



EUROPEAN PARLIAMENT

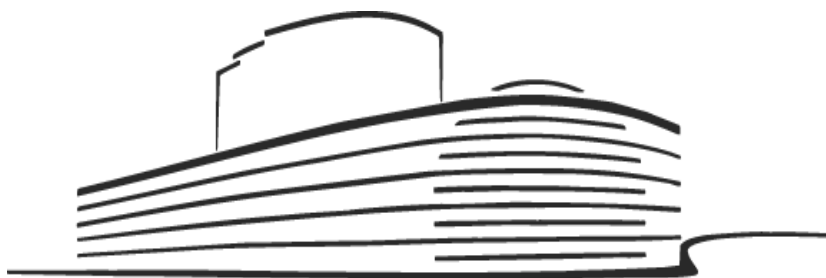
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European Union Agency for Railways *I**

European Parliament legislative resolution of 26 February 2014 on the proposal for a regulation of the European Parliament and of the Council on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (COM(2013)0027 – C7-0029/2013 – 2013/0014(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0027),
 - having regard to Article 294(2) and Article 91(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0029/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 11 July 2013¹,
 - having regard to the opinion of the Committee of the Regions of 8 October 2013²,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Lithuanian Parliament, the Romanian Senate and the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism and the opinions of the Committee on Budgets and the Committee on Budgetary Control (A7-0016/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Requests that the Commission present a financial statement which fully takes into account the result of the legislative agreement between the European Parliament and the Council on all pieces of legislation within the Fourth Railway Package to meet the budgetary and staff requirements of ERA and possibly of the Commission services;
 3. Emphasises that any decision of the legislative authority on the draft regulation shall be without prejudice to the decisions of the budgetary authority in the context of the annual budgetary procedure;

¹ OJ C 327 of 12.11.2013, p. 122

² OJ C 356 of 5.12.2013, p. 92

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

Amendment 1

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) The European Railway Agency was originally established by Regulation (EC) 881/2004 of the European Parliament and of the Council of 29 April 2004⁷, in order to promote the establishment of a European railway area without borders and to help revitalise the railway sector while reinforcing its essential advantages in terms of safety. Regulation 881/2004 has to be replaced by a new act due to substantial **amount of** changes to the tasks of the Agency and its internal organisation.

⁷ OJ L 164, 30.4.2004, p. 1.

Amendment

(3) The European Railway Agency was originally established by Regulation (EC) 881/2004 of the European Parliament and of the Council of 29 April 2004⁷, in order to promote the establishment of a European railway area without borders and to help revitalise the railway sector while reinforcing its essential advantages in terms of safety. Regulation 881/2004 has to be replaced by a new act due to **the** substantial changes **which are required in relation** to the tasks of the Agency and its internal organisation.

⁷ OJ L 164, 30.4.2004, p. 1.

Amendment 2

Proposal for a regulation

Recital 4

Text proposed by the Commission

(4) The Fourth Railway Package proposes important changes to improve the functioning of the **Single** European railway area through amendments by way of recast to Directive 2004/49/EC and Directive 2008/57/EC, both directly linked to the tasks of the Agency. Those Directives, together with this Regulation, provide in particular for performing tasks related to issuing vehicle authorisations and safety certificates at the Union level. It

Amendment

(4) The Fourth Railway Package proposes important changes to improve the functioning of the **single** European railway area through amendments by way of recast to Directive 2004/49/EC and Directive 2008/57/EC, both directly linked to the tasks of the Agency. Those Directives, together with this Regulation, provide in particular for performing tasks related to issuing vehicle authorisations and safety certificates, **especially in cross-**

implies a greater role of the Agency.

border traffic at the Union level. It implies a greater role of the Agency.

Amendment 3

Proposal for a regulation

Recital 5

Text proposed by the Commission

(5) The Agency should contribute to the creation and effective functioning of a Single European railway area without frontiers and guaranteeing a high level of safety while improving the competitive position of the railway sector. That should be attained by contributing, on technical matters, to the implementation of European Union legislation by enhancing the level of interoperability of railway systems and to developing a common approach to safety on the European railway system. The Agency should also perform the role of European authority responsible for issuing authorisations for placing on the market **for railway vehicles** and for types of vehicles, safety certificates for railway undertakings and authorisations for placing in service of trackside **control-command and signalling** sub-systems. Moreover, it should monitor national railway rules and the performance of national authorities acting in the railway interoperability and safety fields.

Amendment

(5) The Agency should contribute to the creation and effective functioning of a Single European railway area without frontiers and guaranteeing a high level of safety while improving the competitive position of the railway sector. That should be attained by contributing, on technical matters, to the implementation of European Union legislation by enhancing the level of interoperability of railway systems and to developing a common approach to safety on the European railway system. The Agency should also perform the role of European authority responsible for issuing, **at Union level**, authorisations for placing **railway vehicles** on the market and for types of vehicles, safety certificates for railway undertakings and authorisations for placing in service of trackside **European Rail Traffic Management System (ERTMS)** sub-systems **located or operated throughout the Union**. Moreover, it should monitor national railway rules and the performance of national authorities acting in the railway interoperability and safety fields.

Amendment 4

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) In pursuing its objectives, the Agency should take full account of the process of

Amendment

(6) In pursuing its objectives, the Agency should take full account of the process of

enlargement of the Union **and of** the specific constraints relating to rail links with third countries. **The Agency should have sole responsibility for the functions and powers assigned to it.**

enlargement of the Union, the specific constraints relating to rail links with third countries, **and the specific situation of rail networks with a different track gauge, particularly where the Member States are well integrated into those networks together with third countries but isolated from the main Union rail network. It should also seek to facilitate the principle of reciprocity between access for third countries to the Union market and access for Union undertakings to the markets of third countries.**

Amendment 5

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) The Agency should have sole responsibility for the functions and powers assigned to it. National safety authorities should have sole responsibility for the decisions that they take.

Amendment 6

Proposal for a regulation Recital 7

Text proposed by the Commission

Amendment

(7) The Agency, while performing its tasks, and particularly in relation to drafting recommendations, should take utmost account of external railway expertise. This expertise should predominantly consist of **professionals** from the **railway sector and the** relevant national authorities. They should form competent and representative working parties of the Agency.

(7) The Agency, while performing its tasks, and particularly in relation to drafting recommendations, should take utmost account of external railway expertise. This expertise should predominantly consist of **experts** from the **national safety authorities and other** relevant national authorities **as well as professionals from the railway sector, including representative bodies and**

independent notified conformity assessment bodies. They should form competent and representative working parties of the Agency. *The Agency should bear in mind the need to maintain a balance between risks and benefits, in particular as regards the management of conflicts of interest, on the one hand, and the objective of obtaining the best possible expertise, on the other.*

Amendment 7

Proposal for a regulation

Recital 10

Text proposed by the Commission

(10) Railway undertakings have been faced with various problems when applying for safety certificates to competent national authorities, ranging from protracting procedures and excessive costs to unfair treatment, especially of new entrants. The certificates issued in one Member State have not been unconditionally recognised in other Member States, with a detriment to the Single European rail area. In order to make the procedures for issuing safety certificates to railway undertakings more efficient and impartial, it is essential to migrate towards a single safety certificate valid throughout the Union and issued by the Agency. The revised Directive ... [Railway Safety Directive] provides a basis for this.

Amendment

(10) Railway undertakings have been faced with various problems when applying for safety certificates to competent national authorities, ranging from protracting procedures and excessive costs to unfair treatment, especially of new entrants. The certificates issued in one Member State have not been unconditionally recognised in other Member States, with a detriment to the Single European rail area. In order to make the procedures for issuing safety certificates to railway undertakings more efficient and impartial, it is essential to migrate towards a single safety certificate valid throughout the Union ***within the specified areas of operation*** and issued by the Agency. The revised Directive ... [Railway Safety Directive] provides a basis for this.

Amendment 8

Proposal for a regulation

Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) In an open European railway market with increasing cross-border operations, the respect of requirements on driving and rest time is essential for railway safety and for fair competition and should be controlled and enforced. National safety authorities should monitor driving and rest times, including for cross-border operations.

Amendment 9

Proposal for a regulation Recital 11 b (new)

Text proposed by the Commission

Amendment

(11b) On-board personnel perform operational safety tasks within the railway system and are responsible for passengers' comfort and safety on-board trains. A certification similar to the certification of locomotive drivers should be set up by the Agency in order to guarantee a high level of qualifications and competences, to recognise the importance of this professional group for safe rail services and also in order to facilitate the mobility of workers.

Amendment 10

Proposal for a regulation Recital 12

Text proposed by the Commission

Amendment

(12) In order to further pursue the development of Single European rail area, in particular with relation to providing appropriate information to freight customers and passengers, and taking into account current involvement of the Agency, it is necessary to give it a strengthened role in the field of telematics

(12) In order to further pursue the development of Single European rail area, in particular with relation to providing appropriate information to freight customers and passengers, and taking into account current involvement of the Agency, it is necessary to give it a strengthened role in the field of telematics

applications. This would ensure their consistent development and swift deployment.

applications *within a flexible framework ensuring interoperability as well as enabling innovative commercial strategies to coexist*. This would ensure their consistent development and swift deployment.

Amendment 11

Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) Given the importance of the European Rail Traffic Management System (ERTMS) for the smooth development of the Single European railway area and its safety, and taking into account *its fragmented* development to date, it is necessary to strengthen its overall coordination at the Union level. Therefore the Agency, as the most competent Union body, should be given a more prominent role in this field to ensure consistent development of the ERTMS, to contribute to ensuring that ERTMS equipment complies with the specifications in force and to ensure that ERTMS-related European research programmes are coordinated with the development of ERTMS technical specifications. Moreover, in order to make the procedures for issuing authorisations for placing in service of trackside control-command and signalling sub-systems more efficient and impartial, it is essential to migrate towards a single authorisation valid in the Union and issued by the Agency. The revised Directive ... [Railway Interoperability Directive] provides a basis for this.

Amendment

(13) Given the importance of the European Rail Traffic Management System (ERTMS) for the smooth development of the Single European railway area and its safety, and taking into account *the failure of the development and deployment* to date, it is necessary to strengthen its overall coordination at the Union level. *The objective of achieving interoperability and harmonisation of train control and signalling systems across the Union is currently seriously undermined by a multitude of diverging national versions of ERTMS.*

Therefore the Agency, as the most competent Union body, should be given a more prominent role in this field to ensure consistent development of the ERTMS, to contribute to ensuring that ERTMS

equipment complies with the specifications in force and to ensure that ERTMS-related European research programmes are coordinated with the development of ERTMS technical specifications.

Moreover, in order to make the procedures for issuing authorisations for placing in service of trackside control-command and signalling sub-systems more efficient and impartial, it is essential to migrate towards a single authorisation valid in the Union and issued by the Agency. The revised Directive ... [Railway Interoperability Directive] provides a basis for this.

Amendment 12

Proposal for a regulation

Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) During recent years, several accidents in the rail freight sector illustrated the need to improve the rules at Union level for the maintenance of freight wagons. The Agency should work on harmonised compulsory requirements for regular maintenance intervals.

Amendment 13

Proposal for a regulation

Recital 14

Text proposed by the Commission

Amendment

(14) Competent national authorities have been normally charging for issuing vehicle authorisations and safety certificates. With the transfer competence to the Union level, the Agency should be entitled to charge the applicants for issuing the certificates and authorisations mentioned in the preceding recitals. The level of those charges should ***be equal to or lower than the current***

(14) Competent national authorities have been normally charging for issuing vehicle authorisations and safety certificates. With the transfer competence to the Union level, the Agency should be entitled to charge the applicants for issuing the certificates and authorisations mentioned in the preceding recitals. The level of those charges should ***vary according to the extent of operations***

average in the *Union* and should be determined in a delegated act to be adopted by the Commission.

and area of use specified in the *certificate or authorisation* and should be determined in a delegated act to be adopted by the Commission. *Establishment plan posts financed by those charges should not be subject to the staff reductions envisaged for all Union institutions and bodies.*

Amendment 14

Proposal for a regulation Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) That delegated act should ensure that the level of charges does not exceed the costs of the certification or authorisation procedures in question.

Amendment 15

Proposal for a regulation Recital 15

Text proposed by the Commission

Amendment

(15) It is a general objective that the transfer of functions and tasks from the Member States to the Agency should be done efficiently, without any reduction in the current high levels of safety. The Agency should have sufficient resources for its new tasks, and the timing of the allocation of these resources should be based on clearly defined needs. Taking into account the know-how of national authorities, in particular the National Safety Authorities, the Agency should be allowed to make appropriate use of that expertise when granting the relevant authorisations and certificates. To this end, secondment of national experts to the Agency should be encouraged.

(15) It is a general objective that the transfer of functions and tasks from the Member States to the Agency should be done efficiently, without any reduction in the current high levels of safety. The Agency should have sufficient resources for its new tasks, and the timing of the allocation of these resources should be based on clearly defined needs. Taking into account the know-how of national authorities, in particular the National Safety Authorities, the Agency should be allowed to make appropriate use of that expertise *including through contractual agreements* when granting the relevant authorisations and certificates. To this end, secondment of national experts to the

Agency should be ***strongly*** encouraged,
promoted and facilitated.

Amendment 16

Proposal for a regulation

Recital 16

Text proposed by the Commission

(16) Directive ... [Railway Safety] and Directive ... [Railway Interoperability] provide for examination of national measures from the point of view of safety and interoperability, and compatibility with competition rules. They also limit the possibility for Member States to adopt new national rules. The current system in which a large number of national rules continue to exist leads to possible conflicts with Union rules and creates a risk of insufficient transparency and disguised discrimination of foreign operators, especially the smaller and new ones. In order to migrate towards a system of truly, transparent and impartial railway rules at Union level, gradual reduction of national rules needs to be reinforced. An opinion based on independent and neutral expertise is essential at Union level. To this end, the role of the Agency needs to be strengthened.

Amendment

(16) Directive ... [Railway Safety] and Directive ... [Railway Interoperability] provide for examination of national measures from the point of view of safety and interoperability, and compatibility with competition rules. They also limit the possibility for Member States to adopt new national rules. The current system in which a large number of national rules continue to exist leads to possible ***safety risks and*** conflicts with Union rules and creates a risk of insufficient transparency and disguised discrimination of foreign operators, especially the smaller and new ones. In order to migrate towards a system of truly, transparent and impartial railway rules at Union level, gradual reduction of national rules, ***including operational rules***, needs to be reinforced. An opinion based on independent and neutral expertise is essential at Union level. To this end, the role of the Agency needs to be strengthened.

Amendment 17

Proposal for a regulation

Recital 17

Text proposed by the Commission

(17) Performance, organisation and decision-making procedures in the field of railway interoperability and safety vary substantially among the national safety authorities and notified conformity

Amendment

(17) Performance, organisation and decision-making procedures in the field of railway interoperability and safety vary substantially among the national safety authorities and notified conformity

assessment bodies, with a detrimental effect to smooth operation of the Single European rail area. In particular, small and medium companies wishing to enter the railway market in another Member State can be negatively affected. Therefore, a strengthened coordination with a view to greater harmonisation at the Union level is essential. To this end, the Agency should monitor the national safety authorities **and notified conformity assessment bodies** through audits and inspections.

assessment bodies, with a detrimental effect to smooth operation of the Single European rail area. In particular, small and medium companies wishing to enter the railway market in another Member State can be negatively affected. Therefore, a strengthened coordination with a view to greater harmonisation at the Union level is essential. To this end, the Agency should monitor the national safety authorities through audits and inspections. ***Monitoring of the notified conformity assessment bodies should be carried out by the national accreditation bodies in accordance with Article 5(3) of Regulation (EC) No 765/2008 . Equal monitoring of the performance of the Agency is also required.***

Amendment 18

Proposal for a regulation Recital 20

Text proposed by the Commission

(20) The interoperability of the Trans-European network should be enhanced and **the** new investment projects chosen for support by the Union should be in line with the objective of interoperability set in Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the Trans-European transport network. The Agency is the right institution to contribute to these objectives.

Amendment

(20) The interoperability of the Trans-European network should be enhanced and **both ongoing and** new investment projects chosen for support by the Union should be in line with the objective of interoperability set in Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the Trans-European transport network. The Agency is the right institution to contribute to these objectives.

Amendment 19

Proposal for a regulation Recital 24

Text proposed by the Commission

(24) In order to ensure the greatest possible transparency and equal access for all parties to relevant information, the documents envisaged for the railway interoperability and safety processes should be accessible to the public. The same applies to licences, safety certificates and other relevant railway documents. The Agency should provide ***an efficient*** means of exchanging and publishing this information.

Amendment

(24) In order to ensure the greatest possible transparency and equal access for all parties to relevant information, the documents envisaged for the railway interoperability and safety processes should be accessible to the public. The same applies to licences, safety certificates and other relevant railway documents. The Agency should provide ***efficient, user-friendly and easily accessible*** means of exchanging and publishing this information.

Amendment 20

**Proposal for a regulation
Recital 26**

Text proposed by the Commission

(26) In order to increase the efficiency of the Union financial support, its quality and compatibility with relevant technical regulations, the Agency, ***as the only Union body with reputable competence in the railway field, should play an active role in the*** assessment of rail projects.

Amendment

(26) In order to increase the efficiency of the Union financial support, its quality and compatibility with relevant technical regulations, the Agency ***should play an active role*** in the assessment of rail projects ***with European added value, in close cooperation with national infrastructure managers.***

Amendment 21

**Proposal for a regulation
Recital 27**

Text proposed by the Commission

(27) Railway interoperability and safety legislation, implementation guides or recommendations of the Agency may sometimes pose interpretation and other problems to the stakeholders. Proper and uniform understanding of those acts is a precondition for effective implementation

Amendment

(27) Railway interoperability and safety legislation, implementation guides or recommendations of the Agency may sometimes pose interpretation and other problems to the stakeholders. Proper and uniform understanding of those acts is a precondition for effective implementation

of the railway acquis and the functioning of the railway market. Therefore, the Agency should actively engage in training and explanatory activities in that regard.

of the railway acquis and the functioning of the railway market. Therefore, the Agency should actively engage in training and explanatory activities in that regard, ***while giving particular attention to small and medium-sized enterprises.***

Amendment 22

Proposal for a regulation Recital 27 a (new)

Text proposed by the Commission

Amendment

(27a) The Agency should cooperate fully with, and give the maximum possible assistance to, national authorities carrying out civil or criminal investigations when the investigations concern issues for which the Agency has responsibility.

Amendment 23

Proposal for a regulation Recital 28

Text proposed by the Commission

Amendment

(28) In order to perform its tasks properly, the Agency should have legal personality and an autonomous budget funded mainly through a contribution by the Union and through fees and charges paid by applicants. In order to ensure independence in its daily management and in the opinions, recommendations and decisions which it issues, the Agency's organisation should be transparent, the Executive Director should have full responsibility. The Agency's staff should be independent and should represent an appropriate balance of short-term and long-term contracts, in order to maintain its

(28) In order to perform its tasks properly, the Agency should have legal personality and an autonomous budget funded mainly through a contribution by the Union and through fees and charges paid by applicants. ***The Union contribution should be assessed and revised each time new powers are added which are not subject to fees or charges paid by applicants. The Agency's independence and impartiality should not be compromised by any financial contributions that it receives from Member States, third countries or other entities.*** In order to ensure independence in its daily management and

organisational knowledge and business continuity while keeping necessary and on-going exchange of expertise with the railway sector.

in the opinions, recommendations and decisions which it issues, the Agency's organisation should be transparent, the Executive Director should have full responsibility. The Agency's staff should be independent and should represent an appropriate balance of short-term and long-term contracts, *of seconded national experts and permanent officials*, in order to maintain its organisational knowledge and business continuity while keeping necessary and on-going exchange of expertise with the railway sector.

Amendment 24

Proposal for a regulation Recital 30

Text proposed by the Commission

(30) In order to guarantee the transparency of the Management Board's decisions, representatives of the sectors concerned should attend its meetings, but without the right to vote, that right being reserved for the representatives of public authorities who are accountable to the democratic control authorities. The representatives of the sector should be appointed by the Commission on the basis of their representativeness at Union level of railway undertakings, infrastructure managers, railway industry, workers unions, passengers and freight customers.

Amendment

(30) In order to guarantee the transparency of the Management Board's decisions, representatives of the sectors concerned should attend its meetings, but without the right to vote, that right being reserved for the representatives of public authorities who are accountable to the democratic control authorities. The representatives of the sector should be appointed by the Commission on the basis of their representativeness at Union level of railway undertakings, infrastructure managers, railway industry, *notified bodies, designated bodies*, workers unions, passengers and, *in particular, passengers with reduced mobility, and also* freight customers.

Amendment 25

Proposal for a regulation Recital 32

Text proposed by the Commission

(32) It is necessary to ensure that parties affected by decisions made by the Agency enjoy the necessary remedies in an independent and impartial manner. An appropriate appeal mechanism should be set up so that decisions of the Executive Director can be subject to appeal to a specialised Board of Appeal, whose decisions are, in turn, open to action before the Court of Justice.

Amendment

(32) It is necessary to ensure that parties affected by decisions made by the Agency enjoy the necessary remedies in an independent and impartial manner. An appropriate appeal mechanism should be set up so that decisions of the Executive Director can be subject to appeal to a specialised Board of Appeal ***that acts in complete independence from the Commission, the Agency, national safety authorities and any actor in the railway sector***, whose decisions are, in turn, open to action before the Court of Justice.

Amendment 26

**Proposal for a regulation
Recital 32 a (new)**

Text proposed by the Commission

Amendment

(32a) The Agency staff advising a Board of Appeal should not themselves have been previously involved in the decision under appeal.

Amendment 27

**Proposal for a regulation
Recital 34**

Text proposed by the Commission

Amendment

(34) The Agency's work should be transparent. Effective control by the European Parliament should be ensured and, to this end, the European Parliament should have the possibility of hearing the Executive Director of the Agency and being consulted on the multi-annual work ***programme***. The Agency should also apply

(34) The Agency's work should be transparent. Effective control by the European Parliament should be ensured and, to this end, the European Parliament should have the possibility of hearing the Executive Director of the Agency and being consulted on the multi-annual ***and annual*** work ***programmes***. The Agency

the relevant Union legislation concerning public access to documents.

should also apply the relevant Union legislation concerning public access to documents.

Amendment 28

Proposal for a regulation Recital 35

Text proposed by the Commission

(35) Over the past years, as more decentralised agencies have been created, the budgetary authority has looked to improve transparency and control over the management of the Union funding allocated to them, in particular concerning the budgetisation of fees, financial control, power of discharge, pension scheme contributions and the internal budgetary procedure (code of conduct). In a similar way, Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)⁹ should apply without restriction to the Agency, which should accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office¹⁰.

⁹ OJ L 136, 31.5.1999, p. 1.

¹⁰ OJ L 136, 31.5.1999, p. 15.

Amendment

(35) Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)⁹ should apply without restriction to the Agency, which should accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office¹⁰.

⁹ OJ L 136, 31.5.1999, p. 1.

¹⁰ OJ L 136, 31.5.1999, p. 15.

Amendment 29

Proposal for a regulation Recital 37

Text proposed by the Commission

(37) In order to properly determine the level of fees and charges which the Agency is entitled to levy, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of articles dealing with issuing and renewal of authorisations for placing in service of trackside ***control-command and signalling*** subsystems, authorisations for placing on the market for vehicles and for types of vehicles, and safety certificates. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

Amendment

(37) In order to properly determine the level of fees and charges which the Agency is entitled to levy, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of articles dealing with issuing and renewal of authorisations for placing in service of trackside ***ERTMS*** subsystems, authorisations for placing on the market for vehicles and for types of vehicles, and safety certificates. ***A differentiated level of fees and charges should be applied according to the areas of use and extent of operations specified in safety certificates and authorisations.*** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. ***Fees and charges should be set in a transparent, fair and uniform manner and should not jeopardize the competitiveness of the European industries concerned.***

Amendment 30

**Proposal for a regulation
Recital 37 a**

Text proposed by the Commission

Amendment

(37a) In order to properly encourage the standardisation of railway spare parts, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of standardisation regarding spare parts. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

Amendment 31

Proposal for a regulation

Article 1 – paragraph 3 – point c

Text proposed by the Commission

(c) certification of train drivers provided for in Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community [Train Drivers Directive].

Amendment

(c) certification of train drivers provided for in Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community **and certification of all safety-relevant staff.**

Amendment 32

Proposal for a regulation

Article 1 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The objectives of the Agency shall be to ensure a high level of rail safety and to help complete the Single European Rail Area. These objectives shall be achieved by:

(a) contributing, on technical matters, to the implementation of Union legislation aimed at enhancing the level of interoperability of the railway system and developing a common approach to safety on the Union railway system;

(b) acting as a European authority, in cooperation with the Member States, for authorising the placing of vehicles on the market and issuing safety certificates to railway undertakings;

(c) harmonising national rules and optimising procedures;

(d) monitoring action taken by the national safety authorities on interoperability and rail safety.

Amendment 33

Proposal for a regulation

Article 3 – paragraph 1 – point b

Text proposed by the Commission

(b) address recommendations to Member States concerning the application of Articles 21, 22 and 30;

Amendment

(b) address recommendations to Member States concerning the application of Articles 21, 22 and 30 ***and to national safety authorities concerning the application of Article 29(4);***

Amendment 34

Proposal for a regulation

Article 4 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The Agency shall set up a limited number of working parties for drawing up recommendations, in particular related to technical specifications for interoperability (TSIs), common safety targets (CSTs) ***and*** common safety methods (CSMs).

Amendment

The Agency shall set up a limited number of working parties for drawing up recommendations, in particular related to technical specifications for interoperability (TSIs), common safety targets (CSTs), common safety methods (CSMs), ***common safety indicators (CSIs), registers, entities in charge of maintenance, the documents referred to in Article 15 and provisions on minimum qualifications of railway staff entrusted with safety-critical tasks.***

Amendment 35

Proposal for a regulation

Article 4 – paragraph 2 – subparagraph 3

Text proposed by the Commission

The Agency shall appoint to the working parties professionals from the railway sector from the list referred to in paragraph 3. It shall ensure adequate representation of

Amendment

The Agency shall appoint to the working parties professionals from the railway sector from the list referred to in paragraph 3. It shall ensure adequate representation ***of***

those sectors of the industry and of those users which could be affected by measures the Commission may propose on the basis of the recommendations addressed to it by the Agency.

all the Member States, of those sectors of the industry and of those users which could be affected by measures the Commission may propose on the basis of the recommendations addressed to it by the Agency.

Amendment 36

Proposal for a regulation

Article 4 – paragraph 2 – subparagraph 4

Text proposed by the Commission

The Agency may, if necessary, appoint to the working parties independent experts and representatives of international organisations recognised as competent in the field concerned. Staff of the Agency may not be appointed to the working parties.

Amendment

The Agency may, if necessary, appoint to the working parties independent experts and representatives of international organisations recognised as competent in the field concerned. Staff of the Agency may not be appointed to the working parties, ***except for the chair of the working parties, who shall be a representative of the Agency.***

Amendment 37

Proposal for a regulation

Article 4 – paragraph 3

Text proposed by the Commission

3. Each representative body referred to in Article 34 shall forward to the Agency a list of the most qualified experts mandated to represent them in each working party.

Amendment

3. Each ***year, each*** representative body referred to in Article 34 shall forward to the Agency a list of the most qualified experts mandated to represent them in each working party.

Amendment 38

Proposal for a regulation

Article 4 – paragraph 4

Text proposed by the Commission

4. Whenever the work of such working parties has **a direct** impact on the working conditions, health and safety of workers in the industry, representatives from the workers' organisations shall participate in the relevant working parties as full members.

Amendment

4. Whenever the work of such working parties has **an** impact on the working conditions, health and safety of workers in the industry, representatives from the workers' organisations **from all the Member States** shall participate in the relevant working parties as full members.

Amendment 39

Proposal for a regulation
Article 4 – paragraph 6

Text proposed by the Commission

6. The working parties shall be chaired by a representative of the Agency.

Amendment

deleted

Amendment 40

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Whenever the work provided for in Articles 11, 12, 15, and 32 has a direct impact on the social environment or working conditions of workers in the industry, the Agency shall consult the social partners within the framework of the sectoral dialogue committee set up pursuant to Decision 98/500/EC¹¹.

¹¹ Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the dialogue between the social partners at European level (OJ L 225, 12.8.1998, p. 27).

Amendment

Whenever the work provided for in Articles 11, 12, 15, and 32 has a direct impact on the social environment or working conditions of workers in the industry, the Agency shall consult the social partners **in all the Member States** within the framework of the sectoral dialogue committee set up pursuant to Decision 98/500/EC¹¹.

¹¹ Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the dialogue between the social partners at European level (OJ L 225, 12.8.1998, p. 27).

Amendment 41

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission

These consultations shall be held before the Agency submits its recommendations to the Commission. The Agency shall take due account of these consultations, and shall, at all times, be available to expound on its recommendations. The opinions expressed by the sectoral dialogue committee shall be forwarded by the Agency to the Commission and by the Commission to the committee referred to in Article 75.

