies that have already been appointed in accordance with Article 45 of Regulation (EC) No 1272/2008 to carry out the tasks under this Article.

2. The bodies appointed by the Member States shall provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used for the following purposes:

(a) to meet medical demand by formulating preventive and curative measures, in particular in case of emergency;

(b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

CHAPTER XIII

THE AGENCY

Article 65

Role of the Agency

The Agency shall carry out the tasks conferred on it by Chapters II, III, IV, VI, VII, VIII, IX, X, XI, XII and XIV of this Regulation.

Article 66

Biocidal Products Committee

1. A Biocidal Products Committee is hereby established within the Agency.

The Biocidal Products Committee shall be responsible for preparing the opinion of the Agency on the following issues:

(a) applications for inclusion and renewal of inclusion of active substances in Annex I;

(b) review of inclusion of active substances in Annex I;

(c) identification of active substances which are candidates for substitution;

(d) applications for Union authorisation of biocidal products and for renewal, cancellation and modifications of Union authorisation;

(e) scientific and technical matters in the case of objections to mutual recognition;

(f) any other questions that arise from the operation of this Regulation relating to risks to human health or the environment.

2. Articles 85, 87 and 88 of Regulation (EC) No 1907/2006 concerning the establishment, the composition and the qualification and interests of the Committee for Risk Assessment shall apply *mutatis mutandis* to the Biocidal Products Committee.

The Biocidal Products Committee may establish working groups and delegate certain tasks to those working groups.

The members of the Biocidal Products Committee shall be supported by the scientific and technical resources available to the Member States. Member States shall provide adequate scientific and technical resources to the members of the Biocidal Products Committee that they have nominated. Competent authorities of Member States shall facilitate the activities of the Biocidal Products Committee and their working groups.

Article 67

Operation of the Biocidal Products Committee and the Secretariat of the Agency

1. Articles 78 to 84, 89 and 90 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* taking into account the role of the Agency with respect to this Regulation.

2. The Secretariat of the Agency referred to in point (g) of Article 76(1) of Regulation (EC) No 1907/2006 shall undertake the following tasks:

(a) establishing and maintaining the Biocides Data Sharing Register;

(b) performing the tasks relating to the validation of the applications referred to in Articles 7(4), 11(3) and 34(2) of this Regulation;

(c) providing technical and scientific guidance and tools for the application of this Regulation by the Commission and the competent authorities of Member States;

(d) providing advice and assistance to applicants***, and in particular to SMEs,*** for the inclusion of an active substance in Annex I of this Regulation or for a Union authorisation;

(e) preparing explanatory information on this Regulation;

(f) establishing and maintaining database(s) with information on active substances and biocidal products;

(g) at the request of the Commission, providing technical and scientific support to improve cooperation between the Union, the competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products;

(h) notification of decisions taken by the Agency;

(i) provision of formats for submission of information to the Agency;

(j) providing guidance and tools for the use phase, particularly:

— ***measures for integrated pest management, for specified vermin,***

— ***monitoring biocidal product use,***

— ***best practice of biocidal product use to limit use of such products to the minimum necessary dose,***

— ***pest management in sensitive areas like schools, workplaces, kindergartens, public spaces, lake, canal and river sides, geriatric care centres,***

— ***technical equipment for biocidal product application and its inspection.***

3. The Secretariat shall make the information identified in Article 56(1) and (2) in the database(s) publicly available, free of charge, over the internet, except where a request made under Article 55(3) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 55.

Article 68

Appeal

1. An appeal against decisions of the Agency taken pursuant to Articles 7(5), 11(4), 34(3), 36(6), 52(3) and 53(1) shall lie with the Board of Appeal.

Articles 92(1) and (2), 93 and 94 of Regulation (EC) No 1907/2006 shall apply to appeal procedures lodged under this Regulation.

A fee may be payable by a person bringing an appeal in accordance with Article 71(2) of this Regulation.

2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

Article 69

The budget of the Agency

1. For the purposes of this Regulation, the revenues of the Agency shall consist of:

(a) a subsidy from the Union, entered in the general budget of the European Union (Commission Section);

(b) the fees paid by undertakings;

(c) any charges paid to the Agency for services provided under this Regulation;

(d) any voluntary contribution from the Member States.

2. Revenue and expenditure for activities related to this Regulation and those relating to activities under Regulation (EC) No 1907/2006 shall be dealt with separately in the Agency's budget with a separate budgetary and accounting reporting.

Revenue of the Agency referred to in Article 96(1) of Regulation (EC) No 1907/2006 shall not be used for carrying out tasks under this Regulation.

Article 70

Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and shall specify software packages and make them available on its website for submissions to the Agency. The competent authorities and applicants shall use these formats and packages in their submissions to the Agency pursuant to this Regulation.

The format of the technical dossier referred to in Articles 6(1), 11(1), 18 and 36(4) shall be IUCLID.

CHAPTER XIV

FINAL PROVISIONS

Article 71

Fees and charges

1. The Commission shall establish rules concerning:

(a) the system of fees payable to the Agency;

(b) the harmonised structure of fees;

(c) the circumstances under which a proportion of the fees is to be transferred to the competent authority of the evaluating Member State;

(d) the partial reimbursement of the fee in the event that the applicant fails to submit the information requested within the deadline during validation of the application.

Those measuresshall be adopted ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***.

2. The harmonised structure of fees and conditions of payment shall be based on the following principles:

(a) a reduced fee shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC; ***this shall have no bearing on the responsibility of the relevant competent authority to carry out a careful assessment in accordance with the provisions of this Regulation;***

(b) the fee structure shall take into account whether information has been submitted jointly or separately;

(c) the fee structure shall take into account whether the product submitted for authorisation complies with the criteria for a low-risk product;

(d) in duly justified circumstances and where it is accepted by the competent authority or the Agency, it shall be possible to waive the fee;

▌

(e) the structure and amount of the fees shall take account of the work required by this Regulation to be carried out by the Agency and the competent authorities and shall be fixed at such level as to ensure that the revenue derived from the fees when combined with other sources of the Agency's revenue pursuant to this Regulation is sufficient to cover the cost of the services delivered.

3. Member States shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex I to pay fees in accordance with the harmonised structure of fees and conditions of payment to be adopted in accordance with paragraph 1.

4. In accordance with the rules referred to in paragraph 1, the Agency shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex I to pay fees. The structure and the amount of fees payable to the Agency shall be determined in accordance with paragraph 1.

The Agency may collect charges for other services it provides.

Article 72

Competent authorities

1. Member States shall designate a competent authority or competent authorities responsible for the application of this Regulation.

Member States shall inform the Commission of the names and addresses of the designated competent authorities by 1 January 2013. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities.

2. The Commission shall make publicly available the list of the competent authorities.

Article 73

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 5(1)(d), 6(4), 8(5), 12(5), 13(1), 14, 16(10), 19(3), 21(5), 25(6), 28(8), 42(1), 46(4), 60(5), 71(1), 77 and 82(1) shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall draw up a report in respect of the delegated power at the latest six months before the end of the five year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 74.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 74 and 75.

Article 74

Revocation of the delegation

1. The delegation of power referred to in Articles 5(1)(d), 6(4), 8(5), 12(5), 13(1), 14, 16(10), 19(3), 21(5), 25(6), 28(8), 42(1), 46(4), 60(5), 71(1), 77 and 82(1) may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Article 75

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of three months from the date of notification.

At the initiative of the European Parliament or the Council that period shall be extended by one month.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.

3. If either the European Parliament or the Council objects to a delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 76

Standing Committee

1. The Commission shall be assisted by the Standing Committee on Biocidal Products.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

▌

Article 77

Adaptation to scientific and technical progress

In order to take account of technical progress, the Commission ***shall, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75,*** adapt the Annexes to scientific and technical progress.

▌

Article 78

Updating of Annex I

By 1 January 2013, the Commission shall, in accordance with the procedure referred to in Article 76(3), amend Annex I with effect from the date of applicability of this Regulation in order to take into account any amendment to Annex I adopted under Directive 98/8/EC since the entry into force of this Regulation.

Article 79

Penalties

Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2015 and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 80

National helpdesks in Member States

Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation. Those national helpdesks shall be in addition to any assistance provided by the Agency under Article 67(2)(d).

Article 81

Safeguard clause

Where, on the basis of new evidence, a Member State has justifiable grounds to consider that a biocidal product, although satisfying the requirements of this Regulation, constitutes a serious ***immediate or long-term*** risk to human ***health, in particular as regards children and vulnerable groups,*** or animal health or to the environment, ***or to achieving the quality standards laid down in Directive 2000/60/EC,*** it may take appropriate provisional measures. The Member State shall without delay inform the Commission and the other Member States thereof and give reasons for its decision ▌.

▌

Article 82

Transitional measures

1. The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC and achieve it by 14 May 2014. ***In order to ensure a smooth transition,*** the Commission may adopt***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75 of this Regulation,*** implementing rules to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme***, and, depending upon the progress of the work programme, a decision to extend the duration of the work programme for a determined period***.

▌

In order to progress with the work programme, the Commission shall decide***, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75 of this Regulation,*** that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 of this Regulation are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective.

2. By way of derogation from Articles 15(1), 16(1) and 18(1), and without prejudice to paragraphs 1 and 3, a Member State may continue to apply its current system or practice of placing biocidal products on the market until two years after the date on which the inclusion in Annex I becomes effective. It may, in particular, according to its national rules, authorise the placing on the market in its territory of a biocidal product containing existing active substances which are evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC ([1]) but which are not yet listed in Annex I to this Regulation for that product type.

In derogation from the first subparagraph, in the case of a decision not to include an active substance in Annex I of this Regulation, a Member State may continue to apply its current system or practice of placing biocidal products on the market no longer than 12 months after the applicability date of a decision taken in accordance with the third subparagraph of paragraph 1.

3. Following a decision to include a particular active substance in Annex I of this Regulation Member States shall ensure that authorisations for biocidal products containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years from the date on which the inclusion becomes effective.

To that effect, applications for authorisation of biocidal products containing only existing active substances shall be submitted to the competent authorities of the Member States no later than the date which the inclusion of the active substance(s) in Annex I becomes effective. In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date on which the inclusion of the last active substance becomes effective.

Biocidal products, for which an application for a product authorisation has not been submitted in accordance with the second subparagraph, shall no longer be placed on the market ▌after the date on which the inclusion becomes effective. Disposal, storage and use of existing stocks of biocidal products for which an application for authorisation has not been submitted in accordance with the second subparagraph are allowed until ***six months*** after the date on which the inclusion becomes effective.

4. Biocidal products for which the competent authority of the Member State has rejected an application for authorisation submitted under paragraph 3 or has decided not to grant authorisation, shall no longer be placed on the market with effect from six months after such a rejection or a decision.

Article 83

Transitional measures concerning active substances evaluated under Directive 98/8/EC

1. The Agency shall be responsible for coordinating the evaluation process of dossiers submitted after 1 January 2012 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission.

2. Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 January 2013 shall continue to be evaluated by the competent authorities in accordance with the provisions of Directive 98/8/EC and, where relevant, Regulation (EC) No 1451/2007.

([1]) OJ L 325, 11.12.2007, p. 3.

Notwithstanding paragraph 1, the Agency shall also be responsible for coordinating the evaluation process of dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 January 2013 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission from 1 January 2014.

Article 84

Transitional measures concerning low-risk biocidal products registered under Directive 98/8/EC

1. Low-risk biocidal products as defined in Article 2(1) (b) of Directive 98/8/EC shall be registered in accordance with point (i) of Article 3(2) of Directive 98/8/EC. The provisions of Directive 98/8/EC shall apply to these products until the expiry of the registration. The registration shall not be renewable.

2. Applications for the registration of low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC shall be submitted at the latest twelve months after the date on which the inclusion in Annex IA becomes effective.

Low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC for which an application was submitted in accordance with the first subparagraph may continue to be placed on the market until the date of the decision granting the registration or refusing to grant the registration. In the case of a refusal to grant a registration to place such low-risk biocidal product on the market, such low-risk biocidal product shall no longer be placed on the market within six months after such decision.

Low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC for which an application was not submitted in accordance with the first subparagraph may continue to be placed on the market until six months after the date referred to in paragraph 1 of this Article.

Disposal, storage and use of existing stocks of low-risk biocidal products which are not authorised for the relevant use by the competent authority are allowed until twelve months after the date of the decision referred to in the second subparagraph or twelve months after the date referred to in the third subparagraph, whichever is the later.

3. This Regulation shall apply to low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC as of the expiry of the registration referred to in paragraph 1 of this Article.

Article 85

Transitional measures concerning in situ generated active substances

1. Applications for the authorisation of substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on … (*) shall be submitted at the latest by 1 January 2017. ***This paragraph shall not apply to active substances generated in situ for the purpose of disinfecting drinking water.***

2. Substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on … (*) and for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In the case of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on … (*) and for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

(*) Date of entry into force of this Regulation.

Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission are allowed until 12 months after the date of the decision referred to in the first subparagraph or 12 months after the date referred to in the second subparagraph, whichever is the later.

Article 86

Transitional measures concerning treated articles and materials

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the Union or in at least one Member State and which were available on the market on … (*) may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by ***1 January 2015***. In the event of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

Disposal and storage of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission shall be allowed until 12 months after the date of the decision referred to in the first subparagraph of Article 85(2) or 12 months after the date referred to in the second subparagraph of Article 85(2), whichever is the later.

Article 87

Transitional measures concerning food contact materials

1. Applications for the authorisation of biocidal products which are food contact materials and which were available on the market on … (*) shall be submitted at the latest 1 January 2017.

Food contact materials which were available on the market on … (*) for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In the event of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Food contact materials which were available on the market on … (*) for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

2. Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission is allowed until 12 months after the date of the decision referred to in the second subparagraph of paragraph 1 or 12 months after the date referred to in the third subparagraph of paragraph 1, whichever is the later.

Article 88

Transitional measures concerning access to the active substance dossier

1. By 1 January 2015, manufacturers of existing active substances ***which are on the market for use in biocidal products*** shall ***submit to the Agency*** a dossier or ▌a letter of access to a dossier ***which complies with*** the requirements ***of*** Annex II for each of these active substances.

For the purpose of subparagraph 1, Article 52(3) shall apply to all data included in the dossier.

The applicant for the authorisation of a biocidal product containing an active substance for which a letter of access has been submitted in accordance with subparagraph 1 shall be allowed to use that letter of access for the purposes of Article 18(1).

(*) Date of entry into force of this Regulation.

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2. The Agency shall make publicly available the list of manufacturers which have submitted a dossier or a letter of access to a dossier in accordance with paragraph 1.

3. Biocidal products ***containing existing active substances*** for which ***a dossier or a letter of access to a dossier has not been submitted in accordance with paragraph 1*** shall ***not*** be placed on the market ***after 1 January 2015***.

Disposal, storage and use of existing stocks of biocidal products ***for*** which ***a dossier or a letter of access to a dossier has not been submitted in accordance with paragraph 1*** is allowed until ***1 January 2016***.

4. For the purpose of paragraph 3, competent authorities shall carry out official controls as required by Article 54(3).

Article 89

Repeal

Without prejudice to Article 83 and 84, Directive 98/8/EC is hereby repealed.

References to the repealed Directive shall be construed as references to this Regulation and be read in accordance with the correlation table set out in Annex VII.

Article 90

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the European Parliament	For the Council
The President	The President

ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS FOR INCLUSION IN BIOCIDAL PRODUCTS

Substances listed in Annex I do not cover nanomaterials, except where specifically mentioned.

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
sulfuryl fluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	Authorisations are subject to the following conditions: (1) the product may only be sold to and used by professionals trained to use it; (2) appropriate risk mitigation measures are included for operators and bystanders; (3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored. Reports of the monitoring referred to in point (3) are to be transmitted by authorisation holders directly to the Commission every fifth year starting from 1 January 2009.
dichlofluanid	N-(Dichlorofluoromethylthio)-N′,N′-dimethyl-N-phenylsulfamide EC No: 214-118-7 CAS No: 1085-98-9	960 g/kg	1 March 2009	28 February 2011	28 February 2019	8	Authorisations are subject to the following conditions: (1) Products authorised for industrial and/or professional use must be used with appropriate personal protective equipment. (2) In view of the risks identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment. (3) Labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitro-guanidine EC No: 433-460-1 CAS No: 210880-92-5	950 g/kg	1 February 2010	31 January 2012	31 January 2020	8	Authorisations are subject to the following conditions: In view of the risk identified for the soil, surface water and groundwater compartments, products shall not be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses shall be collected for reuse or disposal.
Difethialone	3-[3-(4′-bromo[1,1′biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzo-thiopyran-2-one EC No: n/a CAS No: 104653-34-1	976 g/kg	1 November 2009	31 October 2011	31 October 2014	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance shall be considered a candidate for substitution in accordance with Article 9. Authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 0,0025 % w/w and only ready-for-use baits shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	Authorisations are subject to the following conditions: In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use shall be used with appropriate personal protective equipment.
tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Authorisations are subject to the following conditions: In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal. In addition, products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal. In addition, products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance shall be considered a candidate for substitution in accordance with Article 9. Authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye.

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
							(3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
K-HDO	Cyclohexylhydroxydiazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated forms of K-HDO)	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Authorisations are subject to the following conditions: (1) in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 16 and Annex VI; (2) in view of the assumptions made during the risk assessment, products shall be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; (3) in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.
IPBC	3-iodo-2-propynyl butylcarbamate EC No: 259-627-5 CAS No: 55406-53-6	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
							In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.
Thiabendazole	2-thiazol-4-yl-1H-benzoimidazole EC No: 205-725-8 CAS No: 148-79-8	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, with respect to the double-vacuum and dipping application tasks, shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
thiamethoxam	thiamethoxam EC No: 428-650-4 CAS No: 153719-23-4	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal. Products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website:http://ec.europa.eu/comm/environment/biocides/index.htm

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ANNEX II

Data requirements for active substances

1. Dossiers on active substances shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

   Dossiers for Tier 1 shall contain all information necessary for identifying the properties and risks of active substances over their life cycle, in particular pursuant to Article 5, 9 and 17 of this Regulation.

2. Information which is however not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied.

3. A detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods shall be included.

   The formats made available by the Commission must be used for submission of the dossiers. In addition, the special software package (IUCLID) made available by the Commission must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 ([1]). ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are ***scientifically satisfactory*** and ***the validity of which*** must be justified in the application.

5. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ([2]), and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances ([3]) or other international standards recognised as being equivalent by the Commission or the Agency.

6. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided.

7. Where test data exist that have been generated before … (*) by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State concerned, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

8. All available relevant knowledge and information in literature should be provided.

9. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall also be provided.

TITLE 1 — Chemical substances

Tier I

Information required to support the inclusion of a substance in Annex I is listed in the table below. The standard data package consists of tier I data. Tier II data may need to be submitted depending on the characteristics and intended use of the active substance or on the conclusions of the assessment of the tier I data, in particular if a danger for health or the environment has been identified.

([1]) OJ L 142, 31.5.2008, p. 1.
([2]) OJ L 358, 18.12.1986, p. 1.
([3]) OJ L 50, 20.2.2004, p. 44.
(*) Date of entry into force of this Regulation.

The table also provides specific rules according to which the required information may be omitted, replaced by other information or adapted in another way. If the conditions are met to allow adaptations, the applicant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the dossier.

Conditions for not requiring a specific test that are set out in the appropriate test methods in the Regulation (EC) No 440/2008 that are not repeated in column 2, also apply.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on ***intelligent*** testing strategies should be ***sought from experts in alternatives to animal experimentation*** in addition to this Annex.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
1. Applicant		
1.1. Name and address		
1.2. Active substance manufacturer (name, address, location of plant)		
2. Identity of the active substance		
2.1. Common name proposed or accepted by ISO and synonyms		
2.2. Chemical name (IUPAC nomenclature)		
2.3. Manufacturer's development code number(s)		
2.4. CAS and EC numbers (if available)		
2.5. Molecular and structural formula (including full details of any isomeric composition), molecular mass		
2.6. Method of manufacture (syntheses pathway in brief terms) of active substance		
2.7. Specification of purity of the active substance in g/kg or g/l, as appropriate		
2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate		
2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower		
2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC		
3. Physical and chemical properties of the active substance		
3.1. State of the substance at 20 °C and 101,3 kPa		
3.2. Melting/freezing point		3.2. The study does not need to be conducted below a lower limit of – 20 °C.