Amendment

These consultations shall be held before the Agency submits its recommendations to the Commission. The Agency shall take due account of these consultations, and shall, at all times, be available to expound on its recommendations. The opinions expressed by the sectoral dialogue committee shall be forwarded, ***within two months***, by the Agency to the Commission and by the Commission to the committee referred to in Article 75.

Amendment 42

Proposal for a regulation

Article 6 – paragraph 1

Text proposed by the Commission

Whenever the work provided for in Articles 11 and 15 has a direct impact on rail freight customers and passengers, the Agency shall consult the organisations representing them. The list of organisations to be consulted shall be drawn up by the Commission with the assistance of the committee referred to in Article 75.

Amendment

Whenever the work provided for in Articles 11 and 15 has a direct impact on rail freight customers and passengers, the Agency shall consult the organisations representing them, ***including in particular representatives of passengers with reduced mobility***. The list of organisations to be consulted shall be drawn up by the Commission with the assistance of the committee referred to in Article 75.

Amendment 43

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

These consultations shall be held before the Agency submits its proposals to the

Amendment

These consultations shall be held before the Agency submits its proposals to the

Commission. The Agency shall take due account of these consultations, and shall, at all times, be available to expound on its proposals. The opinions expressed by the organisations concerned shall be forwarded by the Agency to the Commission and by the Commission to the committee referred to in Article 75.

Commission. The Agency shall take due account of these consultations, and shall, at all times, be available to expound on its proposals. The opinions expressed by the organisations concerned shall be forwarded, ***within two months***, by the Agency to the Commission and by the Commission to the committee referred to in Article 75.

Amendment 44

Proposal for a regulation Article 7 – paragraph 1

Text proposed by the Commission

1. The Agency shall conduct an impact assessment of its recommendations and opinions. The Management Board shall adopt impact assessment methodology based on the methodology of the Commission. The Agency shall liaise with the Commission to ensure that relevant work at the Commission is duly taken into account.

Amendment

1. The Agency shall conduct an impact assessment of its recommendations and opinions. The Management Board shall adopt impact assessment methodology based on the methodology of the Commission, ***taking into account the requirements laid down in Directive ... [the Railway Safety Directive]***. The Agency shall liaise with the Commission to ensure that relevant work at the Commission is duly taken into account. ***The assumptions used as the basis for the impact assessment and the data sources used shall be clearly identified in the report accompanying each recommendation.***

Amendment 45

Proposal for a regulation Article 7 – paragraph 4

Text proposed by the Commission

4. Member States shall provide the Agency with the data necessary for the impact assessment.

Amendment

4. Member States ***and stakeholders*** shall provide the Agency, ***as required and at its request***, with the data necessary for the impact assessment.

Amendment 46

Proposal for a regulation Article 9 – paragraph 1

Text proposed by the Commission

1. The Agency shall issue opinions at request of **the** national regulatory bodies referred to in Article 55 of Directive 2012/34/EU [Directive establishing a Single European Rail Area (recast)] concerning safety-related and interoperability-related aspects of matters drawn to their attention.

Amendment

1. The Agency shall issue opinions at **the** request of **one or more** national regulatory bodies referred to in Article 55 of Directive 2012/34/EU **of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area^{11a}** concerning safety-related and interoperability-related aspects of matters drawn to their attention.

^{11a} **OJ L 343, 14.12.2012, p. 32.**

Amendment 47

Proposal for a regulation Article 10 – paragraph 1

Text proposed by the Commission

1. The Agency may carry out visits to the Member States in order to perform its tasks, in particular those referred to in Articles 12, 21, 22, 16, 17, 27, 29, 30, 31 and 38, in accordance with the policy defined by the Management Board.

Amendment

1. The Agency may carry out visits to the Member States in order to perform its tasks, in particular those referred to in Articles 12, 21, 22, 16, 17, **18**, 27, **28**, 29, 30, 31, **33** and 38, in accordance with the policy defined by the Management Board.

Amendment 48

Proposal for a regulation Article 11 – paragraph 1

Text proposed by the Commission

1. The Agency shall issue recommendations to the Commission on

Amendment

1. The Agency shall issue recommendations to the Commission on

the Common Safety Methods (CSMs) and the Common Safety Targets (CSTs) provided for in Articles 6 and 7 of Directive ... [the Railway Safety Directive]. The Agency shall also issue recommendations on periodic revision of CSMs and CSTs to the Commission.

the Common Safety Methods (CSMs), ***the Common Safety Indicators (CSIs)*** and the Common Safety Targets (CSTs) provided for in Articles 6 and 7 of Directive ... [the Railway Safety Directive]. The Agency shall also issue recommendations on periodic revision of CSMs and CSTs to the Commission.

Amendment 49

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

The Agency shall issue single safety certificates in accordance with Articles 10 and 11 of Directive ... [the Safety Directive].

Amendment

Without prejudice to Article 10 (2a) of Directive... [the Safety Directive] the Agency shall issue, ***renew, suspend, amend or revoke*** single safety certificates in accordance with Articles 10 and 11 of Directive ... [the Safety Directive].

Amendment 50

Proposal for a regulation

Article 14 a (new)

Text proposed by the Commission

Amendment

Article 14a

Spontaneous reporting of incidents

The Agency shall establish a system enabling the spontaneous and anonymous reporting of any incident that may jeopardise the system's safety. It shall create a mechanism for informing the responsible actors automatically. The Agency shall also coordinate the communication of reports from national agencies, in particular where they affect safety in more than one State.

Amendment 52

Proposal for a regulation

Article 15 – paragraph 1 – point g b (new)

Text proposed by the Commission

Amendment

(gb) issue recommendations to the Commission on European standards to be developed by the relevant European standardisation bodies, particularly concerning spare parts;

Amendment 53

Proposal for a regulation

Article 15 – paragraph 1 – point g c (new)

Text proposed by the Commission

Amendment

(gc) issue detailed requests concerning standards for the relevant European standardisation bodies in order to fulfil the mandate given to them by the Commission;

Amendment 54

Proposal for a regulation

Article 15 – paragraph 1 – point g d (new)

Text proposed by the Commission

Amendment

(gd) issue recommendations to the Commission regarding the training and certification of on-board personnel with safety tasks;

Amendment 55

Proposal for a regulation

Article 15 – paragraph 1 – point g e (new)

Text proposed by the Commission

Amendment

(ge) issue recommendations to the Commission to harmonise national rules

in accordance with Article 22(1), particularly in cases where one rule concerns several Member States. This work shall be carried out in cooperation with the national safety authorities;

Amendment 56

Proposal for a regulation

Article 15 – paragraph 1 – point g f (new)

Text proposed by the Commission

Amendment

(gf) at the request of the Commission, issue opinions to it on interoperability constituents not complying with the essential requirements in accordance with Article 11 of Directive ...[the Interoperability Directive];

Amendment 57

Proposal for a regulation

Article 15 – paragraph 1 – point g g (new)

Text proposed by the Commission

Amendment

(gg) issue recommendations to the Commission on minimum inspection intervals (time periods and kilometrage) in respect of rolling stock (goods wagons, passenger carriages and locomotives).

Amendment 58

Proposal for a regulation

Article 15 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. For drafting recommendations referred to in paragraph 1, points (a) **and** (b), the Agency shall:

2. For drafting recommendations referred to in paragraph 1, points (a), (b) **and** (c), the Agency shall:

Amendment 59

Proposal for a regulation

Article 15 – paragraph 2 – point a

Text proposed by the Commission

(a) ensure that the TSIs and the specifications for registers are adapted to technical progress and market trends and to social requirements;

Amendment

(a) ensure that the TSIs and the specifications for registers are adapted to technical progress and market trends and to social requirements ***with a view to improving the efficiency of the railway system while taking into account its cost-effectiveness***;

Amendment 60

Proposal for a regulation

Article 15 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) participate as an observer in the relevant working groups on standardisation;

Amendment 61

Proposal for a regulation

Article 15 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Agency shall involve the working parties where this is provided for in Article 4.

Amendment 62

Proposal for a regulation

Article 16 – paragraph 1

Text proposed by the Commission

The Agency shall issue authorisations for placing on the market for railway vehicles in accordance with Article 20 of Directive ... [the Interoperability Directive].

Amendment

Without prejudice to Article 20 (9a) of Directive ... [the Interoperability Directive] the Agency shall issue, **renew, suspend, amend or revoke** authorisations for placing on the market for railway vehicles in accordance with Article 20 of **that** Directive

Amendment 63

**Proposal for a regulation
Article 17 – paragraph 1**

Text proposed by the Commission

The Agency shall issue authorisations for placing on the market for types of vehicles in accordance with Article 22 of Directive ... [the Interoperability Directive].

Amendment

The Agency shall issue, **renew, suspend, amend or revoke** authorisations for placing on the market for types of vehicles in accordance with Article 22 of Directive ... [the Interoperability Directive].

Amendment 64

**Proposal for a regulation
Article 18 – title**

Text proposed by the Commission

Authorisations for placing in service of trackside **control-command and signalling sub-systems**

Amendment

Authorisation for placing in service of trackside **ERTMS**

Amendment 65

**Proposal for a regulation
Article 18 – paragraph 1**

Text proposed by the Commission

The Agency shall issue authorisations for placing in service of the trackside control-command and signalling subsystems located or operated in the entire Union in accordance with Article 18 of Directive ...

Amendment

The Agency shall issue, **renew, suspend, amend or revoke** authorisations for placing in service of the trackside **ERTMS** subsystems located or operated in the entire Union in accordance with Article 18

[the Interoperability Directive].

of Directive ... [the Interoperability Directive].

Amendment 66

Proposal for a regulation

Article 19 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The Agency may play a role in promoting open and full access to data including international timetable datasets.

Amendment 67

Proposal for a regulation

Article 19 – paragraph 3

Text proposed by the Commission

Amendment

3. The Agency shall develop and maintain the technical tools for managing the different versions of the telematics applications' specifications.

3. The Agency shall develop and maintain the technical tools for managing the different versions of the telematics applications' specifications ***and enforce the compatibility, both downwards and upwards, of these different versions.***

Amendment 68

Proposal for a regulation

Article 21 – paragraph 2

Text proposed by the Commission

Amendment

2. Where after ***the*** examination referred to paragraph 1 the Agency considers that national rules enable the essential requirements for interoperability to be fulfilled, CSMs to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operation ***between Member States***, the Agency shall inform the Commission and

2. Where after examination ***and within the deadlines*** referred to ***in*** paragraph 1 the Agency considers that national rules enable the essential requirements for interoperability to be fulfilled, CSMs to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operation, the Agency shall inform the Commission and the Member

the Member State concerned about its positive assessment. The Commission may validate the rule in the IT system referred to in Article 23.

State concerned about its positive assessment. The Commission may validate the rule in the IT system referred to in Article 23.

Amendment 69

Proposal for a regulation

Article 21 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The provisions of this Article do not apply to national rules on health and safety at work and qualification and training requirements for railway staff with safety-relevant tasks.

Amendment 70

Proposal for a regulation

Article 21 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4b. In the case of the urgent preventive measures referred to in Article 8 of Directive ... [the Safety Directive] and Article 14(4) of Directive ... [the Interoperability Directive], in particular after an accident or an incident, the Agency shall lead the harmonisation of the rule at Union level, together with the national safety authorities. If necessary, the Agency shall issue a recommendation or an opinion to the Commission.

Amendment 71

Proposal for a regulation

Article 22 – paragraph 1 a (new)

1a. The Agency shall examine the national rules in force on the date of application of this Regulation. Accordingly, the Agency shall propose a plan of work to the Management Board, for carrying out the examination, as part of the annual and multiannual work programmes referred to in Article 48. Each year, pursuant to Article 50, the Agency shall submit a progress report to the Management Board on its work and the results achieved.

Amendment 72

Proposal for a regulation Article 22 – paragraph 2

Text proposed by the Commission

Amendment

2. Where after the examination referred to paragraph 1 the Agency considers that national rules enable the essential requirements for interoperability to be fulfilled, CSMs to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operation ***between Member States***, the Agency shall inform the Commission and the Member State concerned about its positive assessment. The Commission may validate the rule in the IT system referred to in Article 23.

2. Where after examination referred to in paragraph 1 the Agency considers that national rules enable the essential requirements for interoperability to be fulfilled, CSMs to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operation, the Agency shall inform the Commission and the Member State concerned about its positive assessment. The Commission may validate the rule in the IT system referred to in Article 23.

Amendment 73

Proposal for a regulation Article 22 – paragraph 3 – point a

Text proposed by the Commission

(a) issue a recommendation addressed to the Member State concerned stating the reasons why ***the rule in question should*** be modified or repealed;

Amendment

(a) issue a recommendation addressed to the Member State concerned, ***that the rule, which has been the subject of the negative assessment be repealed or modified immediately, and*** stating the reasons why ***that rule has to*** be modified or repealed;

Amendment 74

Proposal for a regulation

Article 22 – paragraph 3 – point b

Text proposed by the Commission

(b) inform the Commission about its negative assessment.

Amendment

(b) inform the Commission about its negative assessment ***and forward to it the recommendation addressed to the Member State concerned.***

Amendment 75

Proposal for a regulation

Article 22 – paragraph 5

Text proposed by the Commission

5. The procedure described in paragraphs 2 ***and*** 3 shall apply, mutatis mutandis, in cases where the Agency becomes aware of any national rule, notified or not, being redundant or in conflict with the CSMs, CSTs, TSIs or any other Union legislation in the railway field.

Amendment

5. The procedure described in paragraphs 2, 3 ***and 4*** shall apply, mutatis mutandis, in cases where the Agency becomes aware of, or is informed about, any national rule, notified or not, being redundant or in conflict with the CSMs, CSTs, TSIs or any other Union legislation in the railway field ***or creating an unjustified barrier to the single railway market. In that event, the time limit laid down in paragraph 1 shall apply.***

Amendment 76

Proposal for a regulation

Article 22 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. On matters dealing with training, occupational health and safety for rail professionals responsible for safety critical tasks, the Agency may only apply this paragraph if the national rule has a potential discriminatory impact.

Amendment 77

Proposal for a regulation

Article 22 a (new)

Text proposed by the Commission

Amendment

Article 22a

Use of the database

The Agency shall carry out the technical examination of the national rules in force referred to in available national legislation as listed in its reference document database as at the date of entry into force of this Regulation.

Amendment 78

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

Amendment

1. The Agency shall set up and manage a dedicated IT system containing national rules referred to in Articles 21(1) and 22(1) and make it accessible to stakeholders and the public.

1. The Agency shall set up and manage a dedicated IT system containing national rules referred to in Articles 21(1) and 22(1) and ***national acceptable means of compliance referred to in Article 2(28a) of Directive ...[Interoperability Directive].*** ***The Agency shall*** make it accessible to stakeholders and the public.

Amendment 79

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Within one month of the entry into force of this Regulation, Member States shall notify to the Commission any existing national rule which has not been notified by the date of entry into force of this Regulation.

Amendment 80

Proposal for a regulation

Article 23 – paragraph 2

Text proposed by the Commission

Amendment

2. Member States shall notify national rules referred to in Articles 21(1) and 22(1) to the Agency and to the Commission through the IT system referred to in paragraph 1. The Agency shall publish the rules in this system and use it for informing the Commission in accordance with Articles 21 and 22.

2. Member States shall notify national rules referred to in Articles 21(1) and 22(1) to the Agency and to the Commission through the IT system referred to in paragraph 1. The Agency shall publish the rules in this system and use it for informing the Commission in accordance with Articles 21 and 22. ***The Agency shall use the IT system to inform the Commission about any negative recommendation forwarded to a Member State pursuant to Article 21(3), and Article 22(3)(b).***

Amendment 81

Proposal for a regulation

Article 23 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Agency shall also make the status of the evaluation of those rules and, when completed, the results of the evaluation, publicly available via the system referred

to in paragraph 1 of this Article.

Amendment 82

Proposal for a regulation

Article 24 – paragraph 3

Text proposed by the Commission

3. The Agency shall recommend the adoption of a new version of ERTMS Technical specifications. However, it shall only do so when the previous version has been deployed at a sufficient rate. The development of new versions shall not be detrimental to the rate of deployment of the ERTMS, the stability of the specifications which is needed to optimise the production of ERTMS equipment, the return on investment for railway undertakings and efficient planning of the deployment of the ERTMS.

Amendment

3. The Agency shall recommend the adoption of a new version of ERTMS Technical specifications. However, it shall only do so when the previous version has been deployed at a sufficient rate. The development of new versions shall not be detrimental to the rate of deployment of the ERTMS, the stability of the specifications which is needed to optimise the production of ERTMS equipment, the return on investment for railway undertakings **and keepers** and efficient planning of the deployment of the ERTMS.

Amendment 83

Proposal for a regulation

Article 26 – paragraph 1

Text proposed by the Commission

1. The Agency **may** assist the railway undertakings, at their request, in checking the technical and operational compatibility between ERTMS on-board and trackside subsystems before placing a vehicle in service.

Amendment

1. The Agency **shall** assist the railway undertakings, at their request, in checking the technical and operational compatibility between ERTMS on-board and trackside subsystems before placing a vehicle in service.

Amendment 84

Proposal for a regulation

Article 26 – paragraph 2

Text proposed by the Commission

2. Where the Agency finds that there is a risk of a lack of technical and operational compatibility between networks and vehicles fitted with ERTMS equipment ***in the context of specific ERTMS projects***, it may request the appropriate actors, in particular manufacturers, notified conformity assessment bodies, railway undertakings, infrastructure managers and national safety authorities, to provide any information relevant to the procedures applied for 'EC' verification and placing in service, and to operational conditions. The Agency shall inform the Commission about such a risk and, if necessary, recommend appropriate measures to the Commission.

Amendment

2. Where the Agency finds that there is a risk of a lack of technical and operational compatibility between networks and vehicles fitted with ERTMS equipment, it may request the appropriate actors, in particular manufacturers, notified conformity assessment bodies, railway undertakings, ***keepers***, infrastructure managers and national safety authorities, to provide any information relevant to the procedures applied for 'EC' verification and placing in service, and to operational conditions. The Agency shall ***immediately*** inform the Commission about such a risk and, if necessary, recommend appropriate measures to the Commission.

Amendment 85

Proposal for a regulation

Article 26 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Agency shall set up a test track and laboratory for centralised testing of ERTMS track-side and on-board equipment.

Amendment 86

Proposal for a regulation

Article 28 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Where the Agency has doubts as to the performance of an accredited laboratory, it shall notify the competent accreditation body, the Member State concerned and the national safety authorities accordingly. The Agency shall be invited to participate as an observer in the peer

review. Where doubts are raised, the Agency shall immediately inform the Member State concerned and the national safety authorities accordingly.

Amendment 87

Proposal for a regulation

Article 29 – paragraph 4

Text proposed by the Commission

4. If the Agency considers that the deficiencies referred to in paragraph 3 prevent the national safety authority concerned from effectively performing its tasks in relation to railway safety and interoperability, the Agency shall recommend to the national safety authority to take appropriate steps within a time limit *to be defined* taking into account the importance of the deficiency.

Amendment

4. If the Agency considers that the deficiencies referred to in paragraph 3 prevent the national safety authority concerned from effectively performing its tasks in relation to railway safety and interoperability, the Agency shall recommend to the national safety authority to take appropriate steps within a time limit ***which it shall define*** taking into account the importance of the deficiency.

Amendment 88

Proposal for a regulation

Article 29 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. In the cases referred to in Article 10(2a) of Directive ... [the Safety Directive] and Article 20(9a) of Directive ... [Interoperability Directive] if national safety authorities take conflicting decisions and no mutually acceptable decision is reached, the applicant concerned by those decisions or a national safety authority that is involved may refer the decisions to the Agency who shall take a decision.

Amendment 89

Proposal for a regulation

Article 30 – paragraph 2

Text proposed by the Commission

2. The Agency shall support harmonised accreditation of notified conformity assessment bodies, in particular by giving appropriate guidance on evaluation criteria and procedures to assess whether notified bodies meet the requirements referred to in **Art. 27** of Directive ... [Interoperability Directive] to the accreditation bodies, via the European Accreditation infrastructure recognised by **Art. 14** of Regulation (EC) No. 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93.

Amendment

2. The Agency shall support harmonised accreditation of notified conformity assessment bodies, in particular by giving appropriate guidance on evaluation criteria and procedures to assess whether notified bodies meet the requirements referred to in **Chapter 6** of Directive ... [Interoperability Directive] to the accreditation bodies, via the European Accreditation infrastructure recognised by **Article 14** of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

Amendment 90

Proposal for a regulation Article 30 – paragraph 4

Text proposed by the Commission

4. The Agency shall issue audit reports covering the activities referred to in paragraph 3 and send them to the notified conformity assessment body concerned and to the Commission. Each audit report shall include, in particular, any deficiencies identified by the Agency and recommendations for improvement. If the Agency considers that these deficiencies prevent the notified body concerned from effectively performing its tasks in relation to railway safety and interoperability, the Agency shall adopt a recommendation requesting the Member State in which that notified body is established to take appropriate steps within a time limit.

Amendment

4. The Agency shall issue audit reports covering the activities referred to in paragraph 3 and send them to the notified conformity assessment body concerned and to the Commission. Each audit report shall include, in particular, any deficiencies identified by the Agency and recommendations for improvement. If the Agency considers that these deficiencies prevent the notified body concerned from effectively performing its tasks in relation to railway safety and interoperability, the Agency shall adopt a recommendation requesting the Member State in which that notified body is established to take appropriate steps within a time limit **set by the Agency**.

Amendment 91

Proposal for a regulation Article 31 – paragraph 2

Text proposed by the Commission

2. The Agency shall monitor the overall safety performance of the railway system. The Agency may in particular seek the assistance of the networks referred to in Article 34, including collection of data. The Agency shall also draw on the data collected by Eurostat and shall cooperate with Eurostat to prevent any duplication of work and to ensure methodological consistency between the common safety indicators and the indicators used in other modes of transport.

Amendment

2. The Agency shall monitor the overall safety performance of the railway system ***and the safety regulatory framework***. The Agency may in particular seek the assistance of the networks referred to in Article 34, including collection of data. The Agency shall also draw on the data collected by Eurostat and shall cooperate with Eurostat to prevent any duplication of work and to ensure methodological consistency between the common safety indicators and the indicators used in other modes of transport.

Amendment 92

Proposal for a regulation Article 31 – paragraph 3

Text proposed by the Commission

3. ***At the Commission's request***, the Agency shall ***issue recommendations on how to improve the interoperability of the railway systems, in particular by facilitating coordination between railway undertakings and infrastructure managers, or between infrastructure managers***.

Amendment

3. The Agency shall ***develop a common occurrence reporting and monitoring system***.

Amendment 93

Proposal for a regulation Article 31 – paragraph 4

Text proposed by the Commission

4. The Agency shall monitor progress on the interoperability and safety of the railway systems. Every two years it shall present to the Commission and publish a

Amendment

4. The Agency shall monitor ***and assess*** progress on the interoperability and safety of the railway ***systems and the related costs and benefits***. Every two years it shall

report on progress on interoperability and safety in the Single European Railway Area.

present to the Commission and publish a report on progress on interoperability and safety in the Single European Railway Area.

Amendment 94

Proposal for a regulation Article 32 – paragraph 2

Text proposed by the Commission

2. The Agency may be requested by the Commission to perform other tasks relating to railway staff in accordance with Directive 2007/59/EC.

Amendment

2. The Agency may be requested by the Commission to perform other tasks relating to railway staff in accordance with Directive 2007/59/EC ***and relating to railway staff entrusted with safety-critical tasks not covered by Directive 2007/59/EC.***

Amendment 95

Proposal for a regulation Article 33 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Agency shall ***set up and keep*** European registers provided for in Article 43, 44 and 45 of Directive ... [Interoperability Directive]. The Agency shall act as the system authority for all registers and databases referred to in the Safety, Interoperability and Train Drivers Directives. This shall include, in particular:

Amendment

1. The Agency shall ***define*** European registers provided for in Article 43, 44 and 45 of Directive ... [Interoperability Directive] ***in a practical, efficient and user-friendly format to fully support business and operational needs.*** The Agency shall act as the system authority for all registers and databases referred to in the Safety, Interoperability and Train Drivers Directives. This shall include, in particular:

Amendment 96

Proposal for a regulation Article 33 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) setting-up and maintaining the registers referred to in points(g), (i) and (ma).

Amendment 97

Proposal for a regulation

Article 33 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(db) creating an European Vehicle Register.

Amendment 98

Proposal for a regulation

Article 33 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The European Vehicle Register:

(a) shall be kept by the Agency;

(b) shall be public;

(c) shall have the national vehicle registers incorporated in it no later than two years after the entry into force of this Regulation. The Commission shall establish, by means of implementing acts, the format type document. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 75;

(d) shall include at least the following details for each type of vehicle:

(i) the technical characteristics of the type of vehicle, as defined in the relevant TSI;

(ii) the manufacturer's name;

(iii) the dates and references of the successive authorisations for that type of

vehicle, including any restrictions or withdrawals, and the Member States granting the authorisations;

(iv) design features intended for persons with reduced mobility and persons with disabilities.

When the Agency issues, renews, amends, suspends or revokes an authorisation to place vehicle types in service, it shall update the register without delay.

Amendment 99

Proposal for a regulation

Article 33 – paragraph 2 – introductory part

Text proposed by the Commission

2. The Agency shall make the following documents and registers provided for by Directive ... [Interoperability Directive] and Directive ... [Railway Safety Directive] publicly available:

Amendment

2. The Agency shall make the following documents and registers provided for by Directive ... [Interoperability Directive] and Directive ... [Railway Safety Directive] publicly available ***through an implemented, user-friendly and easily accessible IT solution:***

Amendment 100

Proposal for a regulation

Article 33 – paragraph 2 – point f

Text proposed by the Commission

(f) the national rules notified to the Commission in accordance with Article 8 of Directive ... [Railway Safety Directive] and **Articles** 14 of Directive ... [Interoperability Directive];

Amendment

(f) the national rules notified to the Commission in accordance with Article 8 of Directive ... [Railway Safety Directive] and **Article** 14 of Directive ... [Interoperability Directive] ***and the Agency's assessment of them;***

Amendment 101

Proposal for a regulation

Article 33 – paragraph 2 – point g

Text proposed by the Commission

(g) the vehicle **registers, including via links to relevant national registers;**

Amendment

(g) the **European** vehicle **register;**

Amendment 102

Proposal for a regulation

Article 33 – paragraph 2 – point m a (new)

Text proposed by the Commission

Amendment

(ma) the register of certified entities in charge of maintenance, in accordance with Article 14 of Directive... [Safety Directive].

Amendment 103

Proposal for a regulation

Article 33 – paragraph 5

Text proposed by the Commission

Amendment

5. The national authorities responsible for issuing the licences and certificates referred to in points (c) and (d) of paragraph 2 shall notify the Agency within **one month** of each individual decision to issue, renew, amend or revoke those licenses and certificates.

5. The national authorities responsible for issuing the licences and certificates referred to in points (c) and (d) of paragraph 2 shall notify the Agency within **ten days** of each individual decision to issue, renew, amend or revoke those licenses and certificates.

Amendment 104

Proposal for a regulation

Article 34 – title

Text proposed by the Commission

Amendment

Networks of national safety authorities, **investigating bodies** and representative bodies

Networks of national safety authorities and representative bodies

Amendment 105

Proposal for a regulation

Article 34 – paragraph 1 – introductory part

Text proposed by the Commission

The Agency shall establish a network of the national safety authorities **and a network of the investigating bodies** referred to in Article **21** of Directive.../... [Railway Safety Directive]. The Agency shall provide them with a secretariat. The tasks of the networks shall, in particular, be:

Amendment

The Agency shall establish a network of the national safety authorities referred to in Article **17(4)** of Directive.../... [Railway Safety Directive]. The Agency shall provide them with a secretariat. The tasks of the networks shall, in particular, be:

Amendment 106

Proposal for a regulation

Article 34 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) provision of information to the Agency, if necessary, on deficiencies of the secondary legislation that derives from Directive ... [Railway Safety Directive] and Directive ... [Interoperability Directive].

Amendment 107

Proposal for a regulation

Article 34 – paragraph 2 – introductory part

Text proposed by the Commission

2. The Agency shall establish a network of representative bodies from the railway sector acting at the Union level. The list of these bodies shall be defined in an

Amendment

2. The Agency shall establish a network of representative bodies from the railway sector, **including representatives of passengers, passengers with reduced**

implementing act adopted by the Commission, in accordance with advisory procedure referred to in Article 75. The Agency shall provide the network with a secretariat. The tasks of the network shall, in particular, be:

mobility and employees, acting at the Union level. The list of these bodies shall be defined in an implementing act adopted by the Commission, in accordance with advisory procedure referred to in Article 75. The Agency shall provide the network with a secretariat. The tasks of the network shall, in particular, be:

Amendment 108

Proposal for a regulation Article 38 – paragraph 1

Text proposed by the Commission

Without prejudice to the derogations provided for by Article 9 of Directive [...] [Railway Interoperability Directive], the Agency shall, at the Commission's request, examine, from the point of view of interoperability and safety, any project involving the design, construction, renewal or upgrading of the subsystem for which an application for Union financial support has been submitted.