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
3.3. Boiling point		3.3. The study does not need to be conducted: — for gases; or — for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured; or — for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
3.4. Relative density		3.4. The study does not need to be conducted if: — the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient; or — the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.
3.5. Vapour pressure		3.5. The study does not need to be conducted if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
3.6. Surface tension		3.6. The study need only be conducted if: — based on structure, surface activity is expected or can be predicted; or — surface activity is a desired property of the material. If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.
3.7. Water solubility		3.7. The study does not need to be conducted if: — the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours); or — the substance is readily oxidisable in water. If the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall be performed.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
3.8. Partition coefficient n-octanol/water		3.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.
3.9. Flash-point		3.9. The study does not need to be conducted if: — the substance is inorganic; or — the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions; or — the estimated flash-point is above 200 °C; or — the flash-point can be accurately predicted by interpolation from existing characterised materials.
3.10. Flammability		3.10. The study does not need to be conducted: — if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability; or — for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit; or — for substances which spontaneously ignite when in contact with air.
3.11. Explosive properties		3.11. The study does not need to be conducted if: — there are no chemical groups associated with explosive properties present in the molecule; or — the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than – 200; or — the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C; or

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		— for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: — less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard) — less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard). *Note:* Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.
3.12. Self-ignition temperature		3.12. The study does not need to be conducted: — if the substance is explosive or ignites spontaneously with air at room temperature; or — for liquids non flammable in air, e.g. no flash point up to 200 °C; or — for gases having no flammable range; or — for solids, if the substance has a melting point < 160 °C, or if preliminary results exclude self-heating of the substance up to 400 °C.
3.13. Oxidising properties		3.13. The study does not need to be conducted if: — the substance is explosive; or — the substance is highly flammable; or — the substance is an organic peroxide; or — the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms). The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties. Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.
3.14. Granulometry		3.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
3.15. Stability in organic solvents and identity of relevant degradation products	Tier II	3.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.
3.16. Dissociation constant	Tier II	3.16. Dissociation constant
3.17. Viscosity	Tier II	3.17. Viscosity
3.18. Solubility in organic solvents, including effect of temperature on solubility ([1])	Tier II	
3.19. Stability in organic solvents used in biocidal products and identity of relevant breakdown products ([2])	Tier II	
4. Methods of detection and identification		
4.1. Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers)		
4.2. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof		
4.3. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedingstuffs and other products where relevant	Tier II	
5. Effectiveness against target organisms and intended uses		
5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide		
5.2. Organism(s) to be controlled and products, organisms or objects to be protected		
5.3. Effects on target organisms, and likely concentration at which the active substance will be used		
5.4. Mode of action (including time delay)		
5.5. Field of use envisaged		
5.6. User: industrial, professional, general public (non-professional)		
5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
5.8. Likely tonnage to be placed on the market per year		
6. Toxicological profile for man and animals including metabolism		

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
6.1. Skin irritation or skin corrosion		6.1. The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) in vitro study for skin corrosion, (4) in vitro study for skin irritation. Steps 3 and 4 do not need to be conducted if: — the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or — the substance is flammable in air at room temperature; or — the substance is classified as very toxic in contact with skin; or — an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).
6.1.1. In vivo skin irritation		▌
6.2. Eye irritation		6.2. The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) in vitro study for eye irritation. Step 3 does not need to be conducted if: — the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or — the substance is flammable in air at room temperature.
6.2.1. In vivo eye irritation		▌
6.3. Skin sensitisation		6.3. The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human, animal and alternative data, (2) In vivo testing.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		Step 2 does not need to be conducted if: — the available information indicates that the substance should be classified for skin sensitisation or corrosivity; or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5); or — the substance is flammable in air at room temperature. The ***reduced*** Murine Local Lymph Node Assay (**rLLNA**) is the first-choice method for in vivo testing ***as a screening test to distinguish between sensitisers and non-sensitisers. The full LLNA should be performed when it is known that an assessment of sensitisation potency is required.*** Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.
6.4. Mutagenicity		6.4. Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Tier I. ***For new substances, it is advisable to assess the parameters of an in-vivo micronucleus test as part of a 28- or 90-day repeated dose toxicity study.***
6.4.1. In vitro gene mutation study in bacteria		6.4.1. Further mutagenicity studies shall be considered in case of a positive result. ***Such a study does not need to be conducted in the case of antimicrobial substances or formulations.***
6.4.2. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study		6.4.2. The study does not usually need to be conducted if: — adequate data from an in vivo cytogenicity test are available or — the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.
6.4.3. In vitro gene mutation study in mammalian cells, if a negative result in Tier I, sections 6.4.1. and section 6.4.2.		6.4.3. The study does not ▌need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available ***elsewhere***.
6.4.4. In vivo genotoxicity study	Tier II	6.4.4. If there is a positive result in any of the in vitro genotoxicity studies in Tier I and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed by the applicant. ***For new substances, it should be possible to assess the parameters of an in-vivo micronucleus test as part of a 28- or 90-day repeated dose toxicity study.***

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.
6.5. Acute toxicity		6.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin. In addition to the oral route (6.5.1), for substances other than gases, the information mentioned under 6.5.2 to 6.5.3 shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided.
6.5.1. By oral route		6.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (6.5.2) is available. ***The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should another test be used, in which case a justification shall be provided.***
6.5.2. By inhalation		6.5.2. Testing by the inhalation route is appropriate ***only*** if ***this constitutes the primary route of human*** exposure ▌ taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. ***The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should the classic 'lethal concentration' (LC50) test be used. Justification for the use of another test shall be provided.***
6.5.3. By dermal route		▌
6.6. Repeated dose toxicity		
6.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.		6.6.1. The short-term toxicity study (28 days) does not need to be conducted if: — a reliable sub-chronic (90 days) or chronic toxicity study is available ***or planned***, provided that an appropriate species, dosage, solvent and route of administration were ***or are to be*** used; or

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		— where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or — relevant human exposure can be excluded in accordance with Annex IV section 3. ***Testing shall be conducted via the oral route unless:*** ***(1) the primary route of human exposure will be dermal, and one of the following conditions is met:*** — ***the physicochemical and toxicological properties, including an in-vitro dermal penetration study (i.e. OECD TG 428), indicate that dermal bioavailability will be substantial; or*** — ***significant dermal toxicity or dermal penetration is recognised for structurally related substances.*** ***(2) the primary route of human exposure will be inhalation, taking into account the vapour pressure of the substance and likely frequency, magnitude and duration of exposure to aerosols, particles or droplets of an inhalable size.*** ***Testing shall only be carried out via one exposure route. Estimates of toxicity via other routes shall be based upon pharmacokinetic modelling.*** The sub-chronic toxicity study (90 days) (Tier II, section 6.6.2) shall be proposed by the applicant ***in lieu of a 28-day study*** if: the frequency and duration of human exposure indicates that a ▌ study ***of > 1 month and < 12 months*** is appropriate and ▌ available data indicate that the ***kinetics or other properties of a*** substance ***or its metabolites are such that adverse effects could go undetected*** in a short-term toxicity study. ***For substances related on a molecular level to known organ-specific toxicants (e.g. neurotoxicity), additional relevant parameters should ideally be examined in the context of a 28-day or 90-day study in lieu of a stand-alone, e.g. neurotoxicity study.*** Further ***stand-alone*** studies ***should be limited to exceptional circumstances***.
6.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	Tier II	6.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure; or

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		— a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake); or — the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure. ***Testing shall be conducted via the oral route unless:*** ***(1) the primary route of human exposure will be dermal, and one of the following conditions is met:*** — ***the physicochemical and toxicological properties, including an in-vitro dermal penetration study (i.e. OECD TG 428), indicate that dermal bioavailability will be substantial; or*** — ***significant dermal toxicity or dermal penetration is recognised for structurally related substances.*** ***(2) the primary route of human exposure will be inhalation, taking into account the vapour pressure of the substance and the likely frequency, magnitude and duration of exposure to aerosols, particles or droplets of an inhalable size.*** ***Testing shall be carried out via one exposure route. Estimates of toxicity via other routes shall be based upon pharmacokinetic modelling.*** ***For substances related on a molecular level to known organ-specific toxicants (e.g. neurotoxicity), additional relevant parameters should ideally be examined in the context of a 28-day or 90-day study in lieu of a standalone, e.g. neurotoxicity study.*** Further ***stand-alone*** studies ***should be limited to exceptional circumstances***.
6.6.3. Long-term repeated toxicity study (≥ 12 months)	Tier II	6.6.3. A long-term repeated ***dose*** toxicity study (≥ 12 months) may be proposed by the applicant or required ***only*** if: — the frequency***, magnitude*** and duration of human exposure, **indicate** that a ***chronic risk assessment*** is appropriate***;*** and — ***if the application of an appropriate uncertainty factor would not be sufficiently protective for risk assessment purposes.***

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		If carcinogenicity data are also required and are not already available, long-term repeated dose and carcinogenicity studies should be carried out using the OECD TG 453 combination study protocol.
6.6.4. Further studies	Tier II	6.6.4. Further studies shall be proposed by the applicant or may be required in case of: — toxicity of particular concern (e.g. serious/severe effects); or — indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or — particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed). If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.
6.7. Reproductive toxicity	Tier II	6.7. The studies need not be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure. If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
		If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.
6.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant.		6.7.1. This study does not need to be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or — ***there is no significant*** human exposure ▌ in accordance with Annex IV section 3; or — a pre-natal developmental toxicity study (Tier II, 6.7.2) or a ***one- or*** two-generation reproductive toxicity study (Tier II, section 6.7.3) is available. If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for ***pre-natal*** development toxicity must be considered. If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered. In cases where there are serious concerns about the potential for adverse effects on fertility or development, ***an enhanced one-***generation reproductive toxicity study***, with or without a pre-natal developmental toxicity module*** (Tier II, section 6.7.3), may be proposed by the applicant instead of the screening study.
6.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Regulation (EC) No 440/2008 or OECD 414).	Tier II	6.7.2. The study shall be ▌ performed on one species ***only, ideally in combination with an enhanced one-generation reproductive toxicity study as applicable (Tier II, section 6.7.3)***.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
6.7.3. ***Pending EU-level or international acceptance of the test method, enhanced one-*** generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure ▌.	Tier II	▌
6.8. Toxicokinetics		
6.8.1. ***In-vitro*** dermal absorption study		
6.9. Carcinogenicity study	Tier II	6.9. A carcinogenicity study may be proposed by the applicant or may be required if: — the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and — the substance is classified as mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions. If the substance is classified as mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required. ***If long-term toxicity data are also required and are not already available, carcinogenicity and long-term repeated dose studies should be carried out using the OECD TG 453 combination study protocol.***
6.9.1. Medical surveillance data on manufacturing plant personnel if available		
6.9.2. Direct observation, e.g. clinical cases, poisoning incidents if available		
6.9.3. Health records, both from industry and any other available sources		
6.9.4. Epidemiological studies on the general population, if available		
6.9.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available		
6.9.6. Sensitisation/allergenicity observations, if available		
6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known		
6.9.8. Prognosis following poisoning		