Amendment

Without prejudice to the derogations provided for by Article 9 of Directive [...] [Railway Interoperability Directive], the Agency shall, at the Commission's request, examine, from the point of view of interoperability and safety, any project involving the design, construction, renewal or upgrading of the subsystem for which an application for Union financial support has been submitted. ***In the case of projects funded under the Trans European Network – Transport (TEN-T) programme, the Agency should closely cooperate with the TEN-T Executive Agency.***

Amendment 109

Proposal for a regulation Article 40 – paragraph 3

Text proposed by the Commission

3. The Management Board shall adopt a strategy for relations with third countries or international organisations concerning matters for which the Agency is competent. This strategy shall be included in the annual and multi-annual work programme of the Agency, with a specification of

Amendment

3. The Management Board shall adopt a strategy for relations with third countries or international organisations concerning matters for which the Agency is competent. This strategy shall be included in the annual and multi-annual work programme of the Agency, with a specification of associated resources. ***The strategy shall***

associated resources.

seek to ensure that the activities of the Agency facilitate reciprocal access for Union railway undertakings to the rail markets of third countries.

Amendment 110

Proposal for a regulation Article 41 – paragraph 1

Text proposed by the Commission

The Agency shall contribute to identifying potential railway spare parts to be standardised. To this end, the Agency *may* establish a working party in order to coordinate the stakeholders' activities and *may* establish contacts with the European standardisation bodies. The Agency shall present the Commission with appropriate recommendations.

Amendment

The Agency shall contribute to identifying potential railway spare parts to be standardised. To this end, the Agency *shall* establish a working party in order to coordinate the stakeholders' activities and *shall* establish contacts with the European standardisation bodies. The Agency shall present the Commission with appropriate recommendations *no later than two years after the entry into force of this Regulation.*

To stimulate the market for rolling stock and reduce the costs for railways undertakings there is a necessity to develop type-approvals for spare parts.

Amendment 111

Proposal for a regulation Article 43 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The Management Board shall be composed of one representative from each Member State and *four* representatives of the Commission, all with a right to vote.

Amendment

1. The Management Board shall be composed of one representative from each Member State and *two* representatives of the Commission, all with a right to vote.

Amendment 112

Proposal for a regulation Article 43 – paragraph 4

Text proposed by the Commission

4. The term of office of the members shall be ***four*** years and may be renewed.

Amendment

4. The term of office of the members shall be ***five*** years and may be renewed ***once***.

Amendment 113

**Proposal for a regulation
Article 44 – paragraph 2**

Text proposed by the Commission

2. The term of office of the Chairperson and Deputy Chairperson shall be ***four*** years and may be renewed. If, however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date also.

Amendment

2. The term of office of the Chairperson and Deputy Chairperson shall be ***five*** years and may be renewed ***once***. If, however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date also.

Amendment 114

**Proposal for a regulation
Article 44 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. The Chairperson of the Management Board shall decide whether or not to accede to a request to exclude a member of the Board of Appeal, in accordance with Article 53(3a), and, if necessary, in accordance with Article 53(3b), shall appoint a temporary member to the Board of Appeal.

Amendment 115

**Proposal for a regulation
Article 45 – paragraph 1**

Text proposed by the Commission

1. Meetings of the Management Board shall be convened by its Chairperson. The Executive Director of the Agency shall participate in the meetings.

Amendment

1. Meetings of the Management Board shall be convened by its Chairperson. The Executive Director of the Agency shall participate in the meetings ***except where the Management Board is to take a decision relating to Article 64.***

Amendment 116

Proposal for a regulation

Article 47 – paragraph 1 – point l

Text proposed by the Commission

(l) adopt an anti-fraud strategy, which is proportionate to the fraud risks having regard to cost-benefit of the measures to be implemented;

Amendment

(l) adopt an anti-fraud ***and transparency*** strategy, which is proportionate to the fraud risks having regard to cost-benefit of the measures to be implemented;

Amendment 117

Proposal for a regulation

Article 47 – paragraph 1 – point n

Text proposed by the Commission

(n) adopt rules for the prevention and management of conflicts of interest in respect of members of the Management Board and of the Board of Appeal.

Amendment

(n) adopt rules for the prevention and management of conflicts of interest ***in the Agency as established in Article 68a and*** in respect of members of the Management Board and of the Board of Appeal.

Amendment 118

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 1

Text proposed by the Commission

The Management Board shall adopt, in

Amendment

The Management Board shall adopt, in

accordance with the procedure provided for in Article 110 of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants delegating the relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director is authorised to sub-delegate these powers.

accordance with the procedure provided for in Article 110 of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants delegating the relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director is authorised to sub-delegate these powers. ***Such sub-delegation of powers shall not affect his or her liability. The Executive Director shall inform the Management Board of such delegations and sub-delegations.***

Amendment 119

Proposal for a regulation

Article 47 – paragraph 2 – subparagraph 2

Text proposed by the Commission

In application of the previous subparagraph, where exceptional circumstances so require, the Management Board may, by way of a decision, suspend temporarily the delegation of appointing authority powers to the Executive Director and those sub-delegated by the latter and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director.

Amendment

In application of the previous subparagraph, where exceptional circumstances so require, the Management Board may, by way of a decision, suspend temporarily the delegation of appointing authority powers to the Executive Director and those sub-delegated by the latter and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director. ***The delegate shall inform the Management Board of such a delegation.***

Amendment 120

Proposal for a regulation

Article 47 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Management Board shall waive the immunity of the Agency or of present or past members of its staff, in accordance

with Article 64.

Amendment 121

Proposal for a regulation Article 48 – paragraph 2

Text proposed by the Commission

2. The work programme shall be adopted without prejudice to the Union's annual budgetary procedure. If, within 15 days of the date of adoption of the work programme, the Commission expresses its disagreement with the programme, the Management Board shall re-examine the programme and adopt it, as amended if necessary, within a period of two months, in second reading *either* by a two-thirds majority of its members entitled to vote, including *by* all Commission representatives, *or by unanimity of the representatives of the Member States*.

Amendment

2. The work programme shall be adopted without prejudice to the Union's annual budgetary procedure. If, within 15 days of the date of adoption of the work programme, the Commission expresses its disagreement with the programme, the Management Board shall re-examine the programme and adopt it, as amended if necessary, within a period of two months, in second reading by a two-thirds majority of its members entitled to vote, including all Commission representatives.

Amendment 122

Proposal for a regulation Article 51 – paragraph 1

Text proposed by the Commission

1. The Agency shall establish one or more Boards of Appeal.

Amendment

1. The Agency shall establish one or more *independent* Boards of Appeal.

Amendment 123

Proposal for a regulation Article 51 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The qualifications required for each member of the Board of Appeal, the power of each member at the preparatory decision-making stage and the voting conditions shall be determined by the Commission with the assistance of the committee referred to in Article 48(3) of Directive ... [Interoperability Directive].

Amendment 124

Proposal for a regulation Article 52 – paragraph 1

Text proposed by the Commission

1. The term of office of the members and alternates of a Board of Appeal shall be ***four*** years and may be renewed.

Amendment

1. The term of office of the members and alternates of a Board of Appeal shall be ***five*** years and may be renewed ***once***.

Amendment 125

Proposal for a regulation Article 52 – paragraph 2

Text proposed by the Commission

2. The members of a Board of Appeal shall be independent ***and*** may not perform any other duties within the Agency. In making their decisions they shall not be bound by any instructions.

Amendment

2. The members of a Board of Appeal shall be independent ***of all parties involved in an appeal. They*** may not perform any other duties within the Agency ***or the Commission***. In making their decisions ***or delivering their opinions*** they shall not be bound by any instructions.

Amendment 126

Proposal for a regulation

Article 53 – paragraph 1

Text proposed by the Commission

1. The members of the Board of Appeal **may** not take part in any appeal proceedings if they have any personal interest in the proceedings, if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal.

Amendment

1. The members of the Board of Appeal **shall** not take part in any appeal proceedings if they have any personal interest in the proceedings, if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal, ***including, in the case of appeals lodged pursuant to Article 54(1), in delivering an opinion pursuant to Article 54(4) in respect of the same authorisation or the same certificate.***

Amendment 127

Proposal for a regulation Article 53 – paragraph 2

Text proposed by the Commission

2. Members of the Board of Appeal who consider that they should not take part in any appeal proceeding, for one of the reasons referred to in paragraph 1 or for any other reason, shall inform the Board of Appeal ***which decides on the exclusion accordingly.***

Amendment

2. Members of the Board of Appeal who consider that they should not take part in any appeal proceeding, for one of the reasons referred to in paragraph 1 or for any other reason, shall inform the Board of Appeal ***of their decision not to take part.***

Amendment 128

Proposal for a regulation Article 53 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. A party may apply in writing to the chair of the Management Board for a member of the Board of Appeal to be excluded. The exclusion application shall be made on one of the grounds referred to

in paragraph 1 or on the grounds of a risk of bias. The application shall be accompanied by relevant supporting documents. The request shall only be admissible if it is made before the start of proceedings before the Board of Appeal, or, where the information constituting the grounds for the exclusion request becomes known after the proceedings have started, within five days of the requesting party becoming aware of that information.

The Board of Appeal member concerned shall be notified of the request. Within five days of being notified of the exclusion request, the Board of Appeal member concerned shall state whether he or she agrees to be excluded. If he or she does not agree, the chair of the Management Board shall take a decision within seven working days of the response by the member concerned, or, where there is no response, after expiry of the deadline set for issuing a response.

Amendment 129

Proposal for a regulation Article 53 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The Board of Appeal shall deliver its opinion or take its decision without the participation of the member who has decided not to take part or who has been excluded in accordance with paragraphs 2 and 3. In order for the decision to be taken or the opinion delivered, the member concerned shall be replaced on the Board of Appeal by his or her substitute.

If the substitute is unable to take his or her seat on the board for whatever reason, the chair of the Management Board shall appoint a temporary member to the board

from the list referred to in Article 51(3) to replace him or her in the case concerned.

Amendment 130

Proposal for a regulation Article 54 – paragraph 1

Text proposed by the Commission

1. An appeal may be brought before the Board of Appeal against decisions taken by the Agency pursuant to Articles 12, 16, 17 and 18.

Amendment

1. An appeal may be brought before the Board of Appeal against decisions taken by the Agency pursuant to Articles 12, 16, 17 and 18 ***or against recommendations issued pursuant to Articles 21 and 22 or against a failure by the Agency to respond within the prescribed time limits.***

Amendment 131

Proposal for a regulation Article 54 – paragraph 2

Text proposed by the Commission

2. An appeal lodged pursuant to paragraph 1 shall not have a suspensory effect. The Agency may, however, suspend the application of the decision appealed against, if it considers that circumstances so permit.

Amendment

2. An appeal lodged pursuant to paragraph 1 shall not have a suspensory effect. The Agency may, however, suspend the application of the decision appealed against, if it considers that circumstances so permit, ***as long as the suspension of the decision does not affect railway safety.***

Amendment 132

Proposal for a regulation Article 55

Text proposed by the Commission

Persons entitled to Appeal, time ***limit*** and

Amendment

Persons entitled to Appeal, time ***limits*** and

form

1. Any natural or legal person may appeal against a decision addressed to that person by the Agency pursuant to Articles 12, 16, 17 and 18.

2. The appeal, together with the statement of grounds thereof, shall be filed in writing at the Agency within two months of the notification of the measure to the person concerned, or, if the person is not notified of the measure, within two months of the day on which it came to their knowledge.

form

1. Any natural or legal person may appeal against a decision addressed to that person by the Agency pursuant to Articles 12, 16, 17 and 18 ***or against a failure to take a decision within the prescribed time limits. Such rights of appeal shall also apply to bodies representing the persons referred to in Article 34(2), as duly authorised in accordance with their statutes.***

2. The appeal, together with the statement of grounds thereof, shall be filed in writing at the Agency within two months of the notification of the measure to the person concerned, or, if the person is not notified of the measure, within two months of the day on which it came to their knowledge.

2a. Appeals against the absence of a decision shall be filed in writing at the Agency within two months of the expiry of the time limit defined in the relevant Article.

Amendment 133

Proposal for a regulation Article 56 – paragraph 1

Text proposed by the Commission

1. ***When examining the appeal,*** The Board of Appeal shall ***act expeditiously***. It shall, as often as necessary, invite the parties to the appeal proceedings to file, within specified time limits, observations on its notifications or on communications from other parties to the appeal proceedings. Parties to the appeal proceedings shall be entitled to make oral presentations.

Amendment

1. The Board of Appeal shall ***decide within three months of the appeal being filed whether to grant or refuse that appeal. It shall request any additional information it may require within one month of the appeal being filed. That relevant information shall be supplied within a reasonable time period set by the Board of Appeal that shall not exceed one month.*** It shall, as often as necessary, invite the parties to the appeal proceedings to file, within specified time limits ***that shall not exceed one month***, observations on its notifications or on communications from other parties to the appeal proceedings. Parties to the appeal proceedings shall be

entitled to make oral presentations.

Amendment 134

Proposal for a regulation

Article 58 – paragraph 2 – introductory part

Text proposed by the Commission

2. The revenue of the Agency shall consist of:

Amendment

2. The revenue of the Agency shall consist, ***in particular***, of:

Amendment 135

Proposal for a regulation

Article 58 – paragraph 2 – point c

Text proposed by the Commission

(c) the fees paid by applicants for, and holders of, certificates and authorisations issued by the Agency in accordance with Articles 12, 16, 17 and 18;

Amendment

(c) the fees paid by applicants for, and holders of, certificates and authorisations issued by the Agency in accordance with Articles 12, 16, 17 and 18. ***The delegated act referred to in Article 73 shall set charges at different levels according to the areas of use of certificates and authorisations and type and extent of railway operations;***

Amendment 136

Proposal for a regulation

Article 58 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Any task or obligation in addition to the tasks stemming from Union legislation and not entailing compensation as laid down in Article 58(2)(b), (c), (d) and (e) shall be subject to an assessment and to

compensation from the budget of the Union.

Amendment 137

Proposal for a regulation Article 59 – paragraph 4

Text proposed by the Commission

4. On ***receipt of*** the Court of Auditors' observations on the Agency's provisional accounts, under Article 148 of the general Financial Regulation, the Executive Director shall draw up the Agency's final accounts under his own responsibility and submit them to the Management Board for ***an opinion***.

Amendment

4. ***Based, where necessary,*** on the Court of Auditors' observations on the Agency's provisional accounts, under Article 148 of the general Financial Regulation, the Executive Director shall draw up the Agency's final accounts under his own responsibility and submit them, ***together with a statement of assurance,*** to the Management Board for ***approval***.

Amendment 138

Proposal for a regulation Article 61 – paragraph 3

Text proposed by the Commission

3. The Agency shall take appropriate administrative measures to organise its services in order to avoid ***any conflict*** of interest.

Amendment

3. The Agency shall take appropriate administrative measures, ***inter alia through training and prevention strategies,*** to organise its services in order to avoid ***conflicts*** of interest, ***including relating to post-employment issues such as: 'revolving doors' and 'insider information'.***

Amendment 139

Proposal for a regulation Article 61 – paragraphs 3 a and 3 b (new)

3a. The Agency and its staff shall carry out the tasks defined in this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field. They shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their work, especially from persons or groups with an interest in the results of this work. The Agency shall have sufficient staff to ensure that the tasks defined in this Regulation are carried out properly.

3b. Staff shall have:

(a) a thorough technical and professional grounding covering all the Agency's activities;

(b) a satisfactory knowledge of the requirements of the assessments that the Agency carries out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the requirements necessary to formulate the Agency's decisions;

(d) the ability to review opinions delivered and decisions taken by the national safety authorities as well as national regulations.

Amendment 140

Proposal for a regulation Article 63 – paragraph 1

The Agency ***may*** also make use of Seconded National Experts or other staff not employed by the Agency under the Staff Regulations and the Conditions of

The Agency ***shall*** also make use of Seconded National Experts ***and, in particular, staff from national safety authorities,*** or other staff not employed by

Employment of Other Servants.

the Agency under the Staff Regulations and the Conditions of Employment of Other Servants. ***The Agency shall adopt and implement a policy to evaluate and manage potential conflicts of interest of seconded national experts including prohibiting them from attending working group meetings when their independence and impartiality could be undermined.***

Amendment 141

Proposal for a regulation Article 64 – paragraph 1

Text proposed by the Commission

The Protocol on the Privileges and Immunities of the European Union shall apply to the agency and its staff.

Amendment

The Protocol on the Privileges and Immunities of the European Union shall apply to the agency and its staff ***without prejudice to judicial and/or extra-judicial proceedings relating to the Agency's remit.***

Amendment 142

Proposal for a regulation Article 66 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1. The Agency shall take full responsibility, including accepting contractual and non-contractual liability, for the authorisations and certifications that it issues.

Amendment 143

Proposal for a regulation Article 67 – paragraph -1 (new)

-1. Without prejudice to any agreement between the Agency and the applicant with regards to translation requirements, the documents provided by applicants and holders of certificates and authorisations, in accordance with Articles 12, 16, 17 and 18, to notify the Agency and national safety authorities of those certificates and authorisations, shall be translated into all the official Union languages of the countries in which the rolling stock is used and in which the railway company concerned operates. Each translation shall be the authentic text in the country concerned, including for procedures under Article 56. The authorisation and the certificate shall be issued in all the Union languages of the countries concerned.

Amendment 144

Proposal for a regulation Article 67 – paragraph 1

Text proposed by the Commission

Amendment

1. The provisions laid down in Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community¹⁸ shall apply to the Agency.

1. ***Where Article 67(-1) does not apply***, the provisions laid down in Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community¹⁸ shall apply to the Agency.

¹⁸ OJ 17, 6.10.1958, p. 385

¹⁸ OJ 17, 6.10.1958, p. 385

Amendment 145

Proposal for a regulation Article 68 – paragraph 1

Text proposed by the Commission

Amendment

1. Without prejudice to Article 40, the Agency shall be open to participation by

1. Without prejudice to Article 40, the Agency shall be open to participation by

third countries, ***in particular by countries within the scope of the European Neighbourhood Policy, the Enlargement policy countries and EFTA countries*** which have concluded agreements with the Union under which the countries concerned have adopted and are applying Union ***legislation***, or its equivalent national measures, in the field covered by this Regulation.

third countries which have concluded agreements with the Union under which the countries concerned have adopted and are applying Union ***law***, or its equivalent national measures, in the field covered by this Regulation. ***This paragraph shall apply, in particular, to countries within the scope of the European Neighbourhood Policy, Union enlargement policy countries and EFTA countries.***

Amendment 146

Proposal for a regulation Article 68 a (new)

Text proposed by the Commission

Amendment

Article 68 a

Conflict of interest

1. The Executive Director, as well as officials seconded by Member States and the Commission on a temporary basis shall make a declaration of commitments and a declaration of interests indicating the absence of any direct or indirect interests, which might be considered prejudicial to their independence. These declarations shall be made in writing on their entry into service and shall be renewed in the event of a change in their personal circumstances. Members of the Administration board, the executive board and the board of appeal shall also make these declarations public together with their curricula vitae. The agency shall publish on its website a list of the members of the bodies described in Article 42 as well as external and in-house experts.

2. The Administrative Board shall implement a policy to manage and avoid conflicts of interest, which shall at least include:

- a) principles for managing and verification of the declarations of interest including rules for making them public taking into consideration Article 77;*
- b) compulsory training requirements on conflict of interest for the staff of the Agency and seconded national experts;*
- c) rules on gifts and invitations;*
- d) detailed rules for incompatibilities for staff and members of the Agency once they have ended their employment relation with the Agency;*
- e) rules of transparency on Agency's decisions including the minutes of the Boards of the Agency which shall be made public taking into consideration sensitive, classified and commercial information; and*
- f) sanctions and mechanisms to safeguard the autonomy and independency of the Agency.*

The Agency shall bear in mind the need to maintain balance between the risks and the benefits, in particular as regards the objective of obtaining the best technical advice and expertise, and the management of conflicts of interest. The Executive Director shall include the information related to implementation of that policy when reporting to the European Parliament and the Council in accordance with this Regulation.

Amendment 147

Proposal for a regulation Article 69 – title

Text proposed by the Commission

Cooperation with national authorities *and
bodies*

Amendment

Cooperation with national authorities

Amendment 148

Proposal for a regulation Article 69 – paragraph 1

Text proposed by the Commission

1. The Agency may enter into agreements with relevant national authorities, in particular the National Safety Authorities, and other competent bodies, in relation to the implementation of Articles 12, 16, 17 and 18.

Amendment

1. The Agency may enter into agreements with relevant national authorities, in particular the National Safety Authorities, and other competent bodies, in relation to the implementation of Articles 12, 16, 17 and 18. ***Such agreements may involve one or more national safety authorities.***

Amendment 149

Proposal for a regulation Article 69 – paragraph 2

Text proposed by the Commission

2. The agreements may include ***contracting of some of the*** tasks of the Agency to the national authorities, such as checking and preparing files, verifying technical compatibility, performing visits and drafting technical studies.

Amendment

2. The agreements may include ***delegating*** tasks ***and responsibilities*** of the Agency to the national authorities, such as checking and preparing files, verifying technical compatibility, performing visits and drafting technical studies.

Amendment 150

Proposal for a regulation Article 69 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Conversely, a national safety authority may subcontract to the Agency tasks other than those conferred on it in accordance with Article 20 of Directive ... [Interoperability Directive] and Article 16(2) of Directive ... [Railway Safety Directive].

Amendment 151

Proposal for a regulation Article 69 – paragraph 4

Text proposed by the Commission

4. The agreements described in paragraphs 1, 2 and 3 **are** without prejudice to the overall responsibility of the Agency for performing its tasks as provided for in Articles 12, 16, 17 and 18.

Amendment

4. The agreements described in paragraphs 1, 2 and 3 ***shall clearly specify the levels of responsibility of the Agency and the national safety authorities in respect of tasks carried out by each contractual party as stipulated in the agreements. This shall be*** without prejudice to the overall responsibility of the Agency for performing its tasks as provided for in Articles 12, 16, 17 and 18.

Amendment 152

Proposal for a regulation Article 72 – title

Text proposed by the Commission

Combating fraud

Amendment

Combating fraud ***and monitoring performance***

Amendment 153

Proposal for a regulation Article 72 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The European Court of Auditors shall monitor the performance and decision-making of the Agency through audit and inspections.

Amendment 154

Proposal for a regulation

Article 73 – Title

Text proposed by the Commission

Delegated acts relating to Articles 12, 16,
17 *and* 18

Amendment

Delegated acts relating to Articles 12, 16,
17, 18 *and 41*

Amendment 155

Proposal for a regulation

Article 73 – paragraph 4

Text proposed by the Commission

4. The amount of the fees and charges shall be fixed at such a level as to ensure that the revenue in respect thereof is sufficient to cover the full cost of the services delivered. All expenditures of the Agency attributed to staff involved in activities referred to in paragraph 3, including the employer's pro-rata contribution to the pension scheme, shall be in particular reflected in this cost. Should a significant imbalance resulting from the provision of the services covered by fees and charges become recurrent, the revision of the level of the fees and charges shall become mandatory.

Amendment

4. The amount of the fees and charges *relating to the Agency* shall be fixed at such a level as to ensure that the revenue in respect thereof is sufficient to cover the full cost of the services delivered. All expenditures of the Agency attributed to staff involved in activities referred to in paragraph 3, including the employer's pro-rata contribution to the pension scheme, shall be in particular reflected in this cost. Should a significant imbalance resulting from the provision of the services covered by fees and charges become recurrent, the revision of the level of the fees and charges shall become mandatory.

Amendment 156

Proposal for a regulation

Article 73 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Commission shall also be empowered to adopt delegated acts in accordance with Article 74 concerning standardisation of railway spare parts in application of Article 41.

Amendment 157

Proposal for a regulation

Article 74 – paragraph 2

Text proposed by the Commission

2. The **delegation of** power referred to in Article 73 shall be conferred on the Commission for **an indeterminate** period of **time** from the date of entry into force of this Regulation.

Amendment

2. The power **to adopt delegated acts** referred to in Article 73 shall be conferred on the Commission for **a** period of **five years** from the date of entry into force of this Regulation. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. Provided the report has been received, the delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

Amendment 158

Proposal for a regulation

Article 76 – paragraph 1

Text proposed by the Commission

1. No later than five years after the entry into force of this Regulation and every five years thereafter, the Commission shall commission an evaluation to assess, in particular, the impact, effectiveness and efficiency of the Agency and its working practices. The evaluation shall address, in particular, any need to amend the mandate of the Agency, and the financial implications of any such amendment.

Amendment

1. No later than five years after the entry into force of this Regulation and every five years thereafter, the Commission shall commission an evaluation to assess, in particular, the impact, effectiveness and efficiency of the Agency and its working practices. **The evaluation shall take account of the views of the representatives of the railway sector, of the social partners and of consumer organisations.** The evaluation shall address, in particular, any need to amend the mandate of the Agency, and the financial implications of any such amendment.

Amendment 159

Proposal for a regulation

Article 77 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Agency shall undertake the certification and authorisation tasks pursuant to Articles 12, 16, 17 and 18 within one year following the entry into force of this Regulation. Until then, Member States shall continue to apply their national legislation.

Amendment 160

Proposal for a regulation

Article 77 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. For an additional period of three years after the one-year period laid down in Article 77(3a), applicants may apply either to the Agency or the national safety authority. During this period, national safety authorities may continue to issue certificates and authorisations by way of derogation from Articles 12, 16, 17 and 18, in accordance with Directives 2008/57 and 2004/49.

Amendment 161

Proposal for a regulation

Article 77 – paragraph 3 c (new)

Text proposed by the Commission

Amendment

3c. In the cases referred to in Article 10(2a) of Directive ... [the Safety Directive] and Article 20 (9a) of Directive... [Interoperability Directive] the national safety authorities may continue to issue certificates and authorisations

*after the period referred in paragraph 3b
of this Article, under the conditions
stipulated in those Articles.*

Normalisation of the accounts of railway undertakings *I**

European Parliament legislative resolution of 26 February 2014 on the proposal for a regulation of the European Parliament and of the Council repealing Regulation (EEC) No 1192/69 of the Council on common rules for the normalisation of the accounts of railway undertakings (COM(2013)0026 – C7-0026/2013 – 2013/0013(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0026),
 - having regard to Article 294(2) and Articles 91 and 109 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0026/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 11 June 2013¹,
 - having regard to the opinion of the Committee of the Regions of 8 October 2013²,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism (A7-0472/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 327, 12.11.2013, p. 122.

² OJ C 356, 5.12.2013, p. 92.

Amendment 1

Proposal for a regulation Recital 2

Text proposed by the Commission

(2) A series of legislative measures has been adopted at European level, opening up the rail freight and international rail passenger markets to competition and establishing, by way of Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast), certain fundamental principles which include that railway undertakings shall be managed according to principles that apply to commercial companies, that entities responsible for the allocation of capacity and charging for rail infrastructure shall be separate from entities which operate rail services and that there shall be a separation of accounts, that any railway undertaking licensed in accordance with EU criteria should have access to railway infrastructure on fair, non-discriminatory terms, and that infrastructure managers may benefit from State financing.

Amendment

(2) A series of legislative measures has been adopted at European level, opening up the rail freight and international rail passenger markets to competition and establishing, by way of Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast)^{3a}, certain fundamental principles which include that railway undertakings shall be managed according to principles that apply to commercial companies, that entities responsible for the allocation of capacity and charging for rail infrastructure shall be separate from entities which operate rail services and that there shall be a separation of accounts, that any railway undertaking licensed in accordance with EU criteria should have access to railway infrastructure on fair, non-discriminatory terms, and that infrastructure managers may benefit from State financing. ***The time limit for transposition of Directive 2012/34/EU into national law is 16 June 2015.***

^{3a} ***OJ L 343, 14.12.2012, p. 32.***

Amendment 2

Proposal for a regulation Article 2 – paragraph 1

Text proposed by the Commission

This Regulation shall enter into force ***on the day following that of*** its publication in the *Official Journal of the European Union*.

Amendment

This regulation shall enter into force ***two years after*** its publication in the *Official Journal of the European Union*.

Occurrence reporting in civil aviation *I**

European Parliament legislative resolution of 26 February 2014 on the proposal for a regulation of the European Parliament and of the Council on occurrence reporting in civil aviation amending Regulation (EU) No 996/2010 and repealing Directive No 2003/42/EC, Commission Regulation (EC) No 1321/2007 and Commission Regulation (EC) No 1330/2007 (COM(2012)0776 – C7-0418/2012 – 2012/0361(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0776),
 - having regard to Article 294(2) and Article 100(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0418/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 17 April 2013¹,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 2 December 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism (A7-0317/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 198, 10.7.2013, p. 73.

Position of the European Parliament adopted at first reading on 26 February 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 and repealing Directive 2003/42/EC, Commission Regulation (EC) No 1321/2007 and Commission Regulation (EC) No 1330/2007

(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 100(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 198, 10.7.2013, p. 73.

² Position of the European Parliament of 26 February 2014.