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
6.10. Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form		
6.11. Additional studies	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
6.11.1. Neurotoxicity study	Tier II	If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered.
6.11.2. Toxic effects on livestock and pets	Tier II	
6.11.3. Studies related to the exposure of the active substance to humans	Tier II	
6.11.4. Food and feedingstuffs	Tier II	If the active substance is to be used in mixtures for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section 9.1 shall be required.
6.11.5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section 9.1, Title I of Annex III shall be required	Tier II	
6.11.6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required	Tier II	
6.11.7. Mechanistic study - any studies necessary to clarify effects reported in toxicity studies	Tier II	
7. Ecotoxicological profile including environmental fate and behaviour		
7.1. Aquatic toxicity		7.1. Long-term toxicity testing shall be proposed by the applicant if the assessment performed under Tier I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
7.1.1. Short-term toxicity testing on invertebrates (preferred species Daphnia) The applicant may consider long-term toxicity testing instead of short-term.		7.1.1. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or — a long-term aquatic toxicity study on invertebrates is available; or — adequate information for environmental classification and labelling is available. The long-term aquatic toxicity study on Daphnia (Tier II, section 7.1.5) shall be considered if the substance is poorly water soluble.
7.1.2. Growth inhibition study aquatic plants (algae preferred)		7.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.
7.1.3. Short-term toxicity testing on fish: ***threshold approach.***		7.1.3. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or — a long-term aquatic toxicity study on fish is available.
7.1.4. Activated sludge respiration inhibition testing		7.1.4. The study does not need to be conducted if: — there is no emission to a sewage treatment plant; or — there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water; or — the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant. The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.
7.1.5. Long-term toxicity testing on invertebrates (preferred species Daphnia), (unless already provided as part of Tier I requirements)	Tier II	

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
7.1.6. Long-term toxicity testing on fish, ***if indicated by substance use profile and/or physical-chemical properties*** The information shall be provided for one of the sections 7.1.6.1, 7.1.6.2 or 7.1.6.3.	Tier II	
7.1.6.1. Fish early-life stage (FELS) toxicity test	Tier II	
7.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages	Tier II	
7.1.6.3. Fish, juvenile growth test	Tier II	
7.2. Degradation		7.2. Further biotic degradation testing shall be considered if the assessment performed under Tier I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I and may include simulation testing in appropriate media (e.g. water, sediment or soil).
7.2.1. Biotic		
7.2.1.1. Ready biodegradability		7.2.1.1. The study does not need to be conducted if the substance is inorganic.
7.2.1.2. Simulation testing on ultimate degradation in surface water	Tier II	7.2.1.2. The study need not be conducted if: — the substances is highly insoluble in water; or — the substance is readily biodegradable.
7.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)	Tier II	7.2.1.3. The study need not be conducted: — if the substance is readily biodegradable; or — if direct and indirect exposure of soil is unlikely.
7.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	Tier II	7.2.1.4. The study need not be conducted: — if the substance is readily biodegradable; or — if direct and indirect exposure of sediment is unlikely.
7.2.2. Abiotic		
7.2.2.1. Hydrolysis as a function of pH.		7.2.2.1. The study does not need to be conducted if: — the substance is readily biodegradable; or — the substance is highly insoluble in water.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
7.2.3. Identification of degradation products	Tier II	7.2.3. Unless the substance is readily biodegradable
7.3. Fate and behaviour in the environment		
7.3.1. Adsorption/desorption screening		7.3.1. The study does not need to be conducted if: — based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or — the substance and its relevant degradation products decompose rapidly.
7.3.2. Bioaccumulation in aquatic species, preferably fish	Tier II	7.3.2. The study need not be conducted if: — the substance has a low potential for bioaccumulation (for instance a log Kow < 3) and/or a low potential to cross biological membranes; or — direct and indirect exposure of the aquatic compartment is unlikely.
7.3.3. Additional information on adsorption/desorption depending on the results of the study required under Tier I	Tier II	7.3.3. The study need not be conducted if: — the substance has a low potential for bioaccumulation (for instance a log Kow < 3) and/or a low potential to cross biological membranes; or — based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or — the substance and its degradation products decompose rapidly.
7.4. Additional studies	Tier II	
▌		
7.4.1. Any other biodegradability tests that are relevant from the results in section 7.2.1.1	Tier II	
7.4.2. Phototransformation in air (estimation method), including identification of breakdown products	Tier II	
7.4.3. If the results from section 7.4.2 indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in sections 10.1.1 and 10.2.1 and, where appropriate, section 10.3 shall be required	Tier II	

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
8. Measures necessary to protect man, animals and the environment	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
8.1. Identification of any substances falling within the scope of List I or List II of the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances ([3]), ***Annex I Part B to Directive 98/83/EC on the quality of water intended for human consumption, or Annex X to Directive 2000/60/EC***. *Notes:* (1) These data must be submitted for the purified active substance of stated specification. (2) These data must be submitted for the active substance of stated specification.	Tier II	
9. Additional human health-related studies	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
9.1. Food and feedingstuffs studies	Tier II	
9.1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedingstuffs	Tier II	
9.1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedingstuffs including the kinetics of disappearance	Tier II	
9.1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health	Tier II	
9.1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means	Tier II	
9.1.5. If residues of the active substance remain on feedingstuffs for a significant period of time then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	Tier II	
9.1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance	Tier II	
9.1.7. Proposed acceptable residues and the justification of their acceptability	Tier II	

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
9.1.8. Any other available information that is relevant	Tier II	
9.1.9. Summary and evaluation of data submitted under 1.1 to 1.8	Tier II	
9.2. Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be required	Tier II	
10. Additional studies on fate and behaviour in the environment	Tier II	10. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in this Section shall be conducted.
10.1. Fate and behaviour in soil	Tier II	
10.1.1. Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions	Tier II	
10.1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products	Tier II	
10.1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	Tier II	
10.1.4. Extent and nature of bound residues	Tier II	
10.2. Fate and behaviour in water	Tier II	
10.2.1. Rate and route of degradation in aquatic systems (as far as is not covered by section 7.2) including identification of metabolites and degradation products	Tier II	
10.2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products	Tier II	
10.3. Fate and behaviour in air If the active substance is to be used in mixtures for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by section 7.4.3	Tier II	
11. Additional ecotoxicological studies	Tier II	11. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in this Section shall be conducted.

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Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
11.1. Effects on birds	Tier II	
▌		
11.1.1. Short-term toxicity - eight-day dietary study in ▌ one species ▌	Tier II	
11.1.2. Effects on reproduction	Tier II	***11.1.2. This test is not required if the dietary toxicity study (section 11.1.1) shows that the LC50 is above 2 000 mg/kg.***
▌		
11.2. Effects on other non-target organisms	Tier II	
11.2.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. ▌	Tier II	
11.2.2. Toxicity to earthworms and to other soil non-target macro-organisms	Tier II	
11.2.3. Effects on soil non-target micro-organisms	Tier II	
11.2.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	Tier II	
12. Classification and labelling		
13. Summary and evaluation of Sections 1 to 12		

(1) These data must be submitted for the purified active substance of stated specification.
(2) These data must be submitted for the active substance of stated specification.
(3) OJ L 20, 26.1.1980, p. 43.

TITLE 2 — Micro-organisms

Dossiers shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogeneous regarding all characteristics, or the applicant provides other arguments.

Where the micro-organism has been genetically modified within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (1), a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in Article 4(2) of that Directive, shall also be submitted.

If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Title 1.

The following data will be required to support submissions.

1. Identity of the micro-organism

1.1. Applicant

1.2. Manufacturer

(1) OJ L 106, 17.4.2001, p. 1.

1.3. Name and species description, strain characterisation

1.3.1. Common name of the micro-organism (including alternative and superseded names)

1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant

1.3.3. Collection and culture reference number where the culture is deposited

1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)

1.4. Specification of the material used for manufacturing of formulated products

1.4.1. Content of the micro-organism

1.4.2. Identity and content of impurities, additives, contaminating micro-organisms

1.4.3. Analytical profile of batches

2. Biological properties of the micro-organism

2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution

2.1.1. Historical background

2.1.2. Origin and natural occurrence

2.2. Information on target organism(s)

2.2.1. Description of the target organism(s)

2.2.2. Mode of action

2.3. Host specificity range and effects on species other than the target organism

2.4. Development stages/life cycle of the micro-organism

2.5. Infectiveness, dispersal and colonisation ability

2.6. Relationships to known plant or animal or human pathogens

2.7. Genetic stability and factors affecting it

2.8. Information on the production of metabolites (especially toxins)

2.9. Antibiotics and other anti-microbial agents

2.10. Robustness to environmental factors

2.11. Effects on materials, substances and products

3. Additional information on the micro-organism

3.1. Function

3.2. Field of use envisaged

3.3. Product type(s) and category of users for which the micro-organism should be listed in Annex I

3.4. Method of production and quality control

3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)

3.6. Methods to prevent loss of virulence of seed stock of the micro-organism

3.7. Recommended methods and precautions concerning handling, storage, transport or fire

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3.8. Procedures for destruction or decontamination

3.9. Measures in case of an accident

3.10. Procedures for waste management

3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

3.12. Classification of the micro-organism in the relevant risk group specified in Article 2 of Directive 2000/54/EC

4. Analytical methods

4.1. Methods for the analysis of the micro-organism as manufactured

4.2. Methods to determine and quantify residues (viable or non-viable)

5. Effects on human health

TIER I

5.1. Basic information

5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel

5.1.3. Sensitisation/allergenicity observations

5.1.4. Direct observation, e.g. clinical cases

5.2. Basic studies

5.2.1. Sensitisation

The assessment of this endpoint shall comprise the following consecutive steps:

(1) an assessment of the available human, animal and alternative data,

(2) in-vivo testing.

The reduced Murine Local Lymph Node Assay (rLLNA) is the first-choice method for in vivo testing as a screening test to distinguish between sensitisers and non sensitisers. The full LLNA should be performed when it is known that an assessment of sensitisation potency is required. Only in exceptional circumstances should another test be used, in which case a justification shall be provided.

5.2.2. Acute toxicity, pathogenicity, and infectiveness

Testing shall be conducted via the oral route unless the primary route of human exposure is expected to be inhalation. Testing shall be carried out via only a single exposure route.

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.

▌

5.2.3. In vitro genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

Testing shall be conducted via the oral route unless the primary route of exposure is expected to be inhalation. Testing shall be carried out via only a single exposure route.

5.2.5.1. Health effects after repeated inhalatory exposure

Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.

5.2.6. Proposed treatment: first aid measures, medical treatment

5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

Testing may be waived if there is no evidence of specific toxicity in earlier studies.

5.4. Genotoxicity — In vivo studies in somatic cells

For new substances, it should be possible to assess the parameters of an in-vivo micronucleus test as part of a repeated exposure study.

5.5. Genotoxicity — In vivo studies in germ cells

Testing may be waived if there is no evidence of genotoxicity in somatic cell studies.

END OF TIER II

5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

6. Residues in or on treated materials, food and feedingstuffs

6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs

6.2. Further information required

6.2.1. Non-viable residues

6.2.2. Viable residues

6.3. Summary and evaluation of residues in or on treated materials, food and feedingstuffs

7. Fate and behaviour in the environment

7.1. Persistence and multiplication

7.1.1. Soil

7.1.2. Water

7.1.3. Air

7.2. Mobility

7.3. Summary and evaluation of fate and behaviour in the environment

8. Effects on non-target organisms

8.1. Effects on birds

An avian dietary toxicity study in a single species may be proposed where a substance use profile indicates the potential for significant exposure to birds.

An avian reproduction study is not generally required, and is not appropriate if the dietary toxicity study shows that the LC50 is above 5 000 mg/kg.

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8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on freshwater invertebrates

8.2.3. Effects on algae growth

8.2.4. Effects on plants other than algae

8.3. Effects on bees

8.4. Effects on arthropods other than bees

8.5. Effects on earthworms

8.6. Effects on soil micro-organisms

8.7. Further studies

8.7.1. Terrestrial plants

8.7.2. Mammals

8.7.3. Other relevant species and processes

8.8. Summary and evaluation of effects on non-target organisms

9. Summary and evaluation of sections 1 to 8 including conclusions of the risk assessment and recommendations

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ANNEX III

Data requirements for biocidal products

1. Dossiers on ***biocidal products*** shall contain the information needed to establish ***that exposure is below the Threshold of Toxicological Concern (TTC), or*** where relevant, ***to establish*** Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC), and Predicted No-Effect Concentration (PNEC).

2. Whenever possible, the information should be derived from existing data in order to reduce the number of tests on animals. In particular, the provisions of Directive 1999/45/EC and Regulation (EC) No 1272/2008 shall apply.

3. Information which is however not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied.

4. A detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods shall be included.

5. The formats made available by the Commission must be used for submission of the dossiers. In addition, the special software package (IUCLID) made available by the Commission must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.

6. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are ***scientifically satisfactory*** and ***the validity of which*** must be justified in the application.

7. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 86/609/EEC, and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency.

8. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided. ▌

9. Where test data exist that have been generated before … (*) by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State ***concerned in agreement with the Agency***, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

10. All available relevant knowledge and information in literature should be provided.

TITLE 1 — Chemical products

Dossier requirements

The following data will be required to support submissions.

1. Applicant

1.1. Name and address, etc.

1.2. Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))

2. Identity

2.1. Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjutants, inert components***, taking account of the concentrations referred to in Article 16(4)***

2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution

3. Physical, chemical and technical properties

3.1. Appearance (physical state, colour)

3.2. Explosive properties

3.3. Oxidising properties

3.4. Flash-point and other indications of flammability or spontaneous ignition

3.5. Acidity/alkalinity and if necessary pH value (1 % in water)

3.6. Relative density

3.7. Storage stability - stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material

Storage stability and shelf life will be generally determined based on the stability of the active substance. In the case of readily decomposable active substances, the storage stability and the shelf life may be determined by other valid scientific means, such as extrapolating the analytical data of the active substance from product aging experiments until reaching the efficacy threshold.

3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability

(*) Date of entry into force of this Regulation.

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3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

4. Methods of identification and analysis

4.1. Analytical method for determining the concentration of the active substance(s) in the biocidal product

4.2. In so far as not covered by Annex II, Section 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:

4.2.1. Soil

4.2.2. Air

4.2.3. Water (including drinking water)

4.2.4. Animal and human body fluids and tissues

4.2.5. Treated food or feedingstuffs

5. Intended uses and efficacy

5.1. Product type and field of use envisaged

5.2. Method of application including description of system used

5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes

5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide

5.6. Pest organism(s) to be controlled and products, organisms or objects to be protected

5.7. Effects on target organisms

5.8. Mode of action (including time delay) in so far as not covered by Annex II, Section 5.4

5.9. User: industrial, professional, general public (non-professional)

5.10. The proposed label claims for the product

5.11. Efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate

5.12. Any other known limitations on efficacy including resistance

6. Toxicological studies

6.1. Acute toxicity

For studies of Sections 6.1.1 to 6.1.2, ***without prejudice to Articles 6 and 9 of regulation (EC) No 1272/2008, classification by calculation may*** be the ***default approach. Only in exceptional cases should additional in-vivo testing be considered, and in such cases, only the single most relevant exposure*** route ***should be tested***. Gases and volatile liquids should be administered by the inhalation route

6.1.1. Oral

▌

6.1.2. Inhalation

Testing by the inhalation route is appropriate only if:

(i) classification by calculation is not feasible; and

(ii) this constitutes the primary route of human exposure, taking into account the vapour pressure of the substance and the possibility of exposure to aerosols, particles or droplets of an inhalable size.

The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should the classic 'lethal concentration' (LC50) test be used. Justification for the use of another test shall be provided.

▌

6.2. Skin and eye irritation [1]

Classification by calculation may be the default approach.

6.3. Skin sensitisation

Classification by calculation may be the default approach.

6.4. Information on ***in-vitro*** dermal absorption

6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)

6.6. Information related to the exposure of the biocidal product to man and the operator

Where necessary, the test(s) described in Annex II, shall be required for the toxicologically relevant non-active substances of the preparation

7. Ecotoxicological studies

7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged

7.2. Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself

7.3. Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

8. Measures to be adopted to protect man, animals and the environment

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Annex II, Title 1, point 8.3

8.3. Procedures, if any, for cleaning application equipment

8.4. Identity of relevant combustion products in cases of fire

[1] Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

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8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration

8.6. Possibility of destruction or decontamination following release in or on the following:

8.6.1. Air

8.6.2. Water, including drinking water

8.6.3. Soil

8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

9. Where relevant, the following additional data shall also be provided

9.1. Further human health-related studies

9.1.1. Food and feedingstuffs studies

9.1.1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin

9.1.1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

9.1.2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product

9.2. Further studies on fate and behaviour in the environment

9.2.1. Where relevant all the information required in Annex II, Section 12

9.2.2. Testing for distribution and dissipation in the following:

9.2.2.1. Soil

9.2.2.2. Water

9.2.2.3. Air

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product

9.3. Further Ecotoxicological studies

9.3.1. Effects on birds

▌

9.3.2. Effects on aquatic organisms

9.3.2.1. In case of application on, in, or near to surface waters

9.3.2.1.1. Particular studies with fish and other aquatic organisms

9.3.2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites

9.3.2.1.3. The studies referred to in Annex II, Section 13.2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product

9.3.2.1.4. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions

9.3.3. Effects on other non-target organisms

▌

9.3.3.1. Acute toxicity to honeybees

9.3.3.2. Effects on beneficial arthropods other than bees

9.3.3.3. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk

9.3.3.4. Effects on soil non-target micro-organisms

9.3.3.5. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

9.3.3.6. If the biocidal product is in the form of bait or granules

9.3.3.6.1. Supervised trials to assess risks to non-target organisms under field conditions

9.3.3.6.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

10. Classification, packaging and labelling

— Proposals for safety-data sheets, where appropriate

— Hazard symbol(s)

— Indications of danger

— Hazard statements

— Precautionary statements

— Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included

11. Summary and evaluation of Sections 2 to 10

TITLE 2 — Micro-organisms

Dossier requirements

The following data will be required to support submissions.

1. Applicant

1.1. Name and address, etc.

1.2. Formulator of the biocidal product and the micro-organism(s) (names, addresses, including location of plant(s))

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2. Identity of the biocidal products

2.1. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product

2.3. Physical state and nature of the biocidal product

2.4. Function

3. Physical, chemical and technical properties of the biocidal product

3.1. Appearance (colour and odour)

3.2. Storage stability and shelf-life

3.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product

3.2.2. Other factors affecting stability

3.3. Explosivity and oxidising properties

3.4. Flash point and other indications of flammability or spontaneous ignition

3.5. Acidity, alkalinity and pH value

3.6. Viscosity and surface tension

3.7. Technical characteristics of the biocidal product

3.7.1. Wettability

3.7.2. Persistent foaming

3.7.3. Suspensibility and suspension stability

3.7.4. Dry sieve test and wet sieve test

3.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

3.7.6. Emulsifiability, re-emulsifiability, emulsion stability

3.7.7. Flowability, pourability (rinsability) and dustability

3.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered

3.8.1. Physical compatibility

3.8.2. Chemical compatibility

3.8.3. Biological compatibility

3.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

4. Analytical methods

4.1. Methods for the analysis of the biocidal product

4.2. Methods to determine and quantify residues

5. Intended use and efficacy

5.1. Field of use envisaged

5.2. Mode of action

5.3. Details of intended use

5.4. Application rate

5.5. Content of micro-organism in material used (e.g. in the application device or bait)

5.6. Method of application

5.7. Number and timing of applications and duration of protection

5.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment

5.9. Proposed instructions for use

5.10. Category of users

5.11. Information on the possible occurrence of the development of resistance

5.12. Effects on the materials or products treated with the biocidal product

6. Effects on human health

6.1. Basic acute toxicity studies

6.1.1. Acute oral toxicity

Without prejudice to Articles 6 and 9 of Regulation (EC) No 1272/2008, classification by calculation may be the default approach. Only in exceptional cases should additional in-vivo testing be considered, and in such cases, only the single most relevant exposure route should be tested.

6.1.2. Acute inhalation toxicity

Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.

6.1.3. Acute percutaneous toxicity

6.2. Additional acute toxicity studies

6.2.1. Skin irritation

Classification by calculation may be the default approach.

6.2.2. Eye irritation

Classification by calculation may be the default approach.

6.2.3. Skin sensitisation

Classification by calculation may be the default approach.

6.3. Data on exposure

6.4. Available toxicological data relating to non-active substances

6.5. Supplementary studies for combinations of biocidal products

6.6. Summary and evaluation of effects on human health

7. Residues in or on treated materials, food and feedingstuffs

8. Fate and behaviour in the environment

9. Effects on non-target organisms

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9.1. Effects on birds

9.2. Effects on aquatic organisms

9.3. Effects on bees

9.4. Effects on arthropods other than bees

9.5. Effects on earthworms

9.6. Effects on soil micro-organisms

9.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

9.7.1. Terrestrial plants

9.7.2. Mammals

9.7.3. Other relevant species and processes

9.8. Summary and evaluation of effects on non-target organisms

10. Classification, packaging and labelling

As established in point b of Article 18(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Regulation (EC) No 1272/2008 and Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying hazard statements for all dangerous properties.

10.1. Packaging and compatibility of the biocidal product with proposed packaging materials

10.2. Procedures for cleaning application equipment

10.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

10.4. Recommended methods and precautions concerning: handling, storage, transport or fire

10.5. Measures in the case of an accident

10.6. Procedures for destruction or decontamination of the biocidal product and its packaging

10.6.1. Controlled incineration

10.6.2. Others

10.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

10.8. Indication on the need for biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC

11. Summary and evaluation of Sections 1 to 10 including conclusions of the risk assessment and recommendations

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ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

The applicant may propose to adapt the data requirements set out in Annexes II and III according to the general rules set out in this Annex. The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex ***and must be based on sufficient scientific grounds and be confirmed by the competent authority***.

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and risk assessment;

(2) sufficient documentation is provided to assess the adequacy of the study; and

(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and risk assessment;

(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods;

(3) exposure duration comparable to or longer than the corresponding test methods if exposure duration is a relevant parameter; and

(4) adequate and reliable documentation of the study is provided.