Whereas:

- (1) A high general level of safety should be ensured in civil aviation in the Union and every effort should be made to reduce the number of accidents and incidents with a view to ensuring public confidence in aviation transport.
- (2) The rate of fatal accidents in civil aviation has remained fairly constant over the last decade. Nevertheless, the number of accidents could rise over the decades to come, due to an increase in air traffic ***and an increase in the technical complexity of aircraft.***
- (3) Regulation (EU) No 996/2010 of the European Parliament and of the Council¹ aims to prevent accidents by facilitating the prompt holding of efficient and high-quality safety investigations. This Regulation should not interfere with the process of accident and incident investigations managed by national safety investigation authorities as defined in Regulation (EU) No 996/2010. ***In the event of an accident or a serious incident, notification of the occurrence is also subject to Regulation (EU) No 996/2010.***

¹ Regulation (EU) No 996/2010 of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC (OJ L 295, 12.11.2010, p. 35).

- (4) *Existing legislative acts of the Union, in particular Regulation (EC) No 216/2008 of the European Parliament and of the Council¹ and its implementing regulations, impose obligations on certain organisations to establish occurrence reporting systems in the context of their safety management systems. Compliance with Regulation (EC) No 216/2008 and its implementing regulations should not exempt organisations from compliance with this Regulation. Likewise, compliance with this Regulation should not exempt organisations from compliance with Regulation (EC) No 216/2008 and its implementing regulations. However, this should not give rise to two parallel reporting systems, and Regulation (EC) No 216/2008, its implementing regulations, and this Regulation should be seen as complementary.*
- (5) Experience has shown that accidents are often preceded by safety-related incidents and deficiencies revealing the existence of safety hazards. *Safety information is therefore an important resource for the detection of potential safety hazards.* In addition, whilst the ability to learn from an accident is crucial, purely reactive systems have been found to be of limited use in continuing to bring forward improvements. *Reactive systems should therefore be complemented by proactive systems which use other types of safety information to make effective improvements in aviation safety. The Union, its Member States, the European Aviation Safety Agency ('the Agency') and organisations* should contribute to the improvement of aviation safety through the introduction of more proactive and evidence based safety systems which focus on accident prevention based on the analysis of all *relevant* safety information, including information on civil aviation occurrences.

¹ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p.1).

- (6) In order to improve aviation safety, relevant civil aviation safety information should be reported, collected, stored, protected, exchanged, disseminated and analysed, and appropriate safety action should be taken on the basis of the information collected. This proactive and evidence-based approach should be implemented by the relevant aviation safety authorities of Member States, by organisations as part of their safety management system and by the Agency.
- (7) *The imposition on organisations of occurrence reporting obligations should be proportionate to the size of the organisation concerned and the scope of its activity. It should therefore be possible, in particular for smaller organisations, to decide to join or merge functions related to occurrence handling within the organisation, to share occurrence reporting tasks with other organisations of the same nature or to outsource the collection, evaluation, processing, analysis and storage of details of occurrences to specialised entities approved by the competent authorities of the Member States. Such entities should comply with the protection and confidentiality principles established by this Regulation. The outsourcing organisation should maintain appropriate control of the outsourced tasks and should be ultimately accountable and responsible for the application of the requirements prescribed by this Regulation.*

- (8) *It is necessary to ensure that front-line aviation professionals report occurrences that pose a significant risk to aviation safety. Voluntary reporting systems should complement the mandatory reporting systems, and both should allow individuals to report details of aviation safety-related occurrences. Mandatory and voluntary reporting systems should be set up within organisations, the Agency and competent authorities of the Member States. The information collected should be transferred to the authority competent for appropriate monitoring in order to enhance aviation safety. Organisations should analyse those occurrences that could have an impact on safety, in order to identify safety hazards and take any appropriate corrective or preventive action. Organisations should send the preliminary results of their analyses to the competent authority of their Member States or to the Agency and should also send them the final results if those results identify an actual or potential aviation safety risk. The competent authorities of the Member States and the Agency should put in place a similar procedure for those occurrences that have been directly submitted to them and should adequately monitor the organisation's assessment and any corrective or preventive action taken.*

- (9) Various categories of staff working *or otherwise engaged* in civil aviation witness events which are of relevance to accident prevention. They should therefore *have access to tools enabling them to report such events, and their protection should be guaranteed. In order to encourage staff to report occurrences and enable them to appreciate more fully the positive impact which occurrence reporting has on air safety, they should be regularly informed about action taken under occurrence reporting systems.*
- (10) *The hazards and risk associated with complex motor-powered aircraft are very different from those associated with other types of aircraft. Therefore, while the entire aviation sector should be covered by this Regulation, the obligations imposed by it should be proportionate to the sphere of activity and the complexity of different types of aircraft. Accordingly, information collected on occurrences involving aircraft other than complex motor-powered ones should be subject to simplified reporting obligations which are better suited to that branch of aviation.*
- (11) The development of other means of collecting safety information in addition to the systems required by this Regulation should be encouraged, with a view to collecting *further* information which could contribute to the improvement of aviation safety. *Where organisations have existing and well-functioning safety information collection systems, they should be allowed to continue to use those systems alongside the systems to be established for the purpose of this Regulation.*

- (12) Safety investigation authorities *and any entity entrusted with regulating civil aviation safety within the Union* should have full access to details *of* occurrences collected and occurrence reports stored by their Member States, in order to decide which incidents require a safety investigation, as well as to identify where lessons can be learned in the interest of aviation safety *and to fulfil their oversight obligations*.
- (13) It is *essential* to have high-quality and complete data, as analysis and trends derived from inaccurate data may show misleading results and may lead to effort being focused on inappropriate action. In addition, such inaccurate data may lead to a loss of confidence in the information produced by occurrence reporting schemes. In order to ensure the quality of occurrence reports, and to facilitate their completeness, they should contain certain minimum information, which may vary depending on the occurrence category. In addition, procedures should be implemented for checking the quality of information and *avoiding inconsistency* between an occurrence report and the *details of the* occurrence ■ that were initially collected. Moreover, with the support of the Commission, adequate guidance material should be developed, notably to ensure the quality and *to facilitate the* completeness of data as well as the consistent and uniform integration of data into databases. Workshops should also be organised, notably by the Commission, to provide necessary support.

- (14) The Commission should develop a common European risk classification scheme to ensure the identification of any rapid action needed when looking at high-risk individual safety occurrences. That scheme should also enable key risk areas to be identified from aggregated information. Such a scheme should help *the relevant entities* in their assessment of occurrences and in determining where best to focus their efforts. *A common European risk classification scheme should facilitate an integrated and harmonised approach to risk management across the European aviation system and thus enable organisations, Member States, the Commission and the Agency to focus on safety improvement efforts in a harmonised manner.*
- (15) A common European risk classification scheme should also *both enable* key risk areas within the Union to be identified on the basis of aggregated information from a European perspective and support the work done in the area of the European Aviation Safety Programme and the European Aviation Safety Plan. Appropriate support should be given *by the Commission* to ensure consistent and uniform risk classification across Member States.
- (16) To facilitate information exchange, occurrence reports should be stored in databases which should be compatible with the European Coordination Centre for Aircraft Incident Reporting Systems (ECCAIRS) (the software used by all Member States and by the European Central Repository to store occurrence reports) and with the ADREP taxonomy (the International Civil Aviation Organisation (ICAO) taxonomy, also used for the ECCAIRS software). *The Agency and the Commission should provide technical support for the interoperability of the systems.*

- (17) *Organisations should store occurrence reports derived from details of occurrences collected under the mandatory and, where applicable, the voluntary reporting systems in one or more databases. It should be possible for the complexity of the database to be proportionate to the size of the organisation concerned and/or its significance with respect to the objectives of this Regulation, and it should at least consist of a data file containing common mandatory data fields and, where applicable, specific mandatory data fields.*
- (18) An occurrence involving an aircraft registered in a Member State or operated by an organisation established in a Member State should be reported even if it happened outside the territory of that Member State.
- (19) Information on occurrences should be exchanged within the Union *to* enhance the detection of actual or potential hazards. This information exchange should also enable Member States to *have access to* all ■ information on occurrences which occur *on* their territory *or in their airspace* but which are reported to another Member State. *It should also allow the Agency to obtain precise information about occurrences and access to all occurrence reports collected in the Union in order, where necessary, to take corrective action to counteract a risk identified in the Union. This information exchange should enable the competent authorities of the Member States to obtain precise information about occurrences in their airspace and, where necessary, to take corrective action to counteract a risk identified on their territory.*

- (20) The objective of the exchange of information on occurrences should be the prevention of aviation accidents and incidents. It should not be used to attribute blame or liability or to establish benchmarks for safety performance.
- (21) The most efficient way to ensure the exchange of large quantities of *safety* information between the Member States, the Commission and the Agency is through the European Central Repository, *provided that the Member States, the Commission and the Agency have full access to it.*
- (22) All safety-related information derived from occurrence reports collected in the Union should be transferred in the European Central Repository in a timely manner. This should include the collection of information on incidents but also information on accidents and serious incidents investigated pursuant to Regulation (EU) No **996**/2010.
- (23) This Regulation should apply to information on **■** occurrences which is stored in the **■** databases *of organisations, Member States or the Agency.*

- (24) All safety-related information contained in the European Central Repository should be available to entities entrusted with regulating civil aviation safety *within the Union*, including the Agency, and to the authorities responsible for investigating accidents and incidents within the Union.
- (25) It should be possible for interested parties to request access to certain information contained in the European Central Repository, *subject to the rules concerning the confidentiality of such information and the anonymity of the persons involved*.
- (26) As national points of contact have the best knowledge of interested parties established in a given Member State, it should be for each national point of contact to deal with requests from interested parties established in the territory of its own Member State. The Commission should deal with requests from interested parties from third countries or from international organisations.

- (27) Information contained in occurrence reports should be analysed, and safety risks identified. Any appropriate consequent action for improving aviation safety should be identified and implemented in a timely manner. Information on the analysis and follow-up of occurrences should be disseminated within organisations **■**, competent authorities of the Member States *and the Agency*, since providing feedback on occurrences that have been reported incentivises individuals to report occurrences. *Where applicable and when possible, information on the analysis and follow-up of occurrences should also be provided to individuals who have directly reported occurrences to the competent authorities of the Member States or to the Agency. Such feedback should comply with the rules on confidentiality and protection of the reporter and the persons mentioned in occurrence reports pursuant to this Regulation.*

- (28) *This Regulation should assist Member States, the Agency and organisations in managing aviation safety risks. The safety management systems of organisations are complemented by the safety management systems of the Member States and of the Agency. While organisations manage safety risks associated with their specific activities, the competent authorities of the Member States and the Agency manage safety risks for the aviation systems of, respectively, entire Member States and of the Union as a whole, addressing common safety risks for aviation in the Member State concerned or at Union level. The responsibilities of the Agency and of the competent authorities of the Member States should not exonerate organisations from their direct responsibilities in managing safety inherent in the products and in the services they provide. For that purpose, organisations should collect and analyse information on occurrences in order to identify and mitigate hazards associated with their activities. They should also assess associated safety risks and allocate resources to take prompt and appropriate safety risk mitigation measures. The overall process should be monitored by the relevant competent authority, which should, when necessary, require that additional action be taken to ensure that the safety deficiencies are correctly addressed. On the other hand, the competent authorities of the Member States and the Agency should complement the safety management systems of the organisations at Member State and European levels respectively.*

- (29) When determining the action to be included within their State Safety Programme and ***State Safety Plan, and*** in order to ensure that the action is evidence-based, Member States should use the information derived from the occurrence reports that have been collected and from their analysis. ***State Safety Programmes and State Safety Plans are complemented at European level by the European Aviation Safety Programme and the European Aviation Safety Plan.***
- (30) Since the objective of aviation safety improvement cannot be sufficiently achieved by the Member States because reporting systems operated by Member States in isolation are less efficient than a coordinated network with exchange of information allowing identification of possible safety problems and key risk areas at Union level, analysis at national level should be complemented by analysis and follow-up at Union level in order to ensure better prevention of aviation accidents and incidents. This Union-level task should be carried out by a ***network of aviation safety analysts in coordination with the Agency and the Commission. It should be possible for that network to decide, by consensus, to invite observers to their meetings, including industry employees or representatives.***

- (31) The European Aviation Safety Programme and the European Aviation Safety Plan should benefit in particular from the work of the *network of aviation safety analysts* for the purpose of determining what action needs to be implemented at Union level from an evidence-based perspective.
- (32) The general public should be provided with general aggregated information on the level of aviation safety in Member States and in the Union. That information should cover, in particular, trends and analysis deriving from the implementation of this Regulation by the Member States, as well as information in an aggregated form on the content of the European Central Repository, and *may be provided by publishing safety performance indicators (SPI)*.

- (33) The civil aviation safety system is established on the basis of feedback and lessons learned from accidents and incidents. Occurrence reporting and the use of occurrence information for the improvement of safety depend on a relationship of trust between the reporter and the entity in charge of the collection and assessment of the information. This requires strict application of rules on confidentiality. The purpose of protecting safety information from inappropriate use, and of limiting access to the European Central Repository solely to interested parties participating in the improvement of civil aviation safety, is to ensure the continuing availability of safety information so that appropriate and timely preventive action can be taken and aviation safety improved. In this context, sensitive safety information should be protected in an appropriate way and its collection should be ensured by guaranteeing its confidentiality, protecting its source and ensuring the confidence of staff working in civil aviation in occurrence reporting systems. Appropriate measures should be put in place to ensure that information collected through occurrence reporting schemes is kept confidential and that access to the European Central Repository is restricted. National rules on freedom of information should take into account the necessary confidentiality of such information. The information collected should be adequately protected from unauthorised use or disclosure. It should be used strictly for the purpose of maintaining or improving aviation safety and should not be used to attribute blame or liability.

- (34) *In order to ensure the confidence of employees or contracted personnel in the occurrence reporting system of the organisation, the information contained in occurrence reports should be protected appropriately and should not be used for purposes other than maintaining or improving aviation safety. The internal 'just culture' rules adopted by organisations pursuant to this Regulation should contribute in particular to the achievement of this objective. In addition, the limitation of the transmission of personal details, or of information allowing the identification of the reporter or of the other persons mentioned in occurrence reports, by a clear separation between the departments handling occurrence reports and the rest of the organisation, may be an efficient way to achieve this objective.*
- (35) A reporter *or a person mentioned in occurrence reports* should be adequately protected. In this context, occurrence reports should be disidentified and details relating to the identity of the reporter *and of the persons mentioned in occurrence reports* should not be entered into databases.

- (36) In addition, the civil aviation system should promote a '**safety culture**' facilitating the spontaneous reporting of occurrences and thereby advancing the principle of a '**iust culture**'. '**Just culture**' is an essential element of a broader '**safety culture**', which forms the basis of a robust safety management system. An environment embracing 'safety culture' principles should not prevent action being taken where necessary to maintain or improve the level of aviation safety.
- (37) A 'just culture' should encourage individuals to report safety-related information. It should not, however, absolve individuals of their normal responsibilities. In this context, employees *and contracted personnel* should not be *subject to any prejudice* on the basis of information provided pursuant to this Regulation, *except in cases of wilful misconduct or where there has been manifest, severe and serious disregard with respect to an obvious risk and profound failure of professional responsibility to take such care as is evidently required in the circumstances, causing foreseeable damage to a person or to property, or seriously compromising the level of aviation safety.*

- (38) *In order to encourage reporting of occurrences, it should be appropriate to protect not only reporters, but also persons mentioned in the occurrence reports concerned. However, such protection should not exonerate those persons from their reporting obligations under this Regulation. In particular, in a situation where a person is mentioned in an occurrence report and has himself or herself the obligation to report that same occurrence, and intentionally fails to report it, then that person should lose his or her protection and face penalties in application of this Regulation.*
- (39) *Without prejudice to national criminal law and the proper administration of justice, it is important to clearly demarcate the extent of the protection of the reporter and other persons mentioned in occurrence reports from prejudice or prosecution* ■ .
- (40) *In order to enhance the confidence of individuals in the system, the handling of occurrence reports should be organised in such a way as to appropriately safeguard the confidentiality of the identity of the reporter and other persons mentioned in occurrence reports with regard to fostering a 'just culture'. The aim, wherever possible, should be to enable an independent occurrence handling system to be established.*

- (41) *Staff of organisations, of the competent authorities of the Member States and of the Agency who are involved in the evaluation, processing or analysis of occurrences have a significant role to play in the identification of safety hazards and safety deficiencies. Experience shows that when occurrences are analysed with the benefit of hindsight following an accident, the analysis leads to the identification of risks and deficiencies that might otherwise not have been identified. It is possible, therefore, that the persons involved in the evaluation, processing or analysis of occurrences may fear potential consequences in terms of prosecution before judicial authorities. Without prejudice to national criminal law and the proper administration of justice, Member States should not institute proceedings against persons who, in the competent authorities of the Member States, are involved in the evaluation, processing or analysis of occurrences in respect of decisions taken as part of their duties which subsequently, and with the benefit of hindsight, prove to have been erroneous or ineffective but which, when they were taken and on the basis of the information available at that time, were proportional and appropriate.*
- (42) Employees *and contracted personnel* should have the opportunity to report breaches of the principles delimiting their protection as established by this Regulation, *and should not be penalised for so doing*. Member States should define the consequences for those who infringe the principles of protection of *the* reporter *and of other persons mentioned in occurrence reports* and should adopt *remedies or impose* penalties as appropriate.

- (43) Individuals may be *discouraged from reporting* occurrences by the fear of self-incrimination and the potential consequences in terms of prosecution before judicial authorities. *The objectives of this Regulation can be achieved without interfering unduly with the justice systems of the Member States. It is therefore appropriate to provide that unpremeditated or inadvertent infringements of the law that come to the attention of the authorities of the Member States solely through reporting pursuant to this Regulation should not be the subject of disciplinary, administrative or legal proceedings, unless where otherwise provided by applicable national criminal law. However, the rights of third parties to institute civil proceedings should not be covered by this prohibition and should be subject only to national law.*
- (44) *Nevertheless, in the context of developing a 'just culture' environment, Member States should retain the option of extending the prohibition on using occurrence reports as evidence against reporters in administrative and disciplinary proceedings to civil or criminal proceedings.*
- (45) In addition, the cooperation between safety authorities and judicial authorities should be enhanced and formalised by means of advance arrangements between themselves which should respect the balance between the various public interests at stake and which should in particular cover, for example, access to and the use of occurrence reports contained in the national databases.

- (46) *To support the increased responsibilities of the Agency under this Regulation, it should be given sufficient resources to enable it to carry out the additional tasks assigned to it.*
- (47) *In order to supplement or amend this Regulation*, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (48) *In applying this Regulation, the Commission should consult the Agency and the network of aviation safety analysts referred to herein.*
- (49) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission ■ . Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹.

¹ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (50) The rules on data processing and the protection of individuals as laid down in Directive 95/46 of the European Parliament and of the Council¹ and in Regulation (EC) No 45/2001 of the European Parliament and of the Council² should be fully respected in the application of this Regulation. The rules on access to data as laid down in Regulation (EC) No 1049/2001 of the European Parliament and of the Council³ should be fully respected in the application of this Regulation *except* as regards the dissemination of data and information contained in the European Central Repository, which are protected under stricter access rules laid down in this Regulation.

¹ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

² Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

³ 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 (OJ L 145, 31.5.2001, p. 43).

- (51) Penalties should, in particular, be applicable against any person who or entity which, contrary to this Regulation, misuses information protected by this Regulation; *acts in a prejudicial manner against the reporter or other persons mentioned in occurrence reports*, except in *cases where the exemptions laid down in this Regulation apply*; does not establish an environment appropriate for allowing the collection of details of occurrences; does not analyse the information collected; does not act to address any safety or potential safety deficiencies detected; or does not share the information collected in application of this Regulation.
- (52) Since the objective of this Regulation, namely the establishment of common rules in the field of occurrence reporting in civil aviation, cannot be sufficiently achieved by the Member States but can rather, by reason of its Union-wide scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (53) Regulation (EU) No 996/2010 should therefore be amended accordingly.

(54) Directive 2003/42/EC of the European Parliament and of the Council¹, Commission Regulation (EC) No 1321/2007² and Commission Regulation (EC) No 1330/2007³ should therefore be repealed.

(55) *The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 10 April 2013⁴,*

HAVE ADOPTED THIS REGULATION:

¹ Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation (OJ L 167, 4.7.2003, p. 23).

² Commission Regulation (EC) No 1321/2007 of 12 November 2007 laying down implementing rules for the integration into a central repository of information on civil aviation occurrences exchanged in accordance with Directive 2003/42/EC of the European Parliament and of the Council (OJ L 294, 13.11.2007, p. 3).

³ Commission Regulation (EC) No 1330/2007 of 24 September 2007 laying down implementing rules for the dissemination to interested parties of information on civil aviation occurrences referred to in Article 7(2) of Directive 2003/42/EC of the European Parliament and of the Council (OJ L 295, 14.11.2007, p. 7).

⁴ OJ C 358, 7.12.2013, p. 19..

Article 1

Objectives

1. This Regulation aims to improve aviation safety by ensuring that relevant safety information relating to civil aviation is reported, collected, stored, protected, exchanged, disseminated ***and*** analysed ■ .


This Regulation ensures:

- (a) that, ***where appropriate***, safety action is taken ***in a timely manner based on analysis*** of the information collected;
 - (b) ***the continued availability of safety information by introducing rules on confidentiality and on the appropriate use of information and through the harmonised and enhanced protection of reporters and persons mentioned in occurrence reports; and***
 - (c) ***that aviation safety risks are considered and dealt with at both Union level and national level.***
2. The sole objective of occurrence reporting is the prevention of accidents and incidents and not to attribute blame or liability.

Article 2
Definitions

For the purposes of this Regulation the following definitions **■** apply:

- (1) *'reporter' means a natural person who reports an occurrence or other safety-related information pursuant to this Regulation;*
- (2) *'aircraft' means any machine that can derive support in the atmosphere from the reactions of the air other than the reactions of the air against the earth's surface;*
- (3) *'incident' means an incident within the meaning of Regulation (EU) No 996/2010;*
- (4) *'serious incident' means a serious incident within the meaning of Regulation (EU) No 996/2010;*
- (5) *'accident' means an accident within the meaning of Regulation (EU) No 996/2010;*
- (6) *'disidentified information' means information arising from occurrence reports from which all personal data such as names or addresses of natural persons have been removed;*
- (7) *'occurrence' means any safety-related event which endangers or which, if not corrected or addressed, could endanger an aircraft, its occupants or any other person and includes in particular an accident or serious incident **■** ;*
- (8) *'organisation' means any organisation providing aviation products and/or which employs, contracts or uses the services of persons required to report occurrences in accordance with Article 4(6);*
- (9) *'anonymisation' means the removal from occurrence reports of all personal details relating to the reporter and to the persons mentioned in occurrence reports and any details, including the name of the organisation(s) involved in the occurrence, which may reveal the identity of the reporter or of a third party or lead to that information being inferred from the occurrence report;*

- (10) *'hazard' means a situation or an object with the potential to cause death or injury to a person, damage to equipment or a structure, loss of material, or a reduction of ability to perform a prescribed function;*
- (11) 'safety investigation authority' means the permanent national civil aviation safety investigation authority conducting or supervising safety investigations as referred to in Article 4 of Regulation (EU) No 996/2010;
- (12) 'just culture' means a culture in which front-line operators or *other persons* are not punished for actions, omissions or decisions taken by them that are commensurate with their experience and training, but *in which* gross negligence, wilful violations and destructive acts are not tolerated;
- (13) 'point of contact' means:
- (a) where a request for information is made by an interested party established in a Member State, the competent authority designated by each Member State in accordance with Article 6(3);
 - (b) where a request for information is made by an interested party established outside the Union, the Commission;
- (14) 'interested party' means any natural *or* legal person or any official body, whether or not having its own legal personality, that is in a position to participate in the improvement of aviation safety by having access to information on occurrences exchanged by the Member States and which falls within one of the categories of interested parties set out in Annex II;
- (15) 'State Safety Programme' means an integrated set of *legal acts* and activities  aimed at managing civil aviation safety *in a Member State*;
- (16) 'European Aviation Safety Plan' means safety issues assessment and *the* related action plan at European level;
- (17) 'European Aviation Safety Programme' means the integrated set of *regulations* at Union level, together with the activities and processes used to jointly manage the safety of civil aviation at European level;

- (18) 'safety management system' means a systematic approach to managing aviation safety including the necessary organisational structures, accountabilities, policies and procedures, ***and includes any management system that, independently or integrated with other management systems of the organisation, addresses the management of safety.***

Article 3

Subject matter and scope

- 1.*** This Regulation ***lays down rules on:***
- (a) the reporting of occurrences which endanger or which, if not corrected ***or addressed***, would endanger an aircraft, its occupants ■, any other person, ***equipment or installation affecting aircraft operations; and the reporting of other relevant safety-related information in that context;***
 - (b) ***analysis and follow-up action in respect of reported occurrences and other safety-related information;***

- (c) *the protection of aviation professionals;*
- (d) *appropriate use collected safety information;*
- (e) *the integration of information into the European Central Repository; and*
- (f) *the dissemination of anonymised information to interested parties for the purpose of providing such parties with the information they need in order to improve aviation safety.*

2. *This Regulation applies to occurrences and other safety-related information involving civil aircraft, with the exception of aircraft referred to in Annex II to Regulation (EC) No 216/2008. Member States may decide to apply this Regulation also to occurrences and other safety-related information involving the aircraft referred to in Annex II to that Regulation.*

Article 4

Mandatory reporting

1. Occurrences which may represent a significant risk to aviation safety and which fall into the following categories shall be reported by the persons listed in paragraph 6 through the mandatory occurrence reporting systems pursuant to this Article:

(a) occurrences related to the operation of the aircraft, such as:

- (i) collision-related occurrences;**
- (ii) take-off and landing-related occurrences;**
- (iii) fuel-related occurrences;**
- (iv) in-flight occurrences;**
- (v) communication-related occurrences;**
- (vi) occurrences related to injury, emergencies and other critical situations;**
- (vii) crew incapacitation and other crew-related occurrences;**
- (viii) meteorological conditions or security-related occurrences;**

(b) occurrences related to technical conditions, maintenance and repair of aircraft, such as:

- (i) structural defects;**
- (ii) system malfunctions;**
- (iii) maintenance and repair problems;**
- (iv) propulsion problems (including engines, propellers and rotor systems) and auxiliary power unit problems;**

(c) occurrences related to air navigation services and facilities, such as:

- (i) collisions, near collisions or potential for collisions;**

- (ii) *specific occurrences of air traffic management and air navigation services (ATM/ANS);*
- (iii) *ATM/ANS operational occurrences;*

(d) *occurrences related to aerodromes and ground services, such as:*

(i) *occurrences related to aerodrome activities and facilities;*

(ii) *occurrences related to handling of passengers, baggage, mail and cargo;*

(iii) *occurrences related to aircraft ground handling and related services.*

2. Each organisation established in a Member State shall establish a mandatory reporting system to facilitate the collection of details *of* occurrences *referred to in paragraph 1*.

3. *Each Member State* shall establish a mandatory reporting system to facilitate the collection of details *of* occurrences including the collection of details *of* occurrences collected by organisations pursuant to paragraph 2 ■ .

4. *The European Aviation Safety Agency ('the Agency') shall establish a mandatory reporting system to facilitate the collection of details of occurrences, including the collection of details of occurrences collected pursuant to paragraph 2 by organisations which have been certified or approved by the Agency.*

5. *The Commission shall, by means of implementing acts, adopt a list classifying occurrences to be referred to when reporting occurrences pursuant to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).*

The Commission shall include in those implementing acts a separate list classifying occurrences applicable to aircraft other than complex motor-powered aircraft. The list shall be a simplified version of the list referred to in the first subparagraph and shall, where appropriate, be adapted to the specificities of that branch of aviation.

6. The following *natural* persons shall report *the* occurrences *referred to in paragraph 1* through the system established in accordance with paragraph 2 by the organisation which employs, contracts or uses the services of the reporter or, *failing that*, through the system established in accordance with paragraph 3 by *the Member State of establishment of their organisation, or by the State which issued, validated or converted the pilot's licence, or through the system established* in accordance with paragraph 4 *by the Agency*:

- (a) the pilot in *command, or, in cases where the pilot in command is unable to report the occurrence, any other crew member next in the chain of* command of an aircraft registered in a Member State or an aircraft registered outside the Union but used by an operator for which a Member State ensures oversight of operations or an operator established in the Union;

- (b) a person *engaged in* designing, manufacturing, *continuous airworthiness monitoring, maintaining* or modifying *an* aircraft, or any equipment or part thereof, under the oversight of a Member State or of the Agency;
- (c) a person who signs *an airworthiness review* certificate ■ , or *a* release to service in respect of ■ an aircraft ■ or any equipment or part thereof, under the oversight of a Member State or of the Agency;
- (d) a person who performs a function which requires him or her to be authorised by a Member State as *a staff member of* an air traffic *service provider entrusted with responsibilities related to air navigation services* or as a flight information *service* officer;
- (e) a *person who performs a function connected with the safety management* of an airport to which Regulation (EC) No 1008/2008 of the European Parliament and of the Council ■ ¹ applies;
- (f) a person who performs a function connected with the installation, modification, maintenance, repair, overhaul, flight-checking or inspection of air navigation facilities for which a Member State *ensures the oversight*;

¹ Regulation (EC) No 1008/2008 of the European Parliament and of the Council of 24 September 2008 on common rules for the operation of air services in the Community (OJ L 293, 31.10.2008, p. 3).

(g) a person who performs a function connected with the ground handling of aircraft, including fuelling, loadsheet preparation, loading, de-icing and towing at an airport covered by Regulation (EC) No 1008/2008.

7. ***The persons*** listed in paragraph 6 shall report occurrences within ***72 hours of becoming aware of the occurrence, unless exceptional circumstances prevent this.***
8. ***Following notification of an occurrence, any*** organisation ***established in*** a Member State ***which is not covered by paragraph 9*** shall report to the competent authority of that Member State, as referred to in Article 6(3), the details ***of*** occurrences collected in accordance with paragraph 2 of this Article ***as soon as possible, and in any event no later than 72 hours after becoming aware of the occurrence.***
9. ***Following notification of an occurrence, each*** organisation ***established in a Member State which is*** certified or approved by the Agency shall report to ***■*** the Agency the details ***of*** occurrences collected in accordance with paragraph 2 ***as soon as possible, and in any event no later than 72 hours after becoming aware of the occurrence.***

Article 5

Voluntary reporting

1. Each organisation established in a Member State shall establish a voluntary reporting system to facilitate the collection of:
 - (a) ■ details of occurrences that may not be captured by the mandatory reporting system;
 - (b) *other safety-related information* which *is* perceived by the reporter as an actual or potential hazard *to aviation safety*.
2. Each Member State shall establish a voluntary reporting system to facilitate the collection of:
 - (a) details of *occurrences that may not be captured by the mandatory reporting system*,
 - (b) *other safety-related information which is perceived by the reporter as an actual or potential hazard to aviation safety*.

That system shall also include, but shall not be limited to, the collection of information transferred by organisations pursuant to paragraph 6.

3. *The Agency shall establish a voluntary reporting system to facilitate the collection of:*

(a) details of occurrences that may not be captured by the mandatory reporting system;

(b) other safety-related information which is perceived by the reporter as an actual or potential hazard to aviation safety.

That system shall also include, but shall not be limited to, the collection of information transferred by organisations certified or approved by the Agency pursuant to paragraph 5.

4. The voluntary reporting systems shall be used to *facilitate* the collection of details of occurrences and safety-related information:

(a) not subject to *mandatory* reporting pursuant to *Article 4(1)*;

(b) reported by persons who are not listed in Article 4(6).

■

5. Each organisation *established in a Member State and* certified or approved by the Agency shall report to the Agency, in a timely manner, details *of occurrences and safety-related information which have been* collected pursuant to paragraph 1 and which *may involve an actual or potential aviation safety risk*.

6. *Each organisation established in a Member State that is not certified or approved by the Agency shall, in a timely manner, report to the competent authority of that Member State, as designated pursuant to Article 6(3), the details of occurrences and other safety-related information which have been collected pursuant to paragraph 1 of this Article and which may involve an actual or potential aviation safety risk. Member States may require any organisation established in their territory to report the details of all occurrences collected pursuant to paragraph 1 of this Article.*

7. Member States, ***the Agency*** and organisations may establish other safety information collection and processing systems to collect details ***of*** occurrences that might not be captured by the reporting systems ***referred to*** in Article 4 and in paragraphs 1, 2 and 3 of this Article. Those systems may include reporting to ■ entities ***other*** than ***those set out*** in Article 6(3) and may involve the active participation of:
- (a) the aviation industry;
 - (b) ***professional organisations of aviation staff.***
8. ***Information received from voluntary and mandatory reporting may be integrated into a single system.***

Article 6

Collection and storage of information

1. Each organisation established in a Member State shall designate one or more persons to handle ***independently*** the collection, evaluation, processing, analysis and storage of details of occurrences reported pursuant to Articles 4 and 5.

The handling of the reports shall be done with a view to preventing the use of information for purposes other than safety, and shall appropriately safeguard the confidentiality of the identity of the reporter and of the persons mentioned in occurrence reports, with a view to promoting a 'just culture'.

2. *By agreement with the competent authority, small organisations may put in place a simplified mechanism for the collection, evaluation, processing, analysis and storage of details of occurrences. They may share those tasks with organisations of the same nature, while complying with the rules on confidentiality and protection pursuant to this Regulation.*
3. Each Member State shall designate one or more competent authorities to establish a mechanism to *independently* collect, evaluate, process, analyse and store details of occurrences reported pursuant to Articles 4 and 5.

The handling of the reports shall be done with a view to preventing the use of information for purposes other than safety, and shall appropriately safeguard the confidentiality of the identity of the reporter and of the persons mentioned in occurrence reports, with a view to promoting a 'just culture'.

The authorities which may be *designated pursuant to the first subparagraph*, either jointly or separately, are the following:

- (a) the national civil aviation authority; and/or
- (b) the safety investigation authority; and/or

- (c) any other independent body or entity ***based in the Union that is*** entrusted with this function.

Where a Member State designates more than one body or entity, it shall designate one of ***them*** as point of contact for the transfer of information ***referred to*** in Article 8(2).

4. ***The Agency shall designate one or more persons to establish a mechanism to independently collect, evaluate, process, analyse and store details of occurrences reported in accordance with Articles 4 and 5.***

The handling of the reports shall be done with a view to preventing the use of information for purposes other than safety, and shall appropriately safeguard the confidentiality of the identity of the reporter and of the persons mentioned in occurrence reports, with a view to promoting a 'just culture'.

5. Organisations shall store occurrence reports drawn up on the basis of details ***of*** occurrences collected in accordance with Articles 4 and 5 in ***one or more databases***.
6. The competent authorities referred to in paragraph 3 shall store occurrence reports drawn up on the basis of details ***of*** occurrences collected in accordance with Articles 4 and 5 in a national database.

7. ***Relevant information on accidents*** and serious incidents ***collected or issued by safety investigation authorities*** shall also be stored in the national database.
8. ***The Agency shall store occurrence reports drawn up on the basis of details of occurrences collected in accordance with Articles 4 and 5 in a database.***
9. ***Safety investigation authorities shall have full access to their respective national database referred to in paragraph 6 for the purpose of discharging their responsibilities pursuant to Article 5(4) of Regulation (EU) No 996/2010.***
10. ***Civil aviation*** authorities of Member States **■** shall have full access to ***their respective*** national database referred to in paragraph 6 ***for the purposes of*** their safety-related responsibilities.

■

Article 7

Quality and *content* of occurrence reports

1. Occurrence reports referred to in Article 6 shall contain at least the information listed in Annex *I*.
2. *Occurrence reports* referred to in *paragraphs 5, 6 and 8* of Article 6 shall *include a* safety risk classification *for the occurrence concerned. That* classification shall be *reviewed and if necessary amended, and shall be endorsed by the competent authority of the Member State or the Agency*, in accordance with the common European risk classification scheme referred to in paragraph 5 *of this Article*.
3. Organisations, Member States *and the Agency* shall establish data quality checking processes ■ to *improve data* consistency, *notably* between the *information collected initially and the report stored in the database*.
4. The databases *referred to* in paragraphs 5, 6 *and 8* of Article 6 shall use formats which are:
 - (a) standardised to facilitate information exchange; and
 - (b) compatible with the ECCAIRS software and the ADREP taxonomy.

5. The Commission, *in close cooperation with the Member States and the Agency through the network of aviation safety analysts, referred to in Article 14(2)*, shall develop a common European risk classification scheme *to enable the organisations, Member States and the Agency* to classify occurrences in terms of safety risk. In so doing, the Commission shall take into account the need for compatibility with existing risk classification schemes.

The Commission shall develop that scheme by ...^{*}

6. The Commission shall be empowered to adopt ■ delegated acts in accordance with Article 18 *to define* the common European risk classification scheme.
7. The Commission shall, by means of implementing acts, adopt the arrangements for the implementation of the common European risk classification scheme. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

^{*}

OJ: Please insert date: *three years after the entry into force of this Regulation*.

8. The Commission *and the Agency* shall support the competent authorities of the Member States in their task of data integration, including for example in:
- (a) the integration of the minimum information referred to in paragraph 1,
 - (b) the risk classification of occurrences referred to in paragraph 2, and
 - (c) the establishment of data quality checking processes referred to in paragraph 3.

The Commission *and the Agency* shall provide that support in such a way as to contribute to the harmonisation of the data entry process across Member States, in particular by providing to *staff working in the bodies or entities referred to in Article 6(1), (3) and (4)*:

- (a) guidance material;
- (b) *workshops; and*
- (c) *appropriate training.*

.Article 8

European Central Repository

1. The Commission shall manage a European Central Repository to store all occurrence reports collected in the Union.
2. Each Member State shall, *in agreement* with the Commission ■ , update ■ the European Central Repository by *transferring to it* all information relating to safety stored in the national databases referred to in Article 6(6).

3. The Agency shall agree with the Commission the technical protocols for transferring to the European Central Repository all occurrence reports collected *by the Agency* under Regulation (EC) No 216/2008 ■ and its implementing rules, *particularly for occurrences stored in the Internal Occurrence Reporting System (IORS)*, as well as the information collected *pursuant to* Articles 4(9) and 5(5).
4. The Commission shall, by means of implementing acts, adopt the arrangements for the management of the European Central Repository as referred to in paragraph *1 and 2*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

■

Article 9

Exchange of information

1. Member States and the Agency shall participate in an exchange of information by making all information relating to safety stored in their respective reporting databases available to the competent authorities of the other Member States, the Agency and the Commission, through the European Central Repository.

Occurrence reports shall be transferred to the European Central Repository *no later than* 30 days after *having been entered in the national database*.

Occurrence reports shall be updated whenever necessary with additional information relating to safety.

2. Member States shall also transfer information related to accidents and serious incidents **to** the European Central Repository as follows:
 - (a) during the course of the investigation: **preliminary** factual information on accidents and serious incidents.
 - (b) when the investigation is completed:
 - (i) **the final investigation report; and,**
 - (ii) when available, a summary in English of the final investigation report.
3. A Member State or the Agency shall forward all pertinent safety-related information to the relevant authority of the Member State or the Agency as soon as possible if, while collecting details **of** occurrences or **when storing** occurrence reports **or carrying out an analysis in accordance with Article 13(6)**, it identifies safety matters which it considers either:
 - (a) to be of interest to other Member States or the Agency; **or**
 - (b) **to** possibly require safety action to be taken **by other Member States or the Agency**.

Article 10

Dissemination of information *stored in the European Central Repository*

1. Any entity entrusted with regulating civil aviation safety, or any *safety investigation authority*, within the Union shall have *secure full* online access to information on occurrences contained in the European Central Repository.

The information shall be used in accordance with Articles 15 and 16.

2. Interested parties listed in Annex *II* may request access to certain information contained in the European Central Repository.

Interested parties established within the Union shall address requests for information to the point of contact of the Member State in which they are established.

Interested parties ■ established *outside* the Union shall address their request to the Commission.

The Commission shall inform the competent authority of the Member State concerned when a request is made pursuant to this paragraph.

3. *Subject to Article 15(2) of Regulation (EU) No 996/2010, information contained in the European Central Repository relating to ongoing safety investigations conducted in accordance with that Regulation shall not be disclosed to interested parties pursuant to this Article.*

4. For security reasons, interested parties shall not be granted direct access to the European Central Repository.

Article 11

Processing of requests and decisions

1. Requests *for information contained in the European Central Repository* shall be submitted using forms approved by the point of contact. Those forms shall contain at least the items set out in Annex *III*.
2. A point of contact which receives a request shall *verify* that:
 - (a) the request is made by an interested party;
 - (b) it is competent to deal with that request.

Where the point of contact determines that another Member State or the Commission is competent to deal with the request, it shall transfer it to that Member State or to the Commission, as appropriate.

3. A point of contact which receives a request shall evaluate on a case-by-case basis whether the request is justified and practicable.

A point of contact may supply information to interested parties on paper or by using secure electronic means of communication.

4. **Where** the request is accepted, the point of contact shall determine the amount and the level of information to be supplied. **Without prejudice to Articles 15 and 16, the** information shall be limited to what is strictly required for the purpose of the request **I**.

Information unrelated to the interested party's own equipment, operations or field of activity shall be supplied only in aggregated or **anonymised** form. Information **in** non-aggregated form may be provided to the interested party if it provides a detailed **written** justification. **That information shall be used in accordance with Articles 15 and 16.**

5. The point of contact shall supply interested parties listed in point (b) of Annex **II** **only** **I** with information relating to the interested party's own equipment, operations or field of activity.
6. A point of contact receiving a request from an interested party listed in point (a) of Annex **II** may take a general decision to supply information on a regular basis to that interested party, provided that:
- (a) the information requested is related to the interested party's own equipment, operations or field of activity;
 - (b) the general decision does not grant access to the entire content of the database;
 - (c) the general decision relates only to **anonymised** information.

7. The interested party shall use the information received pursuant to this Article subject to the following conditions:
 - (a) the interested party shall use the information only for the purpose specified in the request form, which should be compatible with the objective of this Regulation as stated in Article 1; and
 - (b) the interested party shall not disclose the information received without the written consent of the information provider and shall take the necessary measures to ensure appropriate confidentiality of the information received.
8. The decision to disseminate information *pursuant to* this Article shall be limited to what is strictly required for the purpose of its user.

■

Article 12

Record of requests and exchange of information

1. The point of contact shall record each request received and the action taken *pursuant to that request*.

That information shall be transmitted *in a timely manner* to the Commission whenever a request is received and/or action *is* taken.
2. The Commission shall make available ■ the updated list of requests received and action taken by the various points of contact and by the Commission itself *to all points of contact*.

Article 13

Occurrence analysis and follow-up at national level

1. Each organisation established in a Member State shall develop a process to analyse occurrences collected in accordance with Articles 4(2) and 5(1) in order to identify the safety hazards associated with identified occurrences *or groups of occurrences*.

Based on *that* analysis, each organisation shall determine *any* appropriate corrective or preventive action, required to improve aviation safety.

2. When, following the analysis referred to in paragraph 1, an organisation established in a Member State identifies any appropriate corrective or preventive action required to address actual or potential aviation safety deficiencies, it shall:

- (a) implement that action in a timely manner and

- (b) establish a process to monitor the implementation and effectiveness of the action.

3. *Each organisation established in a Member State shall regularly provide its employees and contracted personnel with information concerning the analysis of, and follow-up on, occurrences for which preventive or corrective action is taken.*

4. *Where an organisation established in a Member State which is not covered by paragraph 5 identifies an actual or potential aviation safety risk as a result of its analysis of occurrences or group of occurrences reported pursuant to Article 4(8) and Article 5(6), it shall transmit to the competent authority of that Member State, within 30 days from the date of notification of the occurrence by the reporter:*

(a) *the preliminary results of the analysis performed pursuant to paragraph 1, if any, and*

(b) *any action to be taken pursuant to paragraph 2.*

The organisation shall report the final results of the analysis, where required, as soon as they are available and, in principle, no later than three months from the date of notification of the occurrence.

A competent authority of a Member State may request organisations to transmit to it the preliminary or final results of the analysis of any occurrence of which it has been notified but in relation to which it has received no follow-up or only the preliminary results.

5. Where an organisation established in a Member State and certified or approved by the Agency identifies an actual or potential aviation safety risk as a result of its analysis of occurrences or group of occurrences reported pursuant to Article 4(9) and Article 5(5), it shall transmit to the Agency, within 30 days from the date of notification of the occurrence by the reporter:

(a) *the preliminary results* of the analysis performed pursuant to paragraph 1, if any,; and

(b) *any action to be taken* pursuant to paragraph 2.

The organisation certified or approved by the Agency shall transmit to the Agency *the final results of the analysis, where required, as soon as they are available and, in principle, no later than three months from the date of notification of the occurrence.*

The Agency may request organisations to transmit to it the preliminary or final results of the analysis of any occurrence of which it has been notified but in relation to which it has received no follow-up or only the preliminary results.

6. Each Member State *and the Agency* shall develop a process to analyse the *information relating to* occurrences *which are directly reported to them* in accordance with Articles 4(6), 5(2) *and* 5(3) in order to identify the safety hazards associated with *those* occurrences. Based on that analysis, *they* shall determine any appropriate corrective or preventive action required to improve aviation safety.
7. When, following the analysis referred in paragraph 6, a Member State or the Agency identifies any appropriate corrective or preventive action required to address actual or potential aviation safety deficiencies, it shall:
- (a) implement *that* action in a timely manner and
 - (b) establish a process to monitor the implementation and effectiveness of the action.
8. *For each occurrence or group of occurrences monitored in accordance with paragraph 4 or 5, each* Member State *and the Agency* shall *have access to the analysis made and shall appropriately monitor action taken by the organisations for which it is respectively responsible.*

If a Member State or the Agency concludes that the implementation and *the* effectiveness of ■ the *reported* action *is* inappropriate to address ■ actual or potential safety deficiencies, it shall ensure that additional appropriate action is taken and implemented by the relevant organisation.

9. ***Where available, information*** relating to the analysis and ***the*** follow-up of individual occurrences ***or groups of occurrences*** obtained pursuant to this Article shall be stored in the European Central Repository, ***in accordance with Article 8(2) and (3)***, in a timely manner and no later than two months after their storage in the national database.
10. Member States shall use information obtained from the analysis of occurrence reports to identify remedial action to be taken, ***if any***, within the State Safety Programme.
11. ***In order to inform the public of the level of safety in civil aviation, each*** Member State shall publish a safety review at least once a year. The safety review shall:
 - (a) contain ***aggregated and anonymised*** information on the type of occurrences and safety-related information reported through its national mandatory and voluntary reporting systems;
 - (b) ***identify trends***;
 - (c) identify the action it has taken ■ .
12. Member States may also publish ***anonymised*** occurrence reports ***and risk analysis outcomes***.

Article 14

Occurrence analysis and follow up at ■ Union level

1. The Commission, the Agency and the competent authorities of the Member States shall, in collaboration, participate regularly in the exchange and analysis of information contained in the European Central Repository.

Without prejudice to the confidentiality requirements laid down in this Regulation, observers may be invited on a case-by-case basis, where appropriate.

2. The Commission, the Agency and the competent authorities of the Member States shall collaborate through a ***network of aviation safety analysts***.

The network of aviation safety analysts shall contribute to the improvement of aviation safety in the Union, in particular by performing safety analysis in support of the European Aviation Safety Programme and the European Aviation Safety Plan.

3. The Agency shall support ***the activities of the network of aviation safety analysts*** by, for example, providing assistance for the preparation and organisation of the meetings of the network.

■

4. The Agency shall include information about the result of information analysis referred to in paragraph 1 in the annual safety review ***referred to*** in Article 15(4) of Regulation (EC) No 216/2008.

Article 15

Confidentiality and appropriate use of **■** information

1. Member States and organisations, *in accordance with their national law, and the Agency* shall take the necessary measures to ensure *the* appropriate confidentiality of the details *of* occurrences received by them pursuant to Articles 4, 5 and 10.

Each Member State, each organisation established in a Member State, or the Agency shall process personal data only to the extent necessary for the purposes of this Regulation and without prejudice to national legal acts implementing Directive 95/46/EC.

2. *Without prejudice to the provisions relating to the protection of safety information in Articles 12, 14 and 15 of Regulation (EU) No 996/2010, information* derived from occurrence reports shall be used only for the purpose for which *it has* been collected.

Member States, *the Agency* and organisations shall not make available *or* use the information on occurrences:

- (a) in order *to attribute blame or liability, or*
- (b) *for any purpose other than the maintenance or improvement of* aviation safety.

■

3. The Commission, the Agency and the competent authorities of the Member States, when discharging their obligations under Article 14 in relation to the information contained in the European Central Repository, shall:
 - (a) ensure the confidentiality of the information; and
 - (b) limit the use of the information to what is strictly necessary in order to discharge their safety-related obligations *without attributing blame or liability*; in this respect, the information shall be used in particular for *risk management and for* analysis of safety trends which *may lead to* safety recommendations or *actions, addressing actual or potential safety deficiencies*.
4. Member States shall ensure that their competent authorities referred to in Article 6(3) and their competent authorities for the administration of justice cooperate with each other through advance *administrative* arrangements. These advance *administrative* arrangements shall seek to ensure the correct balance between the need for proper administration of justice, on the one hand, and the necessary continued availability of safety information, on the other.

Article 16

Protection of the information source

1. For the purposes of this Article, 'personal details' includes in particular names or addresses of natural persons.
2. Each organisation established in a Member State shall ensure that all personal *details* are made ■ available to *staff of that organisation other than* persons *designated in accordance with* Article 6(1) *only where absolutely necessary in order to investigate occurrences with a view to enhancing aviation safety.*

Disidentified information shall be disseminated within the organisation as appropriate.

-
3. Each Member State shall ensure *that* no personal *details* are ever recorded in the national database *referred to* in Article 6(6). *Such disidentified* information shall be made available to all relevant parties, for example to allow them to discharge their obligations in relation to aviation safety improvement. ■
 4. *The Agency shall ensure that no personal details are ever recorded in the Agency database referred to in Article 6(8). Such disidentified information shall be made available to all relevant parties, for example to allow them to discharge their obligations in relation to aviation safety improvement.*
 5. *Member States and the Agency shall not be prevented from taking any action necessary for maintaining or improving aviation safety.*

6. *Without prejudice to applicable national criminal law, Member States shall refrain from instituting proceedings in respect of unpremeditated or inadvertent infringements of the law which come to their attention only because they have been reported pursuant to Articles 4 and 5.*

The first subparagraph shall not apply in the cases referred to in paragraph 10. Member States may retain or adopt measures to strengthen the protection of reporters or persons mentioned in occurrence reports. Member States may in particular apply this rule without the exceptions referred to in paragraph 10.

7. *If disciplinary or administrative proceedings are instituted under national law, information contained in occurrence reports shall not be used against:*

(a) the reporters, or

(b) the persons mentioned in occurrence reports.

The first subparagraph shall not apply in the cases referred to in paragraph 10.

Member States may retain or adopt measures to strengthen the protection of reporters or persons mentioned in occurrence reports. Member States may in particular extend that protection to civil or criminal proceedings.

8. *Member States may adopt or maintain in force legislative provisions ensuring a higher level of protection for reporters or for persons mentioned in occurrence reports than those established in this Regulation.*

9. Except where *paragraph 10* applies, employees *and contracted personnel* who report *or are mentioned in occurrence reports collected* in accordance with Articles 4 and 5 shall not be subject to any prejudice by their employer *or by the organisation for which the services are provided* on the basis of the information *supplied by the reporter*.
10. *The protection under paragraphs 6, 7 and 9 of this Article shall not apply to any of the following situations:*
- (a) *in cases of wilful misconduct;*
 - (b) *where there has been a manifest, severe and serious disregard of an obvious risk and profound failure of professional responsibility to take such care as is evidently required in the circumstances, causing foreseeable damage to a person or property, or which seriously compromises the level of aviation safety.*
11. Each organisation established in a Member State shall, *after consulting its staff representatives*, adopt internal rules describing how 'just culture' principles, in particular the principle referred to in paragraph 9, are guaranteed and implemented within that organisation.
- The body designated pursuant to paragraph 12 may ask to review the internal rules of the organisations established in its Member State before those internal rules are implemented.*

12. Each Member State shall ***designate*** a body responsible for the implementation of ***paragraphs 6, 9 and 11***.

Employees and contracted personnel ***may*** report to that body ***alleged*** infringements of the rules established by this Article. ***Employees and contracted personnel shall not be penalised for reporting alleged infringements. Employees and contracted personnel may inform the Commission about such alleged infringements.***

Where appropriate, the designated body shall ***advise the relevant authorities*** of its Member State ***concerning remedies or penalties in application of Article 21***.

13. ***On ...^{*} and every five years thereafter, each Member State shall send the Commission a report on the application of this Article, and in particular on the activities of the body designated pursuant to paragraph 12. The report shall not contain any personal data.***

Article 17

Updating of the ***annexes***

The Commission shall be empowered to adopt delegated acts in accordance with Article 18 ***in order to:***

- (a) ***update the list of mandatory data fields in occurrence reports laid down in Annex I where, in the light of experience gained in the application of this Regulation, changes prove necessary in order to improve aviation safety;***

*

OJ: Please insert date: five years after the date of entry into force of this Regulation.

- (b) *update the request for European Central Repository information form provided in Annex III, to take account of experience gained and of new developments;*
- (c) align *any of* the Annexes with *the ECCAIRS* software and the ADREP taxonomy, *as well as* with *legal acts* adopted by the Union and with international agreements.

With a view to updating the list of mandatory fields, the Agency and the network of aviation safety analysts referred to in Article 14(2) shall provide the Commission with appropriate opinion(s).

Article 18

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 7(6 ■) and 17 shall be conferred on the Commission for *a period of five years from the entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Articles 7(6 ■) and 17 may be revoked at any time by the European Parliament or by the Council. A decision *to revoke* shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 7(6 ■) and 17 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *two* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *two* months at the initiative of the European Parliament or of the Council.

Article 19
Committee procedure

1. The Commission shall be assisted by the committee established by Article 65 of Regulation (EC) No 216/2008. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 *of Regulation (EU) No 182/2011 shall apply. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.*

Article 20
Access to documents and protection of personal data

1. With the exception of Articles 10 and 11, which establish stricter rules on access to the data and information contained in the European Central Repository, this Regulation shall apply without prejudice to Regulation (EC) No 1049/2001.
2. This Regulation shall apply without prejudice to national *legal acts* implementing Directive 95/46/EC and in accordance with Regulation (EC) No 45/2001.

Article 21

Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall *notify to* the Commission *those provisions and any subsequent amendment affecting them*.

Article 22

Amendment to Regulation (EU) No 996/2010

Article 19 of Regulation (EU) No 996/2010 is deleted.

However, that Article shall remain applicable until the date of application of this Regulation in accordance with Article 24(3).

Article 23

Repeals

Directive 2003/42/EC, Regulation (EC) No 1321/2007 and Regulation (EC) No 1330/2007 are repealed. *They shall remain applicable until the date of application of this Regulation in accordance with Article 24(3).*

Article 24

Entry into force *and application*

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. ***By ...^{*}, the Commission shall publish and send to the European Parliament and to the Council an evaluation report on the implementation of this Regulation. That report shall cover, in particular, the contribution made by this Regulation to reducing the number of aircraft accidents and related fatalities. If appropriate and on the basis of that report, the Commission shall make proposals for amending this Regulation.***
3. ***This Regulation shall apply from ...^{**} and not before the entry into force of the implementing measures referred to in Article 4(5). Article 7(2) shall apply once the delegated and implementing acts specifying and developing the European common risk classification scheme referred to in Article 7(6) and (7) enter into force.***

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the European Parliament
The President

For the Council,
The President

^{*}

OJ: Please insert date: five years after the date of application of this Regulation.

^{**}

OJ: Please insert date: 18 months after the date of entry into force of this Regulation.