1.1.3. Historical human data

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data, biomonitoring studies, clinical studies and human volunteer studies performed in accordance with internationally accepted ethical standards shall be considered. The strength of the data for a specific human health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups;

(2) adequate characterisation of exposure;

(3) sufficient length of follow-up for disease occurrence;

(4) valid method for observing an effect;

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(5) proper consideration of bias and confounding factors; and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

1.1.4. Calculation methods for the evaluation of health hazards of preparations

Data requirements for preparations may generally be waived consistent with Annex II to Directive 1999/45/EC and/or Annex I to Regulation (EC) No 1272/2008, which takes into consideration all the health hazards of substances contained in the preparation. Guidance is specifically provided for the following categories of adverse health effects:

— ***acute lethal effects***

— ***non-lethal irreversible effects after a single exposure***

— ***severe effects after repeated or prolonged exposure***

— ***corrosive or irritant effects***

— ***sensitising effects***

— ***carcinogenic effects***

— ***mutagenic effects***

— ***reprotoxic effects.***

1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion. There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the relevant test methods or from an international test method recognised by the Commission as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

— further testing on vertebrate animals for that property shall be omitted,

— further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

— results are derived from a (Q)SAR model whose scientific validity has been established,

— the substance falls within the applicability domain of the (Q)SAR model,

— results are adequate for the purpose of classification and labelling and risk assessment, and

— adequate and reliable documentation of the applied method is provided.

1.4. In vitro methods

Results obtained from suitable in vitro methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, 'suitable' means sufficiently well developed according to internationally agreed test development criteria.

Such confirmation may be waived, if the following conditions are met:

(1) results are derived from an in vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;

(2) results are adequate for the purpose of classification and labelling ***and/or*** risk assessment; and

(3) adequate and reliable documentation of the applied method is provided.

1.5. Grouping of substances and read-across approach

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. The similarities may be based on:

(1) a common functional group;

(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results should:

— be adequate for the purpose of classification and labelling and risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method,

— cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter, and

— adequate and reliable documentation of the applied method shall be provided.

2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the relevant test methods, more specifically on the technical limitations of a specific method, shall always be respected.

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with sections 6 and 7 of Annexes II and III may be omitted based on exposure considerations.

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment in accordance with the Technical Notes for Guidance.

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ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

These product-types exclude products where they are covered by the Directives mentioned in Article 2(2) for the purposes of those Directives.

MAIN GROUP 1: Disinfectants and general biocidal products

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene biocidal products

Products in this group are biocidal products used for human hygiene purposes.

Product-type 2: Private area and public health area disinfectants and other biocidal products

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feedingstuffs contact in private, public and industrial areas, including hospitals, as well as products used as algaecides.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in play-grounds).

Product-type 3: Veterinary hygiene biocidal products

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

Product-type 4: Food and feed area disinfectants

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feedingstuffs or drink (including drinking water) for humans and animals.

Product-type 5: Drinking water disinfectants

Products used for the disinfection of drinking water (for both humans and animals).

MAIN GROUP 2: Preservatives

Product-type 6: In-can preservatives

Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.

This product type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

These include products which inhibit surface build-ups of microorganisms (e.g. pathogenic or odour-generating germs) and thus curb or prevent the creation of odours and/or have other uses.

Product-type 10: Masonry preservatives

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the preservation of drinking water are not included in this product type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Metalworking-fluid preservatives

Products used for the preservation of metalworking fluids by the control of microbial deterioration.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents.

Product-type 15: Avicides

Products used for the control of birds.

Product-type 16: Molluscicides

Products used for the control of molluscs.

Product-type 17: Piscicides

Products used for the control of fish; these products exclude products for the treatment of fish diseases.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

MAIN GROUP 4: Other biocidal products

Product-type 20: -

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Product-type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

Product-type 23: Control of other vertebrates

Products used for the control of vermin.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

DEFINITIONS

(a) Hazard identification

This is the identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) Dose (concentration) - response (effect) assessment

This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) Exposure assessment

This is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) Risk characterisation

This is the estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation' i.e. the quantification of that likelihood.

(e) Environment

Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex lays down principles to ensure that evaluations made and decisions taken by a competent authority or the Agency, or the Commission, where relevant, concerning the authorisation of a biocidal product providing it is a chemical preparation results in a harmonised high level of protection for humans, animals and the environment in accordance with point (b) of Article 16(1).

2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product***, taking due account of cumulative, combination and synergistic effects***.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of the inclusion of the active substance into Annex I. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation***, taking due account of cumulative, combination and synergistic effects***. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

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4. In order to carry out a risk assessment data are required. These data are detailed in Annexes II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Competent authorities or the Agency should take due consideration of the requirements of Article 6 and Article 19 of this Regulation in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VI to Regulation (EC) No 1907/2006; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Annex I to this Regulation. Data may also be required on a substance of concern present in a biocidal product.

5. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

6. When making evaluations and taking decisions concerning the authorisation of a biocidal product the competent authorities or the Agency shall:

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

7. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of 'frame-formulations' is relevant here.

8. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Annex, are subject to a simplified procedure as detailed in Article 16(5) of this Regulation.

9. The application of these common principles shall lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the competent authorities may conclude that more data are required before an authorisation decision can be made.

10. During the process of evaluation and decision-making, applicants and the competent authorities shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 16 and of this Annex. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

11. The judgments made by the competent authorities during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

EVALUATION

General principles

12. The data submitted in support of an application for authorisation of a biocidal product shall be examined for overall scientific value by the receiving competent authorities. After acceptance of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.

13. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then ***all available data*** shall be ***included in the dossier*** for ***authorisation of a biocidal product for*** each of these. The ***data*** shall cover the proposed normal use of the biocidal product together with a realistic worst-case scenario including any relevant production and disposal issue either of the biocidal product itself or any material treated with it.

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14. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include, as appropriate, a dose (concentration) - response (effect) assessment, together with an exposure assessment and a risk characterisation***, taking due account of cumulative, combination and synergistic effects***.

15. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

16. The risk assessment shall determine:

(a) the risk to humans and animals,

(b) the risk to the environment,

(c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.

17. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

18. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

19. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute and chronic toxicity,

— irritation,

— corrosivity,

— sensitisation,

— repeated dose toxicity,

— mutagenicity,

— carcinogenicity,

— reproduction toxicity,

— neurotoxicity,

— ***immunotoxicity***,

— any other special properties of the active substance or substance of concern,

— other effects due to physico-chemical properties.

20. The populations previously mentioned are:

— professional users,

— non-professional users,

— humans exposed indirectly via the environment.

21. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of Article 58 then dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be required.

22. In order to reduce the number of tests on animals, adverse effects should, whenever possible, be studied on the basis of the information on the active substance and existing information on the substances that give cause for concern which the biocidal product contains. In particular, the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 shall be applied for the purpose of ascertaining adverse effects of the biocidal product.

23. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.

24. The competent authorities shall apply points 25 to 28 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

25. For repeated dose toxicity and reproductive toxicity the dose response relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.

26. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Regulation. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.

27. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in point 25.

28. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

29. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.

30. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

31. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 6 and Article 19 and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,

— the form in which the product is marketed,

— the type of biocidal product,

— the application method and application rate,

— the physico-chemical properties of the product,

— the likely routes of exposure and potential for absorption,

— the frequency and duration of exposure,

— the type and size of specific exposed populations where such information is available.

32. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,

— be subjected to an analysis taking into account possible elements of uncertainty,

— be reliably validated with measurements carried out under circumstances relevant for the use of the model,

— be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

33. Where, for any of the effects set out in point 19 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

34. Using the same relevant principles as described in the section dealing with effects on humans, the competent authorities shall consider the risks posed to animals from the biocidal product.

Effects on the environment

35. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments - air, soil and water (including sediment) - and of the biota following the use of the biocidal product.

36. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Regulation then dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be required.

37. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:

— any indications of bioaccumulation potential,

— the persistence characteristics,

— the shape of the toxicity/time curve in ecotoxicity testing,

— indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),

— data on structurally analogous substances,

— endocrine effects.

38. A dose (concentration) - response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) - response (effect) then has to be made.

39. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 6 and Article 18. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).

40. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in point 3.3.1 of Annex I to Regulation (EC) No. 1907/2006.

41. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

42. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.

43. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:

— adequately measured exposure data,

— the form in which the product is marketed,

— the type of biocidal product,

— the application method and application rate,

— the physico-chemical properties,

— breakdown/transformation products,

— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,

— the frequency and duration of exposure.

44. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in point 32. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

45. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

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46. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

Unacceptable effects

47. Data shall be submitted to and evaluated by the competent authorities to assess whether the biocidal product does not cause unnecessary suffering ***and pain*** in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated. ***These findings shall for each authorised biocidal product be made publicly available on the Agency website.***

48. The competent authorities shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.

49. If there are indications that any other unacceptable effects may occur the competent authorities shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

50. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the competent authorities or the Agency must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

51. Testing should be carried out according to Union guidelines if these are available and applicable. Where appropriate, other methods can be used as shown in the list below. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method

— national standard method

— industry standard method (accepted by competent authorities or the Agency)

— individual producer standard method (accepted by competent authorities or the Agency)

— data from the actual development of the biocidal product (accepted by competent authorities or the Agency).

Summary

52. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the competent authorities shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

53. For biocidal products containing more than one active substance any adverse effects shall also be combined to produce an overall effect for the biocidal product itself.

DECISION MAKING

General principles

54. Subject to point 90, the competent authorities or the Commission shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.

55. In making a decision concerning authorisation, the competent authorities or the Commission shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made:

(1) the biocidal product cannot be authorised;

(2) the biocidal product can be authorised subject to specific conditions/restrictions;

(3) more data is required before a decision on authorisation can be made.

56. If the conclusion arrived at by the competent authorities or the Commission is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

57. The competent authorities or the Commission shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Union level to be used in such biocidal products.

58. The competent authorities or the Commission shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.

59. In the decision-making process the competent authorities or the Commission shall take into consideration the following:

— the results of the risk assessment, in particular the relationship between exposure and effect,

— the nature and severity of the effect, ***taking due account of cumulative, combination and synergistic effects,***

— the risk management which can be applied,

— the field of use of the biocidal product,

— the efficacy of the biocidal product,

— the physical properties of the biocidal product,

— the benefits of using the biocidal product.

60. The competent authorities or the Commission shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.

61. The competent authorities or the Commission shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.

Effects on humans

62. The competent authorities or the Commission shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.

63. The competent authorities or the Commission shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.

64. The competent authorities or the Commission shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.

65. The competent authorities or the Commission shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.

66. An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

67. The competent authorities or the Commission shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.

68. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.

69. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the competent authorities or the Commission for the biocidal product.

Effects on animals

70. The competent authorities or the Commission shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.

71. Using the same relevant criteria as described in the section dealing with effects on humans, the competent authorities or the Commission shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

Effects on the environment

72. The competent authorities or the Commission shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments.

In considering whether there is an unacceptable risk competent authorities or the Commission shall, when coming to a final decision in accordance with point 90, take into account the criteria in points 75 to 85.