ANNEX I

LIST OF REQUIREMENTS APPLICABLE TO THE MANDATORY AND VOLUNTARY OCCURRENCE REPORTING *SCHEMES*

NOTE: *The data fields must be completed with the information requested. If it is not possible for the competent authorities of the Member States or the Agency to include that information because it has not been provided by the organisation or the reporter, the data field may be completed with the value 'unknown'. However, with a view to ensuring that the appropriate information is transmitted, use of that 'unknown' value should, to the best extent possible, be avoided, and the report should, where possible, be completed with the information later.*

1. *COMMON MANDATORY DATA FIELDS*

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) Headline

- Headline

(2) Filing Information

- Responsible Entity
- File Number
- Occurrence Status

(3) When

■

- UTC Date

■

(4) Where

- State/ Area of Occurrence
- Location of Occurrence

(5) Classification

- Occurrence Class
- Occurrence Category

I

(6) Narrative

- Narrative Language
- Narrative

(7) Events

- Event Type



(8) Risk classification

2. **SPECIFIC MANDATORY DATA FIELDS**



2.1. *Aircraft-related data fields*

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) Aircraft Identification

- State of Registry
- Make/ Model/ Series
- Aircraft serial number

- Aircraft Registration
 - *Call sign*
- (2) Aircraft Operation
- Operator
 - **■** *Type of operation*
- (3) Aircraft Description
- Aircraft Category
 - Propulsion Type
 -
 - Mass Group
- (4) History of Flight
- Last Departure Point
 - Planned Destination

- Flight Phase

■

(5) *Weather*

- *Weather relevant*

2.2. *Data fields relating to air navigation services*

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) *ATM relation*

- *ATM contribution*
- *Service affected (effect on ATM service)*

(2) *ATS Unit Name*

2.2.1 *Separation Minima Infringement/Loss of Separation and Airspace Infringement-related data fields*

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) Airspace

- ***Airspace type***
- ***Airspace class***
- ***FIR/UIR name***

2.3. *Aerodrome-related data fields*

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

- (1) Location Indicator (ICAO indicator of the airport)*
- (2) Location on the aerodrome*

2.4. Aircraft damage or personal injury-related data fields

When entering, in their respective databases, information on every occurrence mandatorily reported and, to the best extent possible, every occurrence voluntarily reported, organisations, Member States and the Agency must ensure that occurrence reports recorded in their databases contain at least the following information:

(1) Severity

- *Highest Damage*
- *Injury Level*

(2) Injuries to persons

- *Number of injuries on ground (fatal, serious, minor)*
 - *Number of injuries on aircraft (fatal, serious, minor).*
-

ANNEX II

INTERESTED PARTIES

■ (a) List of interested parties which may receive information on the basis of a case-by-case decision under Article 11(4) or on the basis of a general decision under Article 11(6):

1. *Manufacturers*: designers and manufacturers of aircraft, engines, propellers and aircraft parts and appliances, ***and their respective associations***; designers and manufacturers of air traffic management (ATM) systems and constituents; designers and manufacturers of systems and constituents for air navigation services (ANS); designers and manufacturers of systems and equipments used on the air side of aerodromes
2. *Maintenance*: organisations involved in the maintenance or overhaul of aircraft, engines, propellers and aircraft parts and appliances; in the installation, modification, maintenance, repair, overhaul, flight checking or inspection of air navigation facilities; or in the maintenance or overhaul of aerodrome air side systems, constituents and equipment
3. *Operators*: airlines and operators of aircraft and associations of airlines and operators; aerodrome operators and associations of aerodrome operators

4. Air navigation services providers and providers of ATM-specific functions
5. *Aerodrome service providers*: organisations in charge of ground handling of aircraft, including fuelling, loadsheet preparation, loading, de-icing and towing at an aerodrome, as well as rescue and fire fighting, or other emergency services
6. Aviation training organisations
7. *Third-country organisations*: governmental aviation authorities and accident investigation authorities from third countries
8. International aviation organisations
9. *Research*: public or private research laboratories, centres or entities; or universities engaged in aviation safety research or studies

■ (b) List of interested parties which may receive information on the basis of a case-by-case decision under Articles 11(4) and 11(5):

1. *Pilots* (on a personal basis)
 2. *Air traffic controllers* (on a personal basis) and other ATM/ANS staff carrying out safety-related tasks
 3. Engineers/technicians/air traffic safety electronics staff/aviation (or aerodrome) managers (on a personal basis)
 4. Professional representative bodies of staff carrying out safety-related tasks
-

ANNEX III

REQUEST FOR INFORMATION FROM THE EUROPEAN CENTRAL REPOSITORY

1. Name:

Function/position

Company:

Address:

Tel.:

E-mail:

Date:

Nature of business:

Category of interested party (see Annex **II** to Regulation (EU) No.../... of the European Parliament and of the Council of on the reporting, analysis and follow-up of occurrences in civil aviation^{*}):

2. **Information requested** (please be as specific as possible; include the relevant date/period in which you are interested):

--

3. Reason for the request:

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^{*} OJ: Please insert number, date and publication reference of this Regulation.

4. Explain the purpose for which the information will be used:

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5. Date by which the information is requested:
6. The completed form should be sent, via e-mail, to: (point of contact)
7. Access to information

The point of contact is not required to supply any requested information. It may do so only if it is confident that the request is compatible with Regulation (EU) No.../...^{*}. The requestor commits itself and its organisation to restrict the use of the information to the purpose it has described under point 4. It is also recalled that information provided on the basis of this request is made available only for the purposes of flight safety as provided in Regulation (EU) No.../...^{*} and not for other purposes such as, in particular, attributing blame or liability or for commercial purposes.

The requestor is not allowed to disclose information provided to it to anyone without the written consent of the point of contact.

Failure to comply with these conditions may lead to a refusal of access to further information from the European Central Repository and, where applicable, to the imposition of penalties.

8. Date, place and signature:

^{*} OJ: Please insert the number of this Regulation.

Deployment of the eCall in-vehicle system *I**

European Parliament legislative resolution of 26 February 2014 on the proposal for a regulation of the European Parliament and of the Council concerning type-approval requirements for the deployment of the eCall in-vehicle system and amending Directive 2007/46/EC (COM(2013)0316 – C7-0174/2013 – 2013/0165(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0316),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0174/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 19 September 2013¹,
 - having regard to Rule 55 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 Civil Liberties, Justice and Home Affairs, the Committee on Industry, Research and Energy and the Committee on Transport and Tourism (A7-0106/2014),
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.

¹ OJ C 341, 21.11.2013, p. 47.

Amendment 1

Proposal for a regulation Title 1

Text proposed by the Commission

Proposal for a
REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL
concerning type-approval requirements for
the deployment of the eCall in-vehicle
system and amending Directive
2007/46/EC
(Text with EEA relevance)

Amendment

Proposal for a
REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL
concerning type-approval requirements for
the deployment of the eCall in-vehicle
system ***based on the 112 service*** and
amending Directive 2007/46/EC
(Text with EEA relevance)

Amendment 2

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) The deployment of an eCall service available in all vehicles and in all Member States has been one of the high Union priorities in the area of road safety since 2003. To achieve that objective, a series of initiatives have been launched, as part of a voluntary deployment approach, but have not achieved sufficient progress to date.

Amendment 3

Proposal for a regulation Recital 3

Text proposed by the Commission

Amendment

(3) In order to further improve road safety, the Communication ‘eCall: Time for Deployment’⁶ proposes new measures to ***accelerate the deployment of*** an in-vehicle emergency call service in the Union. One of the suggested measures is to make mandatory the fitting of eCall in-vehicle systems in all new vehicles starting with

(3) In order to further improve road safety, the Commission Communication ***of 21 August 2009 entitled: ‘eCall: Time for Deployment’*** proposes new measures to ***deploy*** an in-vehicle emergency call service in the Union. One of the suggested measures is to make mandatory the fitting of ***112-based*** eCall in-vehicle systems in

M1 and N1 vehicle categories as defined in Annex II to Directive 2007/46/EC.

all new vehicles starting with M1 and N1 vehicle categories as defined in Annex II to Directive 2007/46/EC.

⁶ *COM (2009) 434 final.*

Amendment 4

Proposal for a regulation Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) It is still necessary to improve the operation of the 112 service throughout the Union, so that it provides assistance swiftly and effectively in emergencies.

Amendment 5

Proposal for a regulation Recital 5

Text proposed by the Commission

Amendment

(5) The Union eCall system is expected to reduce the number of fatalities in the Union as well as the severity of injuries caused by road accidents. The mandatory introduction of the eCall system would make the service available to all citizens and thus contribute to ***reduce human suffering and*** healthcare and other costs.

(5) The Union eCall system is expected to reduce the number of fatalities in the Union as well as the severity of injuries caused by road accidents, ***thanks to the early alert of the emergency services.*** The mandatory introduction of the ***112-based*** eCall in-vehicle system, ***together with the necessary and coordinated infrastructure upgrade in electronic communication networks for conveying eCalls and Public Safety Answering Points (PSAPs) for receiving eCalls,*** would make the service available to all citizens and thus contribute to ***the reduction of fatalities and severe injuries, of costs relating to*** healthcare, ***of congestion caused by accidents*** and of other costs.

Amendment 6

Proposal for a regulation Recital 5 a (new)

(5a) The eCall system will represent an important structure composed of multiple actors dealing with the safety of lives. Therefore it is essential that the liability aspect is covered by this Regulation in order to enable users to have full confidence and the eCall system to run smoothly.

Amendment 7

Proposal for a regulation Recital 6

(6) The provision of accurate and reliable positioning information is an essential element of the effective operation of the eCall in-vehicle system. Therefore, it is appropriate to require its compatibility with the services provided by satellite navigation programmes, *including* the systems established under the Galileo and EGNOS programmes set out in Regulation (EC) No 683/2008 of the European Parliament and of the Council *of 9 July 2008 on the further implementation of the European satellite navigation programmes (EGNOS and Galileo)*⁸.

(6) The provision of accurate and reliable positioning information *in emergencies* is an essential element of the effective operation of the *112-based* eCall in-vehicle system. Therefore, it is appropriate to require its compatibility with the services provided by satellite navigation programmes, *in particular* the systems established under the Galileo and EGNOS programmes *as* set out in Regulation (EU) No 1285/2013 of the European Parliament and of the Council⁸.

⁸ OJ L 196, 24.7.2008, p.1.

⁸ Regulation (EU) No 1285/2013 of the European Parliament and of the Council of 11 December 2013 on the implementation and exploitation of European satellite navigation systems and repealing Council Regulation (EC) No 876/2002 and Regulation (EC) No 683/2008 of the European Parliament and of the Council (OJ L 347, 20.12.2013, p.1.).

Amendment 8

Proposal for a regulation

Recital 7

Text proposed by the Commission

(7) The mandatory equipping of vehicles with the eCall in-vehicle system should initially apply only to new passenger cars and light commercial vehicles (categories M1 and N1) for which an appropriate triggering mechanism already exists.

Amendment

(7) The mandatory equipping of vehicles with the **112-based** eCall in-vehicle system should initially apply only to new **types of** passenger cars and light commercial vehicles (categories M1 and N1) for which an appropriate triggering mechanism already exists. ***The possibility of extending the application of the 112-based eCall in-vehicle system requirement in the near future to include other vehicle categories, such as heavy goods vehicles (HGVs), buses and coaches, powered two-wheelers (PTW) and agricultural tractors, should be further assessed by the Commission with a view to presenting, if appropriate, a legislative proposal.***

Amendment 9

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission

Amendment

(7a) The equipping of vehicles of existing types to be manufactured after 1 October 2015 with the 112-based eCall in-vehicle system should be promoted in order to increase penetration. In respect of types of vehicles type-approved before 1 October 2015, an eCall system may be retrofitted on a voluntary basis.

Amendment 10

Proposal for a regulation
Recital 7 b (new)

Text proposed by the Commission

Amendment

(7b) The public interoperable Union-wide eCall service based on the single European emergency call number 112 ("emergency number 112") and private eCall services (third party service supported eCall systems) can coexist

provided that the measures necessary to ensure continuity in the provision of the service to the consumer are adopted. In order to ensure continuity of the public 112-based eCall service in all Member States throughout the lifetime of the vehicle and guarantee that the public 112-based eCall service is always automatically available, all vehicles should be equipped with the public 112-based eCall service, regardless of whether or not a vehicle buyer opts for a private eCall service.

Amendment 11

Proposal for a regulation Recital 7 c (new)

Text proposed by the Commission

Amendment

(7c) Consumers should be provided with a realistic overview of the 112-based eCall in-vehicle system and of the private eCall system, if the vehicle is equipped with one, as well as comprehensive and reliable information regarding any additional functionalities or services linked to the private emergency service, in-vehicle emergency or assistance-call applications on offer, and regarding the level of service to be expected with the purchase of third party services and the associated cost. The 112-based eCall is a public service of general interest and should therefore be accessible free of charge to all consumers.

Amendment 12

Proposal for a regulation Recital 8

Text proposed by the Commission

Amendment

(8) The mandatory equipping of vehicles with the eCall in-vehicle system should be without prejudice to the right of all stakeholders such as car manufacturers and independent operators to offer additional

(8) The mandatory equipping of vehicles with the **112-based** eCall in-vehicle system should be without prejudice to the right of all stakeholders such as car manufacturers and independent operators to offer

emergency and/or added value services, in parallel with or building on the 112-based eCall in-vehicle system. However, *these* additional services should be designed not to increase driver distraction.

additional emergency and/or added value services, in parallel with or building on the 112-based eCall in-vehicle system. However, *any* additional services should be designed not to increase driver distraction *or affect the functioning of the 112-based eCall in-vehicle system and the efficient work of emergency call centres. The 112-based eCall in-vehicle system and the system providing private or added-value services should be designed in such a way that no exchange of personal data between them is possible. Where provided, those services should comply with the applicable safety, security and data protection legislation and should always remain optional for consumers.*

Amendment 13

Proposal for a regulation

Recital 9

Text proposed by the Commission

(9) In order to ensure open choice for customers and fair competition, as well as encourage innovation and boost the competitiveness of the Union's information technology industry on the global market, the eCall in-vehicle system should be *accessible free of charge and without discrimination to all independent operators and* based on an interoperable *and* open-access platform for possible future in-vehicle applications or services.

Amendment

(9) In order to ensure open choice for customers and fair competition, as well as encourage innovation and boost the competitiveness of the Union's information technology industry on the global market, the *112-based* eCall in-vehicle system should be based on an interoperable, open-access, *secured and standardised* platform for possible future in-vehicle applications or services. *As this requires technical and legal back-up, the Commission should assess without delay, on the basis of consultations with all stakeholders involved, including vehicle manufacturers and independent operators, all possibilities to promote and ensure such an open-access platform and, if appropriate, put forward a legislative proposal to that effect. Further clarifications should be provided on the conditions under which third parties providing added value services can have access to data stored in the 112-based in-vehicle system. Furthermore, the 112-based eCall in-vehicle system should be*

accessible free of charge and without discrimination to all independent operators for repair and maintenance purposes.

Amendment 14

Proposal for a regulation Recital 9 a (new)

Text proposed by the Commission

Amendment

(9a) The introduction of any additional in-vehicle application or service should not delay the entry into force and the application of this Regulation.

Amendment 15

Proposal for a regulation Recital 10 a (new)

Text proposed by the Commission

Amendment

(10a) The 112-based eCall in-vehicle system, as an emergency system, requires the highest possible level of reliability. The accuracy of the minimum set of data and of the voice transmission and quality should be ensured, and a uniform testing regime should be developed to ensure the longevity and durability of the 112-based eCall in-vehicle system. Periodic technical inspections should therefore be carried out regularly in accordance with Regulation (EU) No .../... of the European Parliament and of the Council ^{1a}. Detailed provisions for the testing should be included in the relevant Annex thereof.*

^{1a} Regulation (EU) No. .../... of the European Parliament and of the Council of ... on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC (OJ L ...).

* OJ: Please insert the number of the Regulation contained in doc. 2012/0184(COD) and complete the

footnote with its number, date and publication reference.

Amendment 16

Proposal for a regulation Recital 11

Text proposed by the Commission

(11) Small series vehicles are excluded under Directive 2007/46/EC from the requirements on the protection of occupants in the case of frontal impact and side impact. Therefore, those small series vehicles should be excluded from the obligation to comply with the eCall requirements.

Amendment

(11) Small series vehicles are excluded under Directive 2007/46/EC from the requirements on the protection of occupants in the case of frontal impact and side impact. Therefore, those small series vehicles should be excluded from the obligation to comply with the eCall requirements *set out in this Regulation*.

Amendment 17

Proposal for a regulation Recital 12

Text proposed by the Commission

(12) Special purpose vehicles should be subject to compliance with the eCall requirements set out in this Regulation, unless type-approval authorities consider, on a case by case basis, that the vehicle cannot meet those requirements due to its special purpose.

Amendment

deleted

Amendment 18

Proposal for a regulation Recital 13

Text proposed by the Commission

(13) According to the recommendations made by the Article 29 Data Protection Working Party and contained in the 'Working document on data protection and privacy implications in eCall initiative', adopted on 26 September 2006⁹, any processing of personal data through the eCall in-vehicle system should comply with the personal data

Amendment

(13) Directive 95/46/EC of the European Parliament and of the Council¹⁰, Directive 2002/58/EC of the European Parliament and of the Council¹¹ *and Articles 7 and 8 of the Charter of Fundamental Rights of the European Union^{11a} govern the processing of personal data carried out in the context of this Regulation. Any processing of data through the 112-based*

*protection rules provided for in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data*¹⁰ and in Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (*Directive on privacy and electronic communications*)¹¹, in particular to guarantee that vehicles equipped with eCall in-vehicle systems, in their normal operational status related to 112 eCall, are not traceable and are not subject to any constant tracking and that the minimum set of data sent by the in-vehicle eCall system includes the minimum information required for the *appropriate* handling of emergency calls.

eCall in-vehicle system should therefore be carried out in accordance with these Directives and under the supervision of the Member States' competent authorities, in particular the independent public authorities designated by the Member States pursuant to those Directives, in particular to guarantee that vehicles equipped with 112-based eCall in-vehicle systems, in their normal operational status related to 112 eCall, are not traceable and are not subject to any constant tracking and that the minimum set of data sent by the in-vehicle eCall system includes only the minimum information required for the handling of emergency calls by PSAPs, and that no personal data is stored after that. Given the consent of the data subject or a contract between both parties, other conditions may apply in case another emergency call system is installed in the vehicle in addition to the 112-based eCall in-vehicle system, but it should nevertheless comply with those Directives.

⁹ 1609/06/EN – WP 125.

¹⁰ OJ L 281, 23.11.1995, p.31.

¹¹ OJ L 201, 31.7.2002, p.37.

¹⁰ *Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data* (OJ L 281, 23.11.1995, p. 31).

¹¹ *Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)* (OJ L 201, 31.7.2002, p. 37).

^{11a} OJ C 303, 14.12.2007, p. 1.

Amendments 19 and 90

Proposal for a regulation Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) This Regulation takes into account the recommendations made by the Article 29 Working Party established by Directive 95/46/EC in its 'Working document on data protection and privacy implications in eCall initiative' of 26 September 2006¹.

¹ 1609/06/EN -WP 125.

Amendment 20

Proposal for a regulation Recital 13 b (new)

Text proposed by the Commission

Amendment

(13b) When complying with technical requirements, vehicle manufacturers should integrate technical forms of data protection into in-vehicle systems and should comply with the principle of 'privacy by design'.

Amendment 21

Proposal for a regulation Recital 15

Text proposed by the Commission

Amendment

(15) In order to ensure the application of common technical requirements regarding the eCall in-vehicle system, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the detailed rules on the application of the relevant standards, on testing, on personal data and privacy protection and on exemptions for certain vehicles or classes of vehicles of categories M1 and N1. It is of particular importance

(15) In order to ensure the application of common technical requirements regarding the ***112-based*** eCall in-vehicle system, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the detailed rules on the application of the relevant standards, on testing, on personal data and privacy protection and on exemptions for certain vehicles or classes of vehicles of categories M1 and

that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council

N1. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, ***consulting in particular the European Data Protection Supervisor, the Article 29 Working Party and consumer protection organisations.*** The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council

Amendment 22

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) Vehicle manufacturers should be allowed sufficient time to adapt to the technical requirements of this Regulation.

Amendment

(16) Vehicle manufacturers should be allowed sufficient time to adapt to the technical requirements of this Regulation ***and the delegated acts adopted pursuant to this Regulation in order to be able to carry out the necessary studies and tests under various conditions, as required, and thus ensure that the 112-based eCall in-vehicle system is fully reliable.***

Amendment 23

Proposal for a regulation Article 2 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

This Regulation shall not apply to small series vehicles.

(Alignment with Recital 11 and point (3)(b) of the Annex.)

Amendment 24

Proposal for a regulation Article 3 – introductory part

Text proposed by the Commission

Amendment

For the purpose of this Regulation and in

For the purpose of this Regulation and in

addition to the definitions laid down in Article 3 of Directive 2007/46/EC **and in Article 2 of Commission Delegated Regulation (EU) No 305/2013¹²**, the following definitions shall apply:

¹² OJ L 91, 03.04.2013, p. 1.

Amendment 25

Proposal for a regulation

Article 3 – point 1

Text proposed by the Commission

(1) ‘*e-Call* in-vehicle system’ means *a* system activated either automatically via in-vehicle sensors or manually, which **carries**, by means of mobile wireless communications networks, a standardised minimum set of data and **establishes** a 112-based audio channel between the occupants of the vehicle and *a* public safety answering point;

Amendment

(1) **‘112-based eCall** in-vehicle system’ means ***an emergency*** system, ***comprising in-vehicle equipment and the means to trigger, manage and enact the eCall transmission, that is*** activated either automatically via in-vehicle sensors or manually, which ***emits signals*** by means of ***a public*** mobile wireless communications networks, ***to enable the transmission of*** a standardised minimum set of data and ***the establishment of*** a 112-based audio channel between the occupants of the vehicle and ***the appropriate*** public safety answering point;

(Horizontal amendment: if adopted, the references to "eCall in-vehicle system" will be replaced with "112-based eCall in-vehicle system" throughout the text)

Amendments 26 and 80

Proposal for a regulation

Article 3 – point 2

Text proposed by the Commission

(2) ‘*in-vehicle system*’ means ***the in-vehicle equipment together with the means to trigger, manage and effect the eCall transmission via a public mobile wireless communications network providing a link between the vehicle and a means of enacting the eCall service via a***

Amendment

deleted

public mobile wireless communications network.

Amendment 27

Proposal for a regulation
Article 3 – point 2 a (new)

Text proposed by the Commission

Amendment

(2a) 'eCall' means an in-vehicle emergency call to 112, made via the 112-based eCall in-vehicle system;

Amendment 28

Proposal for a regulation
Article 3 – point 2 b (new)

Text proposed by the Commission

Amendment

(2b) 'public safety answering point' or 'PSAP' means a physical location where emergency calls are first received under the responsibility of a public authority or a private organisation recognised by the Member State concerned;

Amendment 29

Proposal for a regulation
Article 3 – point 2 c (new)

Text proposed by the Commission

Amendment

(2c) 'minimum set of data' or 'MSD' means the information defined by the standard 'Road transport and traffic telematics — eSafety — eCall minimum set of data (MSD)' (EN 15722) which is sent to the eCall PSAP;

Amendment 30

Proposal for a regulation

Article 3 – point 2 d (new)

Text proposed by the Commission

Amendment

(2d) 'in-vehicle equipment' means equipment permanently installed within the vehicle that provides or has access to the in-vehicle data required for the minimum set of data (MSD) to perform the eCall transaction via a public mobile wireless communications network;

Amendment 31

Proposal for a regulation

Article 3 – point 2 e (new)

Text proposed by the Commission

Amendment

(2e) 'public mobile wireless communications network' means mobile wireless communications network available to the public in accordance with Directives 2002/21/EC^{1a} and 2002/22/EC^{1b} of the European Parliament and of the Council;

^{1a} Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) (OJ L 108, 24.4.2002, p. 33).

^{1b} Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive) (OJ L 108, 24.4.2002, p. 51).

Amendment 32

Proposal for a regulation

Article 4

Text proposed by the Commission

Amendment

Manufacturers shall demonstrate that all

Manufacturers shall demonstrate that all

new types of vehicles referred to in Article 2 are equipped with an eCall in-vehicle system, in accordance with this Regulation and the delegated acts adopted pursuant to this Regulation.

new types of vehicles referred to in Article 2 are equipped with an ***embedded 112-based*** eCall in-vehicle system, in accordance with this Regulation and the delegated acts adopted pursuant to this Regulation.

Amendment 33

Proposal for a regulation

Article 5 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Manufacturers shall demonstrate that ***all their*** new types ***of vehicle*** are constructed to ensure that in the event of a severe accident which occurs in the territory of the Union, an eCall to the ***single European*** emergency number 112 is triggered automatically.

Amendment

Manufacturers shall demonstrate that new ***vehicle*** types are constructed to ensure that in the event of a severe accident, ***detected by activation of one or more sensors and/or processors within the vehicle***, which occurs in the territory of the Union, an eCall to the emergency number 112 is triggered automatically.

Amendment 34

Proposal for a regulation

Article 5 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Manufacturers shall demonstrate that new ***vehicles*** are constructed as to ensure that an eCall to the ***single European*** emergency number 112 can also be triggered manually.

Amendment

Manufacturers shall demonstrate that new ***vehicle types*** are constructed ***in such a way*** as to ensure that an eCall to the emergency number 112 can also be triggered manually.

Amendment 35

Proposal for a regulation

Article 5 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Paragraph 2 is without prejudice to the right of the vehicle owner to use another emergency call system installed in the vehicle and providing a similar service, in addition to the 112-based eCall in-vehicle system. In that case, that other emergency call system shall be compliant

with the standard EN 16102 'Intelligent transport systems – eCall – Operating requirements for third party support', and manufacturers shall ensure that there is only one system active at a time and that 112-based eCall in-vehicle system is triggered automatically in the event that the other emergency call system does not function.

Amendment 36

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission

3. Manufacturers shall ensure that the receivers in the in-vehicle systems are compatible with the positioning services provided by satellite navigation systems **including** the Galileo and the EGNOS systems.

Amendment

3. Manufacturers shall ensure that the receivers in the **112-based eCall** in-vehicle systems are compatible with the positioning services provided by satellite navigation systems, **in particular** the Galileo and the EGNOS systems.

Amendment 37

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

4. Only those eCall in-vehicle systems which can be tested shall be accepted for the purposes of type-approval.

Amendment

4. Only those **embedded 112-based** eCall in-vehicle systems which can be tested shall be accepted for the purposes of type-approval.

Amendment 38

Proposal for a regulation

Article 5 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Manufacturers shall demonstrate that, in the event of a critical system failure which would result in an inability to execute an eCall detected during or following the self-test, a warning shall be given to the occupants of the vehicle.

Amendment 39

Proposal for a regulation

Article 5 – paragraph 6

Text proposed by the Commission

6. The eCall in-vehicle system shall be accessible to all independent operators free of charge and without discrimination **at least** for repair and maintenance purposes.

Amendment

6. The **112-based** eCall in-vehicle system shall be accessible to all independent operators free of charge and without discrimination for repair and maintenance purposes.

Amendment 40

Proposal for a regulation

Article 5 – paragraph 7 – subparagraph 1

Text proposed by the Commission

The Commission shall be empowered to adopt delegated acts in accordance with Article 9 establishing the detailed technical requirements and tests for the type-approval of eCall in-vehicle systems **and amending Directive 2007/46/EC accordingly**.

Amendment

The Commission shall be empowered to adopt delegated acts in accordance with Article 9 establishing the detailed technical requirements and tests for the type-approval of **112-based** eCall in-vehicle systems.

Amendment 41

Proposal for a regulation

Article 5 – paragraph 7 – subparagraph 2 – introductory part

Text proposed by the Commission

The technical requirements and tests referred to in the first subparagraph shall be based on the requirements set out in paragraphs 3, 4 and 6 and on the following standards, where applicable:

Amendment

The technical requirements and tests referred to in the first subparagraph shall be **adopted after consultation of relevant stakeholders and shall be** based on the requirements set out in paragraphs **2, 2a**, 3, 4 and 6 and on the **available** standards **relating to eCall and, UNECE Regulations**, where applicable, **including**:

Amendment 42

Proposal for a regulation

Article 5 – paragraph 7 – subparagraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) EN 15722 'Intelligent transport systems - eSafety - eCall minimum set of data (MSD)';

Amendment 43

Proposal for a regulation

Article 5 – paragraph 7 – subparagraph 2 – point d

Text proposed by the Commission

Amendment

(d) any additional European standards or UNECE Regulations relating to eCall systems.

deleted

Amendment 44

Proposal for a regulation

Article 6 – paragraph -1 a (new)

Text proposed by the Commission

Amendment

-1a. This Regulation is without prejudice to Directives 95/46/EC and 2002/58/EC. Any processing of personal data through the 112-based eCall in-vehicle system shall comply with the personal data protection rules provided for in those Directives.

Amendment 45

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

*In accordance with Directive 95/46/EC and Directive 2002/58/EC, manufacturers shall ensure that vehicles equipped with eCall in-vehicle system are not traceable and are not subject to any constant tracking in their **normal** operational status related to the eCall.*

Manufacturers shall ensure that vehicles equipped with **112-based** eCall in-vehicle system are not traceable and are not subject to any constant tracking in their **pre-emergency** operational status related to the eCall.

Amendment 46

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

2. The **minimum set of data** sent by the eCall in-vehicle system shall **include only** the **minimum** information required for the appropriate handling of emergency calls.

Amendment

2. The **MSD** sent by the **112-based** eCall in-vehicle system shall **as a maximum consist of** the information **required by the standard referred to in point 2c of Article 3**. **The MSD shall not be processed for longer than necessary for the purpose for which they have been processed, and shall not be stored for longer than is required for the appropriate handling of emergency calls. The MSD shall be stored in such a way as to make possible its full deletion.**

Amendment 47

Proposal for a regulation

Article 6 – paragraph 3 – introductory part

Text proposed by the Commission

3. Manufacturers shall ensure that eCall users are provided with clear and comprehensive information about the processing of data carried out through the eCall in-vehicle system, in particular about:

Amendment

3. Manufacturers shall ensure that eCall users are provided with clear and comprehensive information about **the existence of a free public eCall system, based on 112, and** the processing of data carried out through the **112-based** eCall in-vehicle system, in particular about:

Amendment 48

Proposal for a regulation

Article 6 – paragraph 3 – point d

Text proposed by the Commission

(d) the purpose of the eCall processing;

Amendment

(d) the **specific** purpose of the eCall processing **which shall be limited to the emergency situations referred to in the first subparagraph of Article 5(2);**

Amendment 49

Proposal for a regulation

Article 6 – paragraph 3 – point f

Text proposed by the Commission

Amendment

(f) the time limit for the retention of data in the in-vehicle system;

(f) the time limit for the retention of data in the **112-based eCall** in-vehicle system;

Amendment 50

Proposal for a regulation

Article 6 – paragraph 3 – point g

Text proposed by the Commission

Amendment

(g) the fact that there is no **constant** tracking of the vehicle;

(g) the fact that there is no tracking of the vehicle **beyond the collection of the minimum amount of data necessary for the 112-based eCall in-vehicle system to determine and transmit the location and the direction of travel of the vehicle when reporting an incident, as well as the fact that any tracking data are only stored on the device for as long as strictly necessary for that purpose;**

Amendment 51

Proposal for a regulation

Article 6 – paragraph 3 – point h a (new)

Text proposed by the Commission

Amendment

(ha) the fact that data gathered by the PSAPs through the 112-based eCall in-vehicle system must not be transferred to third parties without active prior consent from the data subject;

Amendment 52

Proposal for a regulation

Article 6 – paragraph 3 – point i

Text proposed by the Commission

Amendment

(i) any necessary additional information regarding **the** processing of personal data in relation to the provision of a private eCall service and/or other added value services.