73. The basic tool used in the decision making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

74. For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1 the risk characterisation shall be that no further information and/or testing are necessary.

If the PEC/PNEC ratio is greater than 1 the competent authorities or the Commission shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be given an authorisation at all. Relevant factors to be considered are those previously mentioned in point 37.

Water

75. The competent authorities or the Commission shall not authorise a biocidal product, if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

76. The competent authorities or the Commission shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

— the maximum permissible concentration laid down by Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption ([1]), or

— the maximum concentration as laid down following the procedure for including the active substance in Annex I to this Regulation, on the basis of appropriate data, in particular toxicological data

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

77. The competent authorities or the Commission shall not authorise a biocidal product if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in ***groundwater or*** surface water or its sediments after use of the biocidal product under the proposed conditions of use:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by

  — Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States ([2]),

  — Directive 80/778/EEC or

— has an impact deemed unacceptable on non-target species

— ***risks a non-achievement of the objectives or standards fixed by:***

  — ***Directive 98/83/EC, or***

  — ***Directive 2000/60/EC or***

  — ***Directive 2006/118/EC or***

  — ***Directives 2008/56/EC, or***

  — ***Directive 2008/105/EC, or***

  — ***international agreements containing important obligations on the protection of marine waters from pollution.***

78. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

([1]) OJ L 229, 30.8.1980, p. 11.
([2]) OJ L 194, 25.7.1975, p. 26.

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Soil

79. Where unacceptable contamination of soil is likely to occur, the competent authorities or the Commission shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

— during tests in the field, persists in soil for more than one year, or

— during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days,

— has unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Air

80. The competent authorities or the Commission shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on non-target organisms

81. The competent authorities or the Commission shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur after use of the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.

82. The competent authorities or the Commission shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) is greater than 1 000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms including marine and estuarine organisms after use of the biocidal product according to the proposed conditions of use.

83. The competent authorities or the Commission shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

84. If the development of resistance to the active substance in the biocidal product is likely the competent authorities or the Commission shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or even refusal of any authorisation.

85. An authorisation for a biocidal product intended to control vertebrates shall not be given unless:

— death is synchronous with the extinction of consciousness, or,

— death occurs immediately, or,

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

86. Competent authorities or the Commission shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

87. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State or, where appropriate, in the Union, except where the biocidal product is intended for use in specific circumstances. Competent authorities shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

88. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the competent authorities or the Commission shall combine the conclusions arrived at for the active substance and the substances of concern to produce an overall conclusion for the biocidal product itself. A summary should also be made of the efficacy assessment and of the unacceptable effects.

The result shall be:

— a summary of the effects of the biocidal product on humans,

— a summary of the effects of the biocidal product on animals,

— a summary of the effects of the biocidal product on the environment,

— a summary of the efficacy assessment,

— a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

89. The competent authorities or the Commission shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.

90. The competent authorities or the Commission shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorisation decision on the biocidal product.

91. The competent authorities or the Commission shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Annex and this Regulation.

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CORRELATION TABLE

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[1] The correlation table has not yet been changed to reflect Parliament's position. It will be updated once an agreement between Parliament and Council has been reached.

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European Supervisory Authority (European Insurance and Occupational Pensions Authority) ***I

P7_TA(2010)0334

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council establishing a European Insurance and Occupational Pensions Authority (COM(2009)0502 – C7-0168/2009 – 2009/0143(COD))

(2012/C 50 E/18)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2009)0502),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0168/2009),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Central Bank of 8 January 2010 ([1]),

— having regard to the opinion of the European Economic and Social Committee of 21 January 2010 ([2]),

— having regard to the undertaking given by the Council representative by letter of 15 September 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Budgets, the Committee on Legal Affairs and the Committee on Constitutional Affairs (A7-0170/2010),

1. Adopts its position at first reading hereinafter set out ([3]);

2. Takes note of the Commission statements annexed to this resolution;

3. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

([1]) OJ C 13, 20.1.2010, p. 1.
([2]) Not yet published in the Official Journal.
([3]) This position replaces the amendments adopted on 7 July 2010 (Texts adopted, P7_TA(2010)0273).

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P7_TC1-COD(2009)0143

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1094/2010.)

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Commission Statements

Declaration in relation to supervisory powers on credit rating agencies and other areas

The Commission notes that agreement has been found on granting certain supervisory powers to ESMA with regard to credit rating agencies. The Commission considers that it could in future be useful to entrust supervisory competences to the European Authorities in other areas. In particular, this could concern market infrastructure. The Commission will examine these questions in depth and will make the legislative proposals which it considers appropriate.

Declarations in relation to crisis management and resolution

In its Communication of 26 May 2010 on Bank Resolution Funds, the Commission emphasised that 'an appropriate first step could be a system based around the establishment of a harmonized network of national funds linked to a set of coordinated national crisis management arrangements'.

The Commission confirms that it intends to make legislative proposals for a complete set of tools for prevention and resolution of failing banks in Spring 2011. This will ensure that public authorities are able to resolve failing financial institutions whilst minimising the impact of failures on the financial system, limiting damage to the economy and the use of public sector resources.

The Commission confirms that the ESAs should play an important role in these areas and that it will examine which powers concerning the tools for prevention and resolution of failing banks should be conferred upon it.

These arrangements are a first step and would be reviewed by 2014 with the aim of creating Union integrated crisis management and supervisory arrangements, as well as a Union Resolution Fund in the longer term.

Macro-prudential oversight of the financial system and establishment of a European Systemic Risk Board ***I

P7_TA(2010)0335

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council on Community macro prudential oversight of the financial system and establishing a European Systemic Risk Board (COM(2009)0499 – C7-0166/2009 – 2009/0140(COD))

(2012/C 50 E/19)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2009)0499),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0166/2009),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Central Bank of 26 October 2009 ([1]),

— having regard to the opinion of the European Economic and Social Committee of 22 January 2010 ([2]),

— having regard to the undertaking given by the Council representative by letter of 15 September 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Legal Affairs and the Committee on Constitutional Affairs (A7-0168/2010),

1. Adopts its position at first reading hereinafter set out ([3]);

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

([1]) OJ C 270, 11.11.2009, p. 1.
([2]) Not yet published in the Official Journal.
([3]) This position replaces the amendments adopted on 7 July 2010 (Texts adopted, P7_TA(2010)0271).

P7_TC1-COD(2009)0140

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council on European Union macro-prudential oversight of the financial system and establishing a European Systemic Risk Board

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1092/2010.)

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Powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority) ***I

P7_TA(2010)0336

European Parliament legislative resolution of 22 September 2010 on the proposal for a directive of the European Parliament and of the Council amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC and 2009/65/EC in respect of the powers of the European Banking Authority, the European Insurance and Occupational Pensions Authority and the European Securities and Markets Authority (COM(2009)0576 – C7-0251/2009 – 2009/0161(COD))

(2012/C 50 E/20)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2009)0576),

— having regard to Article 251(2) and Article 44, Article 47(2) and Articles 55 and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0251/2009),

— having regard to the Commission Communication entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 50, Article 53(1) and Articles 62 and 114 of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Central Bank of 18 March 2010 ([1]),

— having regard to the opinion of the Economic and Social Committee of 18 March 2010 ([2]),

— having regard to the undertaking given by the Council representative by letter of 15 September 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs and the opinion of the Committee on Legal Affairs (A7-0163/2010),

1. Adopts its position at first reading hereinafter set out ([3]);

2. Takes note of the Commission statements annexed to this resolution;

([1]) OJ C 87, 1.4.2010, p. 1.
([2]) Not yet published in the Official Journal.
([3]) This position replaces the amendments adopted on 7 July 2010 (Texts adopted, P7_TA(2010)0269).

3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2009)0161

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Directive 2010/…/EU of the European Parliament and of the Council amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC, and 2009/65/EC in respect of the powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority)

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2010/78/EU.)

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Commission Statements

Declaration on the Omnibus Directive: adaptation to the Lisbon Treaty

The Commission is reviewing the Markets in Financial Instruments Directive (MiFID) and, if necessary, will propose improvements of the Directive. In this context, the Commission will examine, among other things, ways to strengthen pre- and post-trade transparency, including the rules and arrangements required from regulated markets, and any necessary amendments to adjust the Directive to the Lisbon Treaty.

The Commission is reviewing Market Abuse Directive (MAD). In this context, the Commission will examine, among other things, any necessary amendments to adjust the Directive to the Lisbon Treaty.

The Commission is reviewing the financial conglomerates directive (FICOD). In this context, the Commission will examine, among other things, any necessary amendments to adjust the Directive to the Lisbon Treaty.

Declaration in relation to Omnibus amendment on the Transparency Directive: country-by-country reporting

The Commission intends to prepare a Communication evaluating the feasibility of requesting certain issuers of shares whose securities are admitted to trading in a regulated market and which prepare consolidated accounts, to disclose in the annual financial report, key financial information regarding their activities in third countries. This Communication could identify the type of issuers that could be concerned; the financial information which would be meaningful to investors and other stakeholders as well as how this information could be presented. The Commission could take due account of the progress made on this issue by the IASB. The Commission intends to prepare the Communication by 30 September 2011, after having consulted ESMA. The Communication could also address the possible impact of these measures, and could be taken into account when carrying out the revision of the Directive 2004/109/EC.

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European Supervisory Authority (European Banking Authority) ***I

P7_TA(2010)0337

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council establishing a European Banking Authority (COM(2009)0501 – C7-0169/2009 – 2009/0142(COD))

(2012/C 50 E/21)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2009)0501),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0169/2009),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Central Bank of 8 January 2010 ([1]),

— having regard to the opinion of the European Economic and Social Committee of 22 January 2010 ([2]),

— having regard to the undertaking given by the Council representative by letter of 15 September 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Legal Affairs, the Committee on Budgets and the Committee on Constitutional Affairs (A7-0166/2010),

1. Adopts the position at first reading hereinafter set out ([3]);

2. Considers that the reference amount indicated in the legislative proposal is compatible with the ceiling for subheading 1a of multiannual financial framework for 2007-2013 (MFF), but the margin remaining in heading 1a for 2011-2013 is very limited and the funding of new activities must not jeopardise the financing of other priorities under subheading 1a; reiterates, therefore, its call for a review of the MFF, accompanied by concrete proposals to adjust and revise it before the end of 2010 by using all the mechanisms available under the Interinstitutional Agreement of 17 May 2006 (IIA), and, in particular, those in points 21 to 23 thereof, in order to ensure the financing of the European Supervisory Authority (European Banking Authority) without jeopardising the financing of the other priorities, and ensuring that a sufficient margin will remain, under subheading 1a;

([1]) OJ C 13, 20.1.2010, p. 1.
([2]) Not yet published in the Official Journal.
([3]) This position replaces the amendments adopted on 7 July 2010 (Texts adopted, P7_TA(2010)0272).

3. Underlines that the provisions of point 47 of the IIA should be applied for the setting-up of the European Supervisory Authority (European Banking Authority); stresses that, should the legislative authority decide in favour of setting up the European Supervisory Authority (European Banking Authority), Parliament will enter into negotiations with the other arm of the budgetary authority with a view to coming to a timely agreement on the financing of the Authority in line with the relevant provisions of the IIA;

4. Takes note of the Commission statements annexed to this resolution;

5. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

6. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2009)0142

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1093/2010.)

ANNEX

Commission Statements

Declaration in relation to supervisory powers on credit rating agencies and other areas

The Commission notes that agreement has been found on granting certain supervisory powers to ESMA with regard to credit rating agencies. The Commission considers that it could in future be useful to entrust supervisory competences to the European Authorities in other areas. In particular, this could concern market infrastructure. The Commission will examine these questions in depth and will make the legislative proposals which it considers appropriate.

Declarations in relation to crisis management and resolution

In its Communication of 26 May 2010 on Bank Resolution Funds, the Commission emphasised that 'an appropriate first step could be a system based around the establishment of a harmonized network of national funds linked to a set of coordinated national crisis management arrangements'.

The Commission confirms that it intends to make legislative proposals for a complete set of tools for prevention and resolution of failing banks in Spring 2011. This will ensure that public authorities are able to resolve failing financial institutions whilst minimising the impact of failures on the financial system, limiting damage to the economy and the use of public sector resources.

The Commission confirms that the ESAs should play an important role in these areas and that it will examine which powers concerning the tools for prevention and resolution of failing banks should be conferred upon it.

These arrangements are a first step and would be reviewed by 2014 with the aim of creating Union integrated crisis management and supervisory arrangements, as well as a Union Resolution Fund in the longer term.

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Specific tasks for the European Central Bank concerning the functioning of the European Systemic Risk Board *

P7_TA(2010)0338

European Parliament legislative resolution of 22 September 2010 on the proposal for a Council regulation entrusting the European Central Bank with specific tasks concerning the functioning of the European Systemic Risk Board (05551/2010 – C7-0014/2010 – 2009/0141(CNS))

(2012/C 50 E/22)

(Special legislative procedure – Consultation)

The European Parliament,

— having regard to the Commission proposal to the Council (COM(2009)0500),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to the proposal for a Council Regulation (05551/2010),

— having regard to Article 127(6) of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0014/2010),

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs (A7-0167/2010),

1. Approves the proposal for a Council Regulation as amended on 7 July 2010 ([1]);

2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 293(2) of the Treaty on the Functioning of the European Union;

3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;

4. Asks the Council to consult Parliament again if it intends to amend the proposal substantially;

5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

([1]) Texts adopted, P7_TA(2010)0275.

Wednesday 22 September 2010

European Supervisory Authority (European Securities and Markets Authority) ***I

P7_TA(2010)0339

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council establishing a European Securities and Markets Authority (COM(2009)0503 – C7-0167/2009 – 2009/0144(COD))

(2012/C 50 E/23)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2009)0503),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0167/2009),

— having regard to the Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

— having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Central Bank of 8 January 2010 ([1]),

— having regard to the opinion of the European Economic and Social Committee of 21 January 2010 ([2]),

— having regard to the undertaking given by the Council representative by letter of 15 September 2010 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Budgets, the Committee on Legal Affairs and the Committee on Constitutional Affairs (A7-0169/2010),

1. Adopts its position at first reading hereinafter set out ([3]);

2. Considers that the reference amount indicated in the legislative proposal is compatible with the ceiling for subheading 1a of multiannual financial framework for 2007-2013 (MFF), but the margin remaining in heading 1a for 2011-2013 is very limited and the funding of new activities must not jeopardise the financing of other priorities under subheading 1a; reiterates, therefore, its call for a review of the MFF, accompanied by concrete proposals to adjust and revise it before the end of 2010 by using all the mechanisms available under the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management ([4]) (IIA), and, in particular, those in points 21 to 23 thereof, in order to ensure the financing of the European Supervisory Authority (European Securities and Markets Authority) without jeopardising the financing of the other priorities, and ensuring that a sufficient margin will remain, under subheading 1a;

([1]) OJ C 13, 20.1.2010, p. 1.
([2]) Not yet published in the Official Journal.
([3]) This position replaces the amendments adopted on 7 July 2010 (Texts adopted, P7_TA(2010)0270).
([4]) OJ C 139, 14.6.2006, p. 1.

3. Underlines that the provisions of point 47 of the IIA shall be applied for the setting-up of the European Supervisory Authority (European Securities and Markets Authority); stresses that, should the legislative authority decide in favour of setting up the European Supervisory Authority (European Securities and Markets Authority), Parliament will enter into negotiations with the other arm of the budgetary authority with a view to coming to a timely agreement on the financing of the European Supervisory Authority (European Securities and Markets Authority) in line with the relevant provisions of the IIA;

4. Takes note of the Commission statements annexed to this resolution;

5. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

6. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2009)0144

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1095/2010.)

ANNEX

Commission Statements

Declaration in relation to supervisory powers on credit rating agencies and other areas

The Commission notes that agreement has been found on granting certain supervisory powers to ESMA with regard to credit rating agencies. The Commission considers that it could in future be useful to entrust supervisory competences to the European Authorities in other areas. In particular, this could concern market infrastructure. The Commission will examine these questions in depth and will make the legislative proposals which it considers appropriate.

Declarations in relation to crisis management and resolution

In its Communication of 26 May 2010 on Bank Resolution Funds, the Commission emphasised that 'an appropriate first step could be a system based around the establishment of a harmonized network of national funds linked to a set of coordinated national crisis management arrangements'.

The Commission confirms that it intends to make legislative proposals for a complete set of tools for prevention and resolution of failing banks in Spring 2011. This will ensure that public authorities are able to resolve failing financial institutions whilst minimising the impact of failures on the financial system, limiting damage to the economy and the use of public sector resources.

The Commission confirms that the ESAs should play an important role in these areas and that it will examine which powers concerning the tools for prevention and resolution of failing banks should be conferred upon it.

These arrangements are a first step and would be reviewed by 2014 with the aim of creating Union integrated crisis management and supervisory arrangements, as well as a Union Resolution Fund in the longer term.

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2012/C 50 E/11 Agreement between the EC and Pakistan on readmission ***

European Parliament legislative resolution of 21 September 2010 on the draft Council decision on the conclusion of the Agreement between the European Union and the Islamic Republic of Pakistan on the readmission of persons residing without authorisation (05942/2010 – C7-0264/2009 – 2009/0036(NLE)) 62

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Wednesday 22 September 2010

2012/C 50 E/12 Multiannual financial framework for 2007-2013

European Parliament resolution of 22 September 2010 on the proposal for a Council regulation laying down the multiannual financial framework for the years 2007-2013 (COM(2010)0072 – 2010/0048(APP)) 64

2012/C 50 E/13 Draft amending budget No 7/2010: guarantee provided by the European Union in accordance with the provisions of Article 122 of the TFEU – financial assistance to Member States

European Parliament resolution of 22 September 2010 on Council's position on Draft amending budget No 7/2010 of the European Union for the financial year 2010, Section III- Commission (13476/2010 – C7-0261/2010 – 2010/2120(BUD)) 68

2012/C 50 E/14 Refund of value added tax *

European Parliament legislative resolution of 22 September 2010 on the proposal for a Council directive amending Directive 2008/9/EC laying down detailed rules for the refund of value added tax, provided for in Directive 2006/112/EC, to taxable persons not established in the Member State of refund but established in another Member State (COM(2010)0381 – C7-0201/2010 – 2010/0205(CNS)) 69

2012/C 50 E/15 Pharmacovigilance of medicinal products (amendment of Regulation (EC) No 726/2004) ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2008)0664 – C6-0515/2008 – 2008/0257(COD)) 70

P7_TC1-COD(2008)0257

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No …/2010 of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products 71

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2012/C 50 E/16 Pharmacovigilance (amendment of Directive 2001/83/EC) ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2008)0665 – C6-0514/2008 – 2008/0260(COD)) ... 72

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P7_TC1-COD(2008)0260

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Directive 2010/.../EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use 73

2012/C 50 E/17 Placing on the market and use of biocidal products ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products (COM(2009)0267 – C7-0036/2009 – 2009/0076(COD)) 73

P7_TC1-COD(2009)0076

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2012/C 50 E/18 European Supervisory Authority (European Insurance and Occupational Pensions Authority) ***I

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P7_TC1-COD(2009)0143

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC 210

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2012/C 50 E/19 Macro-prudential oversight of the financial system and establishment of a European Systemic Risk Board ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council on Community macro prudential oversight of the financial system and establishing a European Systemic Risk Board (COM(2009)0499 – C7-0166/2009 – 2009/0140(COD)) 210

P7_TC1-COD(2009)0140

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council on European Union macro-prudential oversight of the financial system and establishing a European Systemic Risk Board 211

EN

[1] Text with EEA relevance

(Continued overleaf)

2012/C 50 E/20 Powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority) ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a directive of the European Parliament and of the Council amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC and 2009/65/EC in respect of the powers of the European Banking Authority, the European Insurance and Occupational Pensions Authority and the European Securities and Markets Authority (COM(2009)0576 – C7-0251/2009 – 2009/0161(COD)) 212

P7_TC1-COD(2009)0161

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Directive 2010/.../EU of the European Parliament and of the Council amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC, and 2009/65/EC in respect of the powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority) 213

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2012/C 50 E/21 European Supervisory Authority (European Banking Authority) ***I

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P7_TC1-COD(2009)0142

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC 215

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2012/C 50 E/22 Specific tasks for the European Central Bank concerning the functioning of the European Systemic Risk Board *

European Parliament legislative resolution of 22 September 2010 on the proposal for a Council regulation entrusting the European Central Bank with specific tasks concerning the functioning of the European Systemic Risk Board (05551/2010 – C7-0014/2010 – 2009/0141(CNS)) 216

2012/C 50 E/23 European Supervisory Authority (European Securities and Markets Authority) ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council establishing a European Securities and Markets Authority (COM(2009)0503 – C7-0167/2009 – 2009/0144(COD)) 217

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Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC 218

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Key to symbols used

*	Consultation procedure
**I	Cooperation procedure: first reading
**II	Cooperation procedure: second reading
***	Assent procedure
***I	Codecision procedure: first reading
***II	Codecision procedure: second reading
***III	Codecision procedure: third reading

(The type of procedure is determined by the legal basis proposed by the Commission.)

Political amendments: new or amended text is highlighted in bold italics; deletions are indicated by the symbol ▌.

Technical corrections and adaptations by the services: new or replacement text is highlighted in italics and deletions are indicated by the symbol ‖.

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