(i) any necessary additional information regarding **traceability, tracking and** processing of personal data in relation to the provision of a private eCall service and/or other added value services, **which shall be subject to explicit consent by the**

user and in compliance with Directive 95/46/EC. Particular account shall be taken of the fact that differences may exist between the data processing carried out through the 112-based eCall in-vehicle system and the private eCall systems or other added value services.

Amendment 53

Proposal for a regulation

Article 6 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Manufacturers shall provide the information set out in paragraph 3 as part of the technical documentation handed over together with vehicle.

Amendment 54

Proposal for a regulation

Article 6 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. In order to avoid confusion as to the purposes pursued and the added value of the processing, the information referred to in paragraph 3 shall be provided to the user separately for the 112-based eCall in-vehicle system and other eCall Systems prior to the use of the system.

Amendment 55

Proposal for a regulation

Article 6 – paragraph 3 c (new)

Text proposed by the Commission

Amendment

3c. Manufactures shall ensure that the 112-based eCall in-vehicle system and another installed emergency call system and a system providing added-value services are designed in such a way that no exchange of personal data between them is possible. The non-use of another system or an added-value service or the

refusal of the data subject to give consent to the processing of his or her personal data for a private service shall not create any adverse effects on the use of the 112-based eCall in-vehicle system and/or the eCall user.

Amendment 56

Proposal for a regulation Article 6 – paragraph 4

Text proposed by the Commission

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 9 ***which shall define*** further the requirement of the absence of traceability and tracking and the privacy enhancing technologies referred to in paragraph 1 as well as the modalities of the ***private*** data processing and of the user information referred to in paragraph 3.

Amendment

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 9, ***defining*** further the requirement of the absence of traceability and tracking and the privacy enhancing technologies referred to in paragraph 1 ***with respect to eCall, in particular the security measures that providers of eCall services are to adopt in order to ensure lawful data processing and prevent unauthorised access, disclosure, alteration or loss of personal data processed***, as well as the modalities of the ***personal*** data processing and of the user information referred to in paragraph 3.

Amendment 57

Proposal for a regulation Article 7

Text proposed by the Commission

With effect from ***1 October 2015***, national authorities shall only grant EC type-approval in respect of the eCall in-vehicle system to new types of vehicles which comply with this Regulation and the delegated acts adopted pursuant to this Regulation.

Amendment

With effect from ...*, national authorities shall only grant EC type-approval in respect of the ***112-based*** eCall in-vehicle system to new types of vehicles which comply with this Regulation and the delegated acts adopted pursuant to this Regulation.

**** OJ: please insert the date of application of this Regulation.***

Amendment 58

Proposal for a regulation Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7a

Periodic technical inspections

The requirements for periodic technical inspections concerning the 112-based eCall in-vehicle system shall be regulated by Regulation (EU) No ... of the European Parliament and of the Council.*

**OJ: Please insert the number of the Regulation contained in doc. 2012/0184(COD).*

Amendment 59

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission may exempt certain **vehicles or** classes of vehicles of categories M1 and N1 from the obligation to install eCall in-vehicle **systems** set out in Article 4, if following a cost/benefit analysis, carried out or mandated by the Commission, and taking into account all relevant safety aspects, **the application of those systems** proves not to be **appropriate to the vehicle or** class of vehicles concerned.

1. The Commission may exempt certain classes of vehicles of categories M1 and N1 from the obligation to install **112-based** eCall in-vehicle **system** set out in Article 4, if following a cost/benefit analysis **and a technical analysis**, carried out or mandated by the Commission, and taking into account all relevant safety aspects, **the installation of the 112-based eCall in-vehicle system** proves not to be **indispensable for further improving road safety, due to the fact that the** class of vehicles concerned **is designed primarily for off-road use or does not have an appropriate triggering mechanism. Those exemptions shall be limited in number.**

Amendment 60

Proposal for a regulation Article 8 – paragraph 2

Text proposed by the Commission

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 9 setting out the exemptions referred to in paragraph 1. ***Those exemptions shall cover vehicles such as special purpose vehicles and vehicles without airbags and be limited in number.***

Amendment 61

**Proposal for a regulation
Article 9 – paragraph 2**

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Article 5 (7), Article 6(4) and in Article 8(2) shall be conferred on the Commission for ***an indeterminate period of time from [...]******[Publications Office, please insert the exact date of entry into force]***.

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 9 setting out the exemptions referred to in paragraph 1.

Amendment

2. The power to adopt delegated acts referred to in Article 5 (7), Article 6(4) and in Article 8(2) shall be conferred on the Commission for ***a period of five years from ...****. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

**** OJ: please insert the date of entry into force of this Regulation.***

Amendment 62

**Proposal for a regulation
Article 9 – paragraph 5**

Text proposed by the Commission

5. A delegated act adopted pursuant to Article 5(7), Article 6(4) and Article 8(2), shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of ***two*** months of notification of that act to

Amendment

5. A delegated act adopted pursuant to Article 5(7), Article 6(4) and Article 8(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of ***three*** months of notification of that act

the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Amendment 63

Proposal for a regulation Article 10 – paragraph 1

Text proposed by the Commission

1. Member States shall lay down the rules on penalties applicable to non-compliance by manufacturers with the provisions of this Regulation and shall take all measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. **Members** States shall notify those provisions to the Commission, and shall notify it without delay of any subsequent amendment affecting them.

Amendment

1. Member States shall lay down the rules on penalties applicable to non-compliance by manufacturers with the provisions of this Regulation and ***the corresponding delegated acts and*** shall take all measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive, ***in particular where Article 6 of this Regulation is not complied with.*** Member States shall notify those provisions to the Commission, and shall notify it without delay of any subsequent amendment affecting them.

Amendment 64

Proposal for a regulation Article 10 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) breaching provisions contained in Article 6.

Amendment 65

Proposal for a regulation Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10a

Reporting and review

1. The Commission shall report to the European Parliament and to the Council regarding the readiness of the telecommunications and PSAP infrastructure required for eCall in Member States. If it is clear from that report that the eCall infrastructure will not be operational before the date referred to in Article 12, the Commission shall take appropriate action.

2. By 1 October 2018, the Commission shall prepare an evaluation report to be presented to the European Parliament and to the Council on the achievements of the 112-based eCall in-vehicle system, including its penetration rate. The Commission shall investigate whether the scope of the Regulation should be extended to other categories of vehicles, such as powered two-wheelers, heavy goods vehicles, busses and coaches, and agricultural tractors. If appropriate, the Commission shall present a legislative proposal to that effect.

3. As soon as possible and in any event not later than by..., the Commission shall report to the European Parliament and to the Council, following a broad consultation with all stakeholders, including vehicle manufacturers and independent operators, and an impact assessment, on the technical requirements for an interoperable, standardised, secure and open-access platform. The Commission shall accompany that report, if appropriate, with a legislative proposal to that effect. The 112-based eCall in-vehicle system shall be based on the standards for that platform as soon as they become available.*

**OJ: please insert the date: one year after the entry into force of this Regulation.*

Amendment 66

Proposal for a regulation

Article 12 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Article 5(7), Article 6(4), Article 8(2) and Articles 9 and 10a shall apply from ...*.

*** OJ: please insert the date of entry into force of this Regulation.**

Amendment 67

Proposal for a regulation Article 12 – paragraph 2

Text proposed by the Commission

Amendment

It shall apply from 1 October 2015.

Articles other than those referred to in paragraph 1a shall apply as from 1 October 2015.

Amendment 68

Proposal for a regulation Annex – point 6

Directive 2007/46/EC

Annex XI – appendix 1 – item 71

Text proposed by the Commission

(6) In Appendix 1 to Annex XI, the following item 71. is added to the table:

<i>Item</i>	<i>Subject</i>	<i>Regulatory act reference</i>	<i>$M_1 \leq 2\,500$ (l) kg</i>	<i>$M_1 > 2\,500$ (l) kg</i>	<i>M_2</i>	<i>M_3</i>
71.	eCall system	Regulation (EU) No.....	A	A	N/A	N/A

Amendment

deleted

(Alignment with Amendments to Recital 12 and Article 8)

Insurance mediation *I**

Amendments adopted by the European Parliament on 26 February 2014 on the proposal for a directive of the European Parliament and of the Council on the insurance mediation (recast) (COM(2012)0360 – C7-0180/2012 – 2012/0175(COD))¹

(Ordinary legislative procedure – recast)

[Amendment No 1, unless otherwise indicated]

AMENDMENTS BY THE EUROPEAN PARLIAMENT*

to the Commission proposal

**DIRECTIVE 2014/.../EU
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on insurance mediation
(recast)**

(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* 53(1) and *Article* 62 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national *parliaments*,

Having regard to the opinion of the European Economic and Social Committee,

Acting in accordance with the ordinary legislative procedure,

Whereas:

¹ The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0085/2014).

* Amendments: new or amended text is highlighted in bold italics; deletions are indicated by the symbol ***■*** .

- (1) Amendments are to be made to Directive 2002/92/EC of the European Parliament and the Council¹. ***Thus it is proposed that the*** Directive be recast.
- (2) Since the main objective and subject-matter of this proposal is to harmonise national provisions concerning the mentioned areas, the proposal should be based on Article 53(1) and *Article* 62 TFEU. The form of a Directive is appropriate in order to enable the implementing provisions in the areas covered by this Directive, when necessary, to be adjusted to any existing specificities of the particular market and legal system in each Member State. This Directive should also aim at coordinating national rules concerning the access to the activity of insurance and reinsurance mediation, and is therefore based on Article 53(1) TFEU. In addition, since this is a sector offering services across the Union, this Directive is also based on Article 62 TFEU.
- (3) Insurance and reinsurance intermediaries play a central role in the distribution of insurance and reinsurance products in the Union.
- (4) Various types of persons or institutions, such as agents, brokers and 'bancassurance' operators, insurance undertakings, travel agents and car rental companies can distribute insurance products.
- (4a) ***In order to guarantee that the same level of protection applies and that the consumer can benefit from comparable standards it is essential that this Directive promotes a level playing field and competition on equal terms between intermediaries whether they are tied to an insurance undertaking or not. Consumers benefit if insurance products are mediated through a variety of channels and intermediaries with different forms of cooperation with insurance undertakings, provided that those channels and intermediaries have to apply the same rules on consumer protection. It is important that those aspects are taken into account by the Member States in the implementation of this Directive.***
- (5) The application of Directive 2002/92/EC has shown that a number of provisions require further precision with a view to facilitating the exercise of insurance and reinsurance mediation and that the protection of consumers requires an extension of the scope of that Directive to all sales of insurance products ***as a main professional activity***, whether by insurance intermediaries or insurance undertakings. In respect of their sales, after-sales and claims processes insurance undertakings which sell directly insurance products, should be brought into the scope of the new Directive on a similar basis as insurance agents and brokers.
- (8) There are still substantial differences between national provisions which create barriers to the taking-up and pursuit of the activities of insurance and reinsurance intermediaries in the internal market. ***There is a need to further strengthen the internal market and create a true European internal market for life and non-life insurance products and services.***
- (9) Current and recent financial turbulence has underlined the importance of ensuring effective consumer protection across all financial sectors. It is appropriate therefore to

¹ Directive 2002/92/EC of the European Parliament and the Council of 9 December 2002 on insurance mediation (OJ L 9, 15.1.2003, p. 3).

strengthen the confidence of customers and to make regulatory treatment of the distribution of insurance products more uniform in order to ensure an adequate level of customer protection across the Union. ***The level of consumer protection should be raised in relation to Directive 2002/92/EC in order to reduce the need for varying national measures. It is important to take into consideration the specific nature of insurance contracts in comparison to investment products regulated under Directive 2014/.../EU of the European Parliament and of the Council [MiFID]¹. The distribution of insurance contracts, including so called insurance investment products should therefore be regulated under this Directive and be aligned with Directive 2014/.../EU [MiFID]. The minimum standards need to be raised with regard to distribution rules and the creation of a level playing field applicable to all packaged insurance investment products.*** Measures to protect customers should be ***higher for 'non professional' than for 'professional' customers.***

- (10) This Directive should apply to persons whose activity consists of providing insurance or reinsurance mediation services to third parties for remuneration, which may be pecuniary or take some other form of agreed economic benefit tied to performance.
- (11) This Directive should apply to persons whose activity consists of the provision of information on one or more contracts of insurance or reinsurance in response to criteria selected by the customer whether via a website or other means, or the provision of a ranking of insurance or reinsurance products or a discount on the price of a contract, when the customer is able to directly conclude an insurance contract at the end of the process; it should not apply to mere introducing activities consisting of the provision of data and information on potential policyholders to insurance or reinsurance intermediaries or undertakings or of information about insurance or reinsurance products or an insurance or reinsurance intermediary or undertaking to potential policyholders.
- (12) This Directive should not apply to persons with another professional activity, such as tax experts or accountants, who provide advice on insurance cover on an incidental basis in the course of that other professional activity, neither should it apply to the mere provision of information of a general nature on insurance products, provided that the purpose of that activity is not to help the customer conclude or fulfil an insurance or reinsurance contract. ***It should not apply to the professional management of claims on behalf of an insurance or reinsurance undertaking, nor to the loss adjusting and expert appraisal of claims.***
- (13) This Directive should not apply to persons practising insurance mediation as an ancillary activity under certain restrictions regarding the policy, in particular the knowledge required to sell it, the risks covered and the amount of premium.
- (14) This Directive defines 'tied insurance intermediary' to take account of the characteristics of certain Member States' markets and to establish conditions applicable to such intermediaries.
- (15) Insurance and reinsurance intermediaries who are natural persons should be registered with the competent authority of the Member State where they have their residence; those which are legal persons should be registered with the competent authority of the Member State where they have their registered office (or, if under their national law they have no

¹ ***Directive 2014/.../EU of the European Parliament and of the Council on markets in financial instruments repealing Directive 2004/39/EC (OJ ...)***

registered office, their head office), provided that they meet strict professional requirements in relation to their ability, good reputation, professional indemnity cover and financial capacity. Insurance intermediaries already registered in Member States shall not be required to register again under this Directive.

- (16) Insurance and reinsurance intermediaries should be able to avail themselves of the freedom of establishment and the freedom to provide services which are enshrined in the *TFEU*. Accordingly, registration with or a declaration to their home Member State should allow insurance and reinsurance intermediaries to operate in other Member States in accordance with the principles of freedom of establishment and freedom to provide services, provided that an appropriate notification procedure has been followed between the competent authorities.

■

- (18) In order to enhance transparency and facilitate cross-border trade, *the European Insurance and Occupational Pensions Authority ('EIOPA'), established by Regulation (EU) No 1094/2010 of the European Parliament and of Council¹* should establish, publish and keep up to date a single electronic database containing a record of each insurance and reinsurance intermediary which has notified an intention to exercise its freedom of establishment or to provide services. Member States should provide relevant information to EIOPA promptly to enable it to do this. This database should show a hyperlink to each relevant competent authority in each Member State. Each competent authority of each Member State should show on its website a hyperlink to this database.
- (19) The relative rights and responsibilities of home and host Member States in respect of the supervision of insurance and reinsurance intermediaries registered by them or carrying on insurance or reinsurance mediation activities within their territory in exercise of the rights of freedom of establishment or freedom to provide services, should be clearly established.

■

- (21) The inability of insurance intermediaries to operate freely throughout the Union hinders the proper functioning of the single market in insurance. ***This Directive is an important step towards an increased level of consumer protection and market integration within the internal market.***
- (21a) An insurance or reinsurance intermediary carries on insurance mediation activities under the terms of freedom to provide services if he or she performs insurance or reinsurance mediation activities for a policy-holder or potential policy-holder resident or established in a Member State other than the Member State of origin of the intermediary, and each risk to be insured is located in a Member State other than the Member State of origin of the intermediary. An insurance or reinsurance intermediary carries on insurance or reinsurance mediation activities under the terms of freedom of establishment if it maintains a permanent presence in a Member State other than its Member State of origin.***

¹ Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

- (22) It is important to guarantee a high level of professionalism and competence among insurance and reinsurance intermediaries and the employees of direct insurers who are involved in activities preparatory to, during and after the sales of insurance policies. Therefore, the professional knowledge of an intermediary **and** of the employees of direct insurers needs to match the level of complexity of these activities. Continuing education should be ensured. ***Issues of form, substance and required documentary evidence should be regulated by the Member States. Professional training organisations linked to the sector or belonging to an association should receive certification in that context.***
- (22a) ***For employees of an intermediary who advise on or sell insurance investment products to retail customers, Member States should ensure that they possess an appropriate level of knowledge and competence in relation to the products offered. This is particularly important given the increased complexity and the continuous innovation in the design of insurance investment products. Buying an insurance investment product implies a risk and investors should be able to rely on the information and quality of assessments provided. It is furthermore necessary that employees are given adequate time and resources to be able to provide all relevant information to clients about the products that they provide.***
- (23) The coordination of national provisions on professional requirements and registration of persons taking up and pursuing the activity of insurance or reinsurance mediation can contribute both to the completion of the single market for financial services and to the enhancement of customer protection in this field.
- (24) In order to enhance cross border trade, principles regulating mutual recognition of intermediaries' knowledge and abilities should be introduced.
- (25) A national qualification accredited to level 3 or above under the European Qualification Framework established under the Recommendation of the European Parliament and Council of 23 April 2008 on the establishment of the European Qualifications Framework for lifelong learning should be accepted by a host member state as demonstrating that an insurance or reinsurance intermediary meets the requirements of knowledge and ability which are a condition of registration in accordance with this Directive. This framework helps Member States, education institutions, employers and individuals compare qualifications across the Union's diverse education and training systems. This tool is essential for developing a employment market throughout the Union. This framework is not designed to replace national qualifications systems but to supplement the actions of the Member States by facilitating cooperation between them.
- (26) Despite the existing single passport systems for insurers and intermediaries, the European insurance market remains very fragmented. In order to facilitate cross-border business and enhance transparency for consumers, Member States shall ensure publication of the general good rules applicable in their territories, and a single electronic register and information on all Member States' general good rules applicable to insurance and reinsurance mediation should be made publicly available.
- (27) Cooperation and exchange of information between the competent authorities are essential in order to protect customers and ensure the soundness of insurance and reinsurance business in the single market.
- (28) There is a need for appropriate and effective out-of-court complaint and redress

procedures in the Member States in order to settle disputes between insurance intermediaries or undertakings and customers, using, where appropriate, existing procedures. Effective out-of-court complaint and redress procedures should be available to deal with disputes concerning rights and obligations under this Directive between insurance undertakings or persons selling or offering insurance products and customers.

In the case of alternative dispute resolution (ADR), the provisions of Directive 2013/11/EU of the European Parliament and of the Council¹ should be binding also for the purposes of this Directive. In order to enhance the effectiveness of out-of-court resolution of disputes procedures dealing with complaints submitted by customers, this Directive should provide that insurance undertakings or persons selling or offering insurance products have to participate in dispute resolution procedures, ***and the decisions which upon explicit request may be binding for the intermediary and the customer,*** instituted against themselves by customers and concerning rights and obligations established under this Directive. Such out-of-court resolution of disputes procedures would aim to achieve a quicker and less expensive settlement of disputes between insurance undertakings or persons selling or offering insurance products and customers and lightening of the burden on the court system. ■

Without prejudice to the right of customers to bring their action before the courts, Member States should ensure that ADR entities dealing with disputes referred to under this Directive cooperate in resolving cross-border disputes. Member States should encourage ADR entities dealing with such disputes to become part of *the Financial Services Complaints Network (FIN-NET)*.

- (29) The expanding range of activities that many insurance intermediaries and undertakings carry on simultaneously has increased potential for conflicts of interest between those different activities and the interests of their customer. It is therefore necessary that Member States ■ provide ■ rules to ensure ***the interest*** of the customer ***are addressed***.
- (30) Consumers should be provided in advance with clear information about the status of the persons who sell the insurance product. ***It would be worth considering introducing*** a mandatory status disclosure for European insurance intermediaries and insurance undertakings. This information should be given to the consumer at the pre-contractual stage. Its role is to show the relationship between the insurance undertaking and the intermediary, where applicable.
- (31) In order to mitigate conflicts of interest between the seller and the buyer of an insurance product, it is necessary to ensure sufficient disclosure of remuneration of insurance distributors. ■ The intermediary and the employee of the insurance intermediary or the insurance undertaking should be obliged to inform the customer, ***on request***, about ***the nature and source of its remuneration*** in advance of the sale ***and, free of charge***.
- (32) In order to provide a customer with comparable information on the insurance mediation services provided regardless of whether the customer purchases through an intermediary, or directly from an insurance undertaking, and to avoid the distortion of competition by encouraging insurance undertakings to sell direct to customers rather than via intermediaries in order to avoid information requirements, insurance undertakings should

¹ ***Directive 2013/11/EU of the European Parliament and of the Council on alternative dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (OJ L 165, 18.6.2013, p. 63).***

also be required to provide information about remuneration to customers with whom they deal directly in the provision of insurance mediation services about the remuneration they receive for the sale of insurance products. (32a) *Where the cost of fees and inducements cannot be ascertained prior to the provision of the advice, then the manner of calculation must be disclosed in a comprehensive, accurate and understandable manner in the key services documents with the total aggregate cost and its impact on returns of the advice being disclosed to the client as soon as practically possible thereafter. Where investment advice is provided on an ongoing basis, disclosure as to the cost of investment advice, including inducements, must be provided on a periodic basis and at least annually. The periodic report shall disclose all inducements paid or received in the preceding period.*

(32b) *Any person selling insurance products, who is not the product manufacturer, should provide the retail investor in a separate key service document with details of their costs and services in accordance with this Directive and Directive 2014/.../EU [MiFID] as well as additional relevant information needed for the retail investor to assess the appropriateness of the of the insurance product for their needs which cannot be provided by the investment product manufacturer.*

(32c) *There is a benefit to consumers if insurance products are sold through various channels and intermediaries with different forms of cooperation with insurance undertakings provided they have to apply the same rules on consumer protection and transparency.*

(33) As the current proposal aims to enhance consumer protection, some of its provisions are only applicable in "business to consumer" (B2C) relationships, especially those which regulate conduct of business rules of insurance intermediaries or of other sellers of insurance products.

(34a) *Member States should require that remuneration policies of insurance intermediaries and insurance undertakings in relation to their employees or representatives do not impair the ability to act in the best interests of customers. For employees who advise on or sell insurance investment products to customers, Member States should require that insurance intermediaries and insurance undertakings ensure that their remuneration by the firm does not affect employees' impartiality in making a suitable recommendation or appropriate sale or presenting information in a form that is fair, clear and not misleading. Remuneration in such situations should not be solely dependent on sales targets or the profit to the firm from a specific product.*

(35) It is **important** for the customer to know whether he/she is dealing with an intermediary who is advising the customer on products from a broad range of insurance undertakings or on products provided by a specific number of insurance undertakings.

(36) Due to the increasing dependence of consumers on personal recommendations, it is appropriate to include a definition of advice. *The quality of advice is crucial and any advice should reflect the personal characteristics of the customer.* Before advice is provided, the insurance intermediary or undertaking should assess the customer's needs, **expectations** and its financial situation. If the intermediary declares that it is giving advice on products from a broad range of insurance undertakings, it should carry out a fair and

wide-ranging analysis of a sufficiently large number of insurance products available on the market. In addition, all insurance intermediaries and insurance undertakings should explain the reasons underpinning their advice and recommend suitable insurance products according to the customer's preferences, needs, financial situation and personal circumstances.

- (37) Prior to the conclusion of a contract, including in the case of non-advised sales, the customer should be given the relevant information about the insurance product to allow the customer to make an informed decision. The insurance intermediary should explain to the customer the key features of the insurance products it sells ***and therefore its staff should be given appropriate resources and time to do so.***
- (38) Uniform rules should be laid down in order to ***facilitate the*** choice of the medium in which ***mandatory*** information is provided to the customer allowing for use of electronic communications where it is appropriate having regard to the circumstances of the transaction. However, the customer should be given the option to receive it on paper. In the interest of consumer access to information, all pre-contractual information ***should*** be ***accessible*** free of charge.
- (39) There is less of a need to require that such information be disclosed when the customer is seeking reinsurance or insurance cover for commercial and industrial risks, or is a professional customer ■
- (40) This Directive should specify the minimum obligations which insurance undertakings and insurance intermediaries should have in providing information to customers. A Member State should be able to in this area maintain or adopt more stringent provisions which may be imposed on insurance intermediaries and insurance undertakings independently of the provisions of their home Member State where they are pursuing insurance mediation activities on its territory provided that any such more stringent provisions comply with Union law, including Directive 2000/31/EC of the European Parliament and of the Council¹. A Member State which proposes to apply and applies provisions regulating insurance intermediaries and the sale of insurance products in addition to those set out in this Directive should ensure that the administrative burden stemming from these provisions ***remains limited.***
- (41) Cross-selling practices are a common ***and appropriate*** strategy for retail financial service providers throughout the Union. ■
- (41a) When insurance is offered together with another service or product as part of a package or as a condition for the same agreement or package, it is subject to Directive 2005/29/EC of the European Parliament and of the Council². This Directive also***

¹ 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') (OJ L 178, 17.7.2000, p. 1).

² Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).

provides a set of safeguards for customers purchasing insurance as part of a package. Member States may require national competent authorities to adopt or maintain additional measures to address cross selling practices that are detrimental to consumers.

- (42) Contracts of insurance that involve investments are often made available to customers as potential alternatives or substitutes to investment products subject to Directive 2014/.../EU [MiFID]. To deliver consistent investor protection and avoid the risk of regulatory arbitrage, it is important that retail investment products (insurance investment products as defined in the Regulation on key information documents for investment products) are subject to the same conduct of business standards: these include provision of appropriate information, requirements for advice to be suitable and restrictions on inducements, as well as requirements to manage conflicts of interest **further** restrictions on ■ remuneration. The *European Supervisory Authority (European Securities and Markets Authority) ('ESMA'), established by Regulation (EU) No 1095/2010 of the European Parliament and of the Council¹* and EIOPA should work together to achieve as much consistency as possible in the conduct of business standards for retail investment products that are subject to either Directive 2014/.../EU [MiFID] or to this Directive through guidelines. ***The specificities of non-life insurance products should, however, be taken into account in those guidelines. Also, in line with the analogous principle in Directive 2014/.../EU [MIFID], an analogous regime for insurance undertakings, when implementing this Directive at national level, and in the joint committee's guidelines should be considered.*** For insurance investment products, ***there should be enhanced conduct of business standards that replace*** the standards of this Directive which are applicable to ***general*** insurance contracts ■. Accordingly, persons carrying out insurance mediation in relation to insurance investment products should comply with the ■ enhanced standards applicable to ***such*** products.

(42a) The European Parliament will seek to ensure the alignment of this Directive with Directive 2014/.../EU [MIFID II] during its negotiations with the Council. [Am. 4]

(42b) The European Parliament will seek to ensure the alignment of this Directive with Directive 2014/.../EU [MIFID II] in its negotiations with the Council. [Am. 5]

- (42c) This Directive lays down rules concerning the taking-up and pursuit of the activities of insurance and reinsurance mediation by natural and legal persons which are established in a Member State or which wish to be established there. Provisions of other Union instruments which depart from or supplement those rules should not apply to the activities of insurance and reinsurance mediation.***(43) In order to ensure compliance with the provisions of this Directive by insurance undertakings and persons who pursue insurance mediation, and to ensure that they are subject to similar treatment across the Union, Member States should be required to provide for administrative *penalties* and *other* measures which are effective, proportionate and dissuasive. A review of existing powers and their practical application has been carried out with the aim of promoting convergence of *penalties* and *other* measures in the Commission

¹ Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

Communication of 8 December 2010 on reinforcing *penalty* regimes in the financial sector. Therefore, administrative *penalties* and *other* measures laid down by Member States should satisfy certain essential requirements in relation to addressees, criteria to be taken into account when applying a *penalty* or *other* measure, publication **and** key powers **to impose penalties**.

- (44) In particular, the competent authorities should be empowered to impose pecuniary *penalties* which are sufficiently high to offset the benefits that can be expected and to be dissuasive even for larger institutions and their managers.
- (45) In order to ensure a consistent application of *penalties* across Member States, when determining the type of administrative *penalties* or *other* measures and the level of administrative pecuniary *penalties*, Member States should be required to ensure that the competent authorities take into account all relevant circumstances. ***Member States are however not obliged to provide for administrative penalties when national law provides for penalties within the criminal justice system.***
- (46) In order to strengthen the dissuasive effect on the public at large and to inform about breaches of rules which may be detrimental to customer protection, *penalties* and measures imposed should be published, except in certain well-defined circumstances. In order to ensure compliance with the principle of proportionality, *penalties* and *other* measures imposed should be published on an anonymous basis where publication would cause a disproportionate damage to the parties involved.
- (47) In order to detect potential breaches, the competent authorities should have the necessary investigatory powers, and should establish effective mechanisms to encourage reporting of potential or actual breaches ***which provide appropriate protection for those who denounce such breaches. However this Directive does not imply that Member States have to give administrative authorities the power to conduct criminal investigations.***
- (48) This Directive should refer to both administrative *penalties* and *other* measures irrespective of their qualification as a *penalty* or *other* a measure under national law.
- (49) This Directive should be without prejudice to any provisions in the laws of Member States in respect of criminal offences.
- (49a) Whistleblowers bring new information to the attention of competent authorities which assists them in detecting and penalising cases of insider dealing and market manipulation. However, whistleblowing may be deterred for fear of retaliation, or for lack of adequate procedures for reporting breaches. This Directive should therefore ensure that adequate arrangements are in place to encourage whistleblowers to alert competent authorities to possible breaches of this Directive and to protect them from retaliation. Member States should also ensure that whistleblowing schemes they implement include mechanisms that provide appropriate protection of a reported person, particularly with regard the right to the protection of personal data and procedures to ensure the rights of the defence of the reported person and the right to be heard before the adoption of a decision concerning that person as well as the right to seek effective remedy before a court against a decision concerning that person.***
- (50) In order to attain the objectives set out in this Directive, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in

respect of ■ management of conflicts of interest, conduct of business obligations in relation to insurance packaged retail investment products and procedures and forms for submitting information in relation to *penalties*. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council

- (51) Technical standards in financial services should ensure consistent harmonisation and adequate protection of consumers across the Union. As *EIOPA* is a body with highly specialised expertise, ***but limited capacities, it could be entrusted solely*** with the elaboration of draft *proposals* which do not *necessitate* policy choices, for submission to the ***European Parliament and to the*** Commission.
- (52) By means of delegated acts pursuant to Articles 290 and 291 of the *TFEU* and in accordance with Articles 10 to 15 of Regulation (EU) No 1094/2010 [...], the Commission should adopt delegated acts as set out in ***this Directive*** regarding management of conflicts of interest, regarding conduct of business obligations in relation to insurance packaged retail investment products as well as implementing technical standards *and* regarding procedures and forms for submitting information in relation to *penalties*. These delegated acts and implementing technical standards should be developed in draft by EIOPA.
- (53) Directive 95/46 of the European Parliament and of the Council [...] ¹ and Regulation (EU) No 45/2001 of the European Parliament and of the Council [...] ² shall govern the processing of personal data carried out by EIOPA within the framework of this Regulation, under the supervision of the European Data Protection Supervisor.
- (54) This Directive respects the fundamental rights and observes the principles recognised in the Charter of Fundamental Rights of the European Union, as enshrined in the Treaty.
- (55) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011 ³, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (55a) The supervisory authorities of the Member States should have at their disposal all means necessary to ensure the orderly pursuit of business by insurance intermediaries and reinsurance undertakings throughout the Union, whether pursued in accordance with the right of establishment or the freedom to provide services. In order to ensure***

¹ Directive 95/46 of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States (OJ L 281, 23.11.1995, p. 31).

² Regulation (EU) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

³ OJ C 369, 17.12.2011, p. 14.

the effectiveness of the supervision all actions taken by the supervisory authorities should be proportionate to the nature, scale and complexity of the risks inherent in the business of an insurance or reinsurance undertaking, regardless of the importance of the undertaking concerned for the overall financial stability of the market.

(55b) This Directive should not be too burdensome for small and medium-sized insurance undertakings. One of the tools by which to achieve that objective is the proper application of the proportionality principle. That principle should apply both to the requirements imposed on the insurance and reinsurance undertakings and to the exercise of supervisory powers.

(56) A review of this Directive should be carried out **three** years after the date on which this Directive enters into force in order to take account of market developments as well as developments in other areas of Union law or Member States experiences in implementation of Union law, in particular with regard to products covered by Directive 2003/41/EC of the European Parliament and of the Council¹.

(57) Directive 2002/92/EC should accordingly be repealed.

(58) The obligation to transpose this Directive into national law should be confined to those provisions which represent an amendment of the substance of Directive 2002/92/EC. The obligation to transpose the provisions which are unchanged arises under Directive 2002/92/EC.

(59) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of Directive 2002/92/EC,


HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Scope

1. This Directive lays down rules concerning the taking-up and pursuit of the activities of insurance and reinsurance mediation,  by natural and legal persons which are established in a Member State or which wish to be established there.
2. This Directive shall not apply to persons providing mediation services for insurance contracts if all the following conditions are met:

¹ Directive 2003/41/EC of the European Parliament and of the Council of 3 June 2003 on the activities and supervision of institutions for occupational retirement provision (OJ L 235, 23.9.2003).

- (a) the insurance contract only requires knowledge of the insurance cover that is provided;
 - (b) the insurance contract is not a life assurance contract;
 - (c) the insurance contract does not cover any liability risks;
 - (d) the principal professional activity of the person is other than insurance mediation.
 - (e) the insurance is complementary to ***the supply of goods*** by any provider, where such insurance covers the risk of breakdown, loss of or damage to the goods supplied by that provider;
 - (f) the amount of the annual premium for the insurance contract, when pro-rated to produce an annual amount, does not exceed EUR 600.
3. This Directive shall not apply to insurance and reinsurance mediation services provided in relation to risks and commitments located outside the Union.

This Directive shall not affect a Member State's law in respect of insurance and reinsurance mediation business pursued by insurance and reinsurance undertakings or intermediaries established in a third country and operating on its territory under the principle of freedom to provide services, provided that equal treatment is guaranteed to all persons carrying out or authorised to carry out insurance and reinsurance mediation activities on that market.

This Directive shall not regulate insurance or reinsurance mediation activities carried out in third countries.

Member States shall inform the Commission of any general difficulties which their insurance intermediaries encounter in establishing themselves or carrying out insurance mediation activities in any third country.

- 3a. ***This Directive shall ensure that the same level of protection applies and that the consumer can benefit from comparable standards. This Directive shall promote a level playing field and competition on equal terms between intermediaries whether or not they are tied to an insurance undertaking. There is a benefit to consumers if insurance products are mediated through various channels and intermediaries with different forms of cooperation with insurance undertakings provided that they have to apply the similar rules on consumer protection. This shall be taken into account by the Member States in the implementation of this Directive.***

Article 2 Definitions

1. For the purposes of this Directive:

- (1) ‘insurance undertaking’ means ***an insurance undertaking as defined in Article***

13(1) of Directive 2009/138/EC of the European Parliament and of the Council¹;

- (2) 'reinsurance undertaking' means a **reinsurance** undertaking *as defined in Article 13(4) of Directive 2009/138/*;
- (3) 'insurance mediation' means the activities of advising on, proposing, or carrying out other work preparatory to the conclusion of insurance, concluding such contracts or assisting in the administration and performance of such contracts. ***The activities of advising on, proposing or concluding contracts of insurance*** shall be considered to be insurance mediation also if carried on by an **employee of an** insurance undertaking ***in direct contact with the insured***, without the intervention of an insurance intermediary.

Provision of information concerning one or more insurance contracts in accordance with criteria selected by customers through a website or other media and the compilation of an insurance product ranking list, including price and product comparison, or the discounting of premiums, when at the end of the process the customer is able directly to conclude an insurance contract using a website or other media shall be considered to be insurance mediation.

Neither of the following activities shall be considered to be insurance mediation for the purposes of this Directive:

- (a) the provision of information on an incidental basis to a customer in the context of another professional activity, if the provider does not take any additional steps to assist the customer in concluding or performing an insurance contract;
 - (b) the mere provision of data and information on potential policyholders to insurance intermediaries or insurance undertakings or of information about insurance products or an insurance intermediary or insurance undertaking to potential policyholders.
- (4) **'insurance-based investment product'** means ***an insurance product which offers a maturity or surrender value and where that maturity or surrender value is wholly or partially exposed, directly or indirectly, to market fluctuations, not including:***
- (a) ***non-life insurance products as listed in Annex I of Directive 2009/138/EC (Classes of Non-life Insurance);***
 - (b) ***life insurance contracts where the benefits under the contract are payable only on death or in respect of incapacity due to injury, sickness or disability;***
 - (c) ***pension products which, under national law, are recognised as having the primary purpose of providing the investor with an income in retirement, and which entitles the investor to certain benefits;***

¹ ***Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009).***

- (d) *occupational pension schemes that are officially recognised and that fall within the scope of Directive 2003/41/EC or Directive 2009/138/EC;*
 - (e) *individual pension products for which a financial contribution from the employer is required by national law and where the employer or the employee has no choice as to the pension product or provider;*
- (5) 'insurance intermediary' means a natural or legal person, other than an insurance undertaking *or its employees*, who, for remuneration, takes up or pursues reinsurance mediation;
- (6) 'reinsurance mediation' means the activities of advising on, proposing, or carrying out other work preparatory to the conclusion of contracts of *insurance or* reinsurance, of concluding such contracts or assisting in the administration and performance of such contracts, in particular in the event of a claim, *including when* carried on by a reinsurance undertaking without the intervention of a reinsurance intermediary;

None of the following activities shall be considered to be reinsurance mediation for the purposes of this Directive:

- (a) the provision of information on an incidental basis in the context of another professional activity provided that the purpose of that activity is not to assist the customer in concluding or performing a reinsurance contract;
 - (aa) *the management of claims of a reinsurance undertaking on a professional basis, and loss adjusting and expert appraisal of claims;*
 - (b) the mere provision of data and information on potential policyholders to reinsurance intermediaries or reinsurance undertakings or of information about reinsurance products or a reinsurance intermediary or reinsurance undertaking to potential policyholders.
- (7) 'reinsurance intermediary' means any natural or legal person, other than a reinsurance undertaking *or its employees*, who, for remuneration, takes up or pursues reinsurance mediation;
- (8) 'tied insurance intermediary' means any person who carries on the activity of insurance mediation for and on behalf of one or, *in the case of insurance products not in competition, several* insurance undertakings or insurance intermediaries, *but does not collect premiums or amounts intended for the customer* and who acts under the full responsibility of those insurance undertakings or insurance intermediaries, provided that the insurance intermediaries under whose responsibility the person acts do not themselves act under the responsibility of another insurance undertaking or intermediary;

Any person who carries out the activity of insurance mediation in addition to a principal professional activity shall also be considered to be a tied insurance intermediary acting under the responsibility of one or several insurance undertakings for the products which concern them respectively if the insurance is

complementary to the goods supplied or to the services provided within the framework of that principal professional activity;

- (9) 'advice' means the provision of a ***personal*** recommendation to a customer, either upon their request or at the initiative of the insurance undertaking or the insurance intermediary;
- (10) 'contingent commission' means ■ remuneration in the form of a commission ■ based on the achievement of ***pre-agreed*** targets ***or thresholds*** relating to the ***volume of*** business placed by the intermediary with ***the*** insurer;
- (11) 'large risks' ***means large risks*** as defined ***in Article 13(27)*** of Directive ***2009/138/EC***;
- (12) 'home Member State' means:
 - (a) where the intermediary is a natural person, the Member State in which his residence is situated ;
 - (b) where the intermediary is a legal person, the Member State in which its registered office is situated or, if under its national law it has no registered office, the Member State in which its head office is situated;
- (13) 'host Member State' means the Member State in which an insurance or reinsurance intermediary has a permanent presence or establishment or provides services and which is not its home Member State;
- (14) 'durable medium' means a durable medium as defined in Article 2(m) of Directive 2009/65/EC of the European Parliament and of the Council¹;
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- (16) 'close links' means a situation referred to in ***Article 13(7)*** of Directive ***2009/138/EC***;
- (17) 'primary place of business' means the location from where the main business is managed;
- (18) 'remuneration' means any commission, fee, charge or other payment, including an economic benefit ***or a benefit-in-kind*** of any kind, ***and any other incentives*** offered or given in connection with insurance mediation activities;
- (19) 'tying practice' means the offering ***or the selling of an insurance product in a package with other distinct ancillary products or services where the*** insurance product is not made available to the consumer separately;
- (20) 'bundling practice' means the offering ***or the selling of an insurance product*** in a package ***with other distinct ancillary products or services where the insurance*** product is also made available to the consumer separately but not necessarily on the

¹ Directive 2009/65/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (OJ L 302, 17.11.2009).

same terms or conditions as when offered bundled with the ancillary services;(20a)

'product' means an insurance contract covering one or more risks;

(20b) 'retail' means non-professional.

2. ***In order to guarantee that the same level of protection applies and that the consumer can benefit from comparable standards it is essential that this Directive promotes a level playing field and competition on equal terms between intermediaries whether they tied to an insurance undertaking or not. The Member States shall take into account the importance of promoting a level playing field and competition on equal terms in the implementation of this Directive.***

CHAPTER II

REGISTRATION REQUIREMENTS

Article 3

Registration

1. Except as provided in Article 4, insurance and reinsurance intermediaries shall be registered with a competent authority ***as referred to in Article 10(2)***, in their home Member State. Insurance ***and reinsurance*** undertakings registered in Member States under *Council Directive 73/239/EEC*¹, *Directive 2002/83/EC of the European Parliament and of the Council*² and *Directive 2005/68/EC of the European Parliament and of the Council*³ and their employees shall not be required to register again under this Directive.

Without prejudice to the first subparagraph, Member States may stipulate that insurance and reinsurance undertakings and other bodies may cooperate with the competent authorities in registering insurance and reinsurance intermediaries and in the application of the requirements of Article 8 to such intermediaries. In particular, in the case of tied insurance intermediaries, they may be registered by an insurance undertaking by an association of insurance undertakings, or by an insurance or reinsurance intermediary under the supervision of a competent authority.

¹ *First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance (OJ L 228, 16.8.1973, p. 3).*

² *Directive 2002/83/EC of the European Parliament and of the Council of 5 November 2002 concerning life assurance (OJ L 345, 19.2.2002, p. 1).*

³ *Directive 2005/68/EC of the European Parliament and of the Council of 16 November 2005 on reinsurance and amending Council Directives 73/239/EEC, 92/49/EEC as well as Directives 98/78/EC and 2002/83/EC (OJ L 323, 9.12.2005, p. 1).*

Member States may stipulate that, where an insurance or reinsurance intermediary acts under the responsibility of an insurance or reinsurance undertaking or intermediary, the *insurance* intermediary ***shall not be required to provide the competent authority with the information in Article 3(7)(a) and (b) and the insurance*** entity *responsible* shall ***ensure that the insurance intermediary meets the conditions for registration and other provisions*** set out in *this Directive*. Member States may also stipulate that the person or entity which takes responsibility for the intermediary shall register that intermediary.

Member States need not apply the requirement referred to in the first and second subparagraphs to all the natural persons who work in an insurance or reinsurance undertaking or a registered insurance or reinsurance intermediary and who pursue the activity of insurance or reinsurance mediation.

Member States shall ensure the registration of legal persons and shall also specify in the register the names of the natural persons within the management who are responsible for the mediation business.

2. Member States may establish more than one register for insurance and reinsurance intermediaries provided that they lay down the criteria according to which intermediaries are to be registered.

Member States shall establish an online registration system consisting of one single registration form available on an internet website, which should be easily accessible for insurance intermediaries and undertakings, and allowing the form to be completed directly online.

3. Member States shall see to it that a single information point is established allowing quick and easy access to information from these various registers, which shall be compiled electronically and kept constantly updated. This information point shall also provide the identification details of the competent authorities of each Member State referred to in paragraph 1, first subparagraph. The register shall indicate further the country or countries in which the intermediary conducts business under the rules on the freedom of establishment or on the freedom to provide services.
4. EIOPA shall establish, publish on its website and keep up-to-date a single electronic register containing records of insurance and reinsurance intermediaries which have notified their intention to carry on cross-border business in accordance with Chapter IV. Member States shall provide relevant information to EIOPA promptly to enable it to do this. This register shall show a hyperlink to each relevant competent authority in each Member State. That register shall contain links to, and be accessible from, each of the Member States' competent authorities' websites. ***EIOPA shall have right of access to the data stored there. EIOPA and the competent authorities shall have the right to modify this data. Data subjects whose personal details can be stored and exchanged shall be entitled to access and have the right to be appropriately informed.***

EIOPA shall establish a website with hyperlinks to each single information point established by Member States under Article 3(3).

Member States shall ensure that registration of insurance intermediaries, including tied ones, and reinsurance intermediaries is made subject to the fulfilment of the professional requirements laid down in Article 8.

Member States shall also ensure that insurance intermediaries, including tied ones, and reinsurance intermediaries who cease to fulfil these requirements are ***immediately*** removed from the register. The validity of the registration shall be subject to a regular review by the competent authority. If necessary, the home Member State shall inform the host Member State of such removal.

5. Member States shall ensure that the competent authorities do not register an insurance or reinsurance intermediary unless that the intermediary meets the requirements laid down in Article 8, ***or that another intermediary or undertaking will take responsibility for ensuring that the intermediary meets these requirements in accordance with subparagraph 3 of Article 3(1).***

- 5a. ***Registered insurance and reinsurance intermediaries shall be allowed to take up and pursue the activity of insurance and reinsurance mediation in the Union by means of both freedom of establishment and freedom to provide services.***

An insurance intermediary is operating under Freedom to provide services if it intends to supply a policyholder, who is established in a Member State different from the one where the insurance intermediary is established, with an insurance contract relating to a risk situated in a Member States different from the Member State where the insurance intermediary is established.

The competent authorities may provide the insurance and reinsurance intermediaries with a document enabling any interested party by consultation of any of the registers referred to in paragraph 2 to verify that they are duly registered.

That document shall at least provide the information specified in Article 16(a) ***(i) and (iii)*** and (b)***(i) and (iii)***, and, in the case of a legal person, the name(s) of the natural person(s) referred to in the fourth subparagraph of paragraph 1 of this Article.

The Member State shall require the return of the document to the competent authority which issued it when the insurance or reinsurance intermediary concerned ceases to be registered.

6. Member States shall provide that applications by intermediaries for inclusion in the register shall be treated within ***two*** months of the submission of a complete application, and that the applicant shall be notified promptly of the decision.

Member States shall ensure that the competent authorities have in place appropriate measures enabling them to monitor whether insurance and reinsurance intermediaries continue to meet the registration requirements of this Directive at all times.

7. Member States shall ensure that their competent authorities request ***evidence of the following as a condition of registration*** from insurance and reinsurance intermediaries ***other than for tied intermediaries and intermediaries where another insurance entity takes responsibility for ensuring that the intermediary meets these requirements in accordance with subparagraph 3 of Article 3(1).***

- (a) to provide information to their competent authorities of the identities of shareholders or members, whether natural or legal persons, that have a holding in the intermediary that exceeds 10% and the amounts of those holdings;

- (b) to provide information to their competent authorities of the identities of persons who have close links with the insurance or reinsurance intermediary;
- (c) to demonstrate in a satisfactory manner that the holdings or close links do not prevent the effective exercise of the supervisory functions of the competent authority.

Member States shall ensure that their competent authorities require that insurance and reinsurance intermediaries to whom Article 3(7) applies inform them without undue delay where information provided under Article 3(7)(a) and (b) changes.

- 8. Member States shall ensure that the competent authorities refuse registration if the laws, regulations or administrative provisions of a third country governing one or more natural or legal persons with which the insurance or reinsurance intermediary has close links, or difficulties involved in the enforcement of those laws, regulations or administrative provisions, prevent the effective exercise of their supervisory functions.
- 8a. ***Member States may provide that those persons who exercised a mediation activity before 1 January 2014, who were entered in a register and who had a level of training and experience similar to that required by this Directive, shall be automatically entered in the register to be created, once the requirements set down in Article 4(3) and (4) are complied with.***

CHAPTER III

SIMPLIFIED REGISTRATION PROCEDURE – DECLARATION OF ACTIVITIES

Article 4

Declaration procedure for providing ancillary insurance mediation; professional management of claims or loss assessment services

- 1. The registration requirements in Article 3 shall not apply to an insurance intermediary which conducts insurance mediation on an ancillary basis, provided that its activities meet all the following conditions:
 - (a) the principal professional activity of the insurance intermediary is other than insurance mediation;
 - (b) the insurance intermediary only mediates certain insurance products that are complementary to a product or service and clearly identifies them in the declaration;
 - (c) the insurance products concerned do not cover life assurance or liability risks, unless that cover ***complements the product or service which the intermediary provides as his principal professional activity;***
 - (ca) ***the intermediary works under the responsibility of a registered intermediary.***

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3. Any insurance intermediary who is subject to paragraphs 1 and 2 of this Article shall submit to the competent authority of its home Member State a declaration whereby it informs the competent authority of its identity, address and professional activities.
 4. Intermediaries who are subject to paragraphs 1 and 2 of this Article shall be subject to the provisions of Chapters I, III, IV, V, VIII, IX and Articles 15 and 16 of this Directive.
 - 4a. *Member States may apply the registration requirements in Article 3 to insurance intermediaries within the scope of Article 4, if they consider it necessary to do so in the interests of consumer protection.*

CHAPTER IV

FREEDOM TO PROVIDE SERVICES AND FREEDOM OF ESTABLISHMENT

Article 5

Exercise of the freedom to provide services

1. Any insurance or reinsurance intermediary who intends to carry on business within the territory of another Member State for the first time under the freedom to provide services shall communicate the following information to the competent authority of his home Member State .
 - (a) the name, address and any registration number of the intermediary;
 - (b) the Member State or States in which the intermediary intends to operate;
 - (c) the category of intermediary and, if applicable, the name of any insurance or reinsurance undertaking represented;
 - (d) the relevant classes of insurance, if applicable;
 - (e) demonstration of professional knowledge and ability.
2. The competent authority of the home Member State shall, within one month of receiving the information referred to in paragraph 1, forward it to the competent authority of the host Member State, which shall acknowledge the receipt without delay. The home Member State shall inform the insurance or reinsurance intermediary in writing that the information has been received by the host Member State and that the insurance or reinsurance undertaking can commence its business in the host Member State.

When receiving the information referred to in paragraph 1, the host Member State shall accept previous experience in insurance or reinsurance mediation activity, as

demonstrated by proof of registration or declaration in the home Member State, as evidence of the required knowledge and ability.

3. The proof of the previous registration or declaration shall be established by evidence of registration issued or declaration received by the competent authority or body of the home Member State of the applicant, which the latter shall submit in support of his application presented to the host Member State.
 4. In the event of a change in any of the particulars communicated in accordance with paragraph 1, the insurance or reinsurance intermediary shall give written notice of that change to the competent authority of the home Member State at least one month before implementing the change. The competent authority of the host Member State shall also be informed of that change by the competent authority of the home Member State as soon as is practicable and no later than one month from the date of receipt of the information by the competent authority of the home Member State.
- 4a. *A registered insurance or reinsurance intermediary carries on an insurance mediation activity under the 'freedom of services' if:***
- (a) *it carries on insurance or reinsurance mediation with or for a policyholder who resides or is established in a Member State different from the home Member State of the intermediary;***
 - (b) *any risk to be insured is situated in a Member State different from the home Member State of the intermediary;***
 - (c) *it complies with paragraphs 1 and 4.***

Article 6

Exercise of the freedom of establishment

1. Member States shall require any insurance or reinsurance intermediary who intends to exercise his freedom of establishment to establish a branch within the territory of another Member State first to notify the competent authority of his home Member State and to provide it with the following information:
 - (a) the name, address and registration number, where applicable, of the intermediary;
 - (b) the Member State within the territory of which he plans to establish a branch or permanent presence;
 - (c) the category of intermediary and, if applicable, the name of any insurance or reinsurance undertaking represented ;
 - (d) the relevant classes of insurance, if applicable;
 - (e) a programme of operations setting out, the insurance or reinsurance mediation activities to be carried on and the organisational structure of the establishment; also indicating the identity of agents where the intermediary intends to use them ;

- (f) the address in the host Member State from which documents may be obtained;
- (g) the name of any person responsible for the management of the establishment or permanent presence.

1a. An insurance intermediary is operating under freedom of establishment if it carries on business in a host Member State for an indefinite period via a permanent presence in that Member State.

- 2. Unless the competent authority of the home Member State has grounds for considering the organisational structure or the financial situation of the insurance or reinsurance intermediary to be inadequate, taking into account the mediation activities envisaged, it shall, within one month of receiving the information referred to in paragraph 1, communicate it to the competent authority of the host Member State, which shall acknowledge the receipt without delay. The home Member State shall inform the insurance or reinsurance intermediary in writing that the information has been received by the host Member State and that the insurance or reinsurance undertaking can commence its business in the host Member State.
- 3. Where the competent authority of the home Member State refuses to communicate the information to the competent authority of the host Member State, it shall give reasons for its refusal to the insurance or reinsurance intermediary within one month of receiving all the information referred to in paragraph 1.
- 4. In the event of a change in any of the particulars communicated in accordance with paragraph 1, an insurance or reinsurance intermediary shall give written notice of that change to the competent authority of the home Member State at least one month before implementing the change. The competent authority of the host Member State shall also be informed of that change by the competent authority of the home Member State as soon as is practicable and no later than one month from the date of receipt of the information by the competent authority of the home Member State.

Article 7

Division of competence between home and host Member States

- 1. If an insurance intermediary's primary place of business is located in another Member State, then the competent authority of that other Member State may agree with the home Member State competent authority to act as if it were the home Member State competent authority with regard to the obligations in chapters VI, VII and VIII of this Directive. In the event of such an agreement, the home Member State competent authority shall notify the insurance intermediary and EIOPA without delay.
- 2. The competent authority of the host Member State shall assume responsibility for ensuring that the services provided by the establishment within its territory comply with the obligations laid down in Chapters VI and VII and in measures adopted pursuant thereto.

The competent authority of the host Member State shall have the right to examine establishment arrangements and to request such changes as are strictly needed to enable the competent authority to enforce the obligations under Chapter VI and Chapter VII and

measures adopted pursuant thereto with respect to the services or activities provided by the establishment within its territory.

3. Where the host Member State has grounds for concluding that an insurance or reinsurance intermediary acting within its territory under the freedom to provide services or through an establishment is in breach of any obligation set out in this Directive it shall refer those findings to the competent authority of the home Member State which shall take the appropriate measures. In cases where, despite measures taken by the competent authority of the home Member State, an insurance or reinsurance intermediary persists in acting in a manner that is clearly prejudicial to the interests of host Member State consumers or the orderly functioning of insurance and reinsurance markets, the insurance or reinsurance intermediary shall be subject to the following measures:
 - (a) the competent authority of the host Member State, after informing the competent authority of the home Member State, shall take all the appropriate measures needed in order to protect consumers and the proper functioning of insurance and reinsurance markets including by preventing the offending insurance or reinsurance intermediaries from initiating any further transactions within its territory; the competent authority of the host Member State shall inform the Commission of such measures without undue delay;
 - (b) the competent authority of the host Member State may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010; in that case, EIOPA may act in accordance with the powers conferred on it by that Article in cases of a disagreement between the competent authorities of the host and home Member States.
4. Where the competent authorities of a host Member State ascertain that an insurance or reinsurance intermediary who has an establishment within its territory is in breach of the legal or regulatory provisions adopted in that Member State pursuant to those provisions of this Directive which confer powers on the host Member State's competent authorities, those authorities shall require the insurance or reinsurance intermediary concerned to put an end to this situation.

In cases where, despite measures taken by the competent authority of the host Member State, an insurance or reinsurance intermediary persists in acting in a manner that is clearly prejudicial to the interests of host Member State consumers or the orderly functioning of insurance and reinsurance markets, the insurance or reinsurance intermediary shall be subject to the following measures:

- (a) the competent authority of the host Member State, after informing the competent authority of the home Member State, shall take all the appropriate measures needed in order to protect consumers and the proper functioning of the markets including by preventing the offending insurance or reinsurance intermediaries from initiating any further transactions within its territory; the competent authority of the host Member State shall inform the Commission of such measures without undue delay;
- (b) the competent authority of the host Member State may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010; in that case, EIOPA may act in accordance with the powers

conferred on it by that Article in cases of a disagreement between the competent authorities of the host and home Member States.

CHAPTER V

OTHER ORGANISATIONAL REQUIREMENTS

Article 8

Professional and organisational requirements

1. Insurance and reinsurance intermediaries, ■ and members of staff of insurance undertakings carrying out insurance mediation activities, shall possess appropriate knowledge and ability, as determined by the home Member State of the intermediary or undertaking, to complete their tasks and perform their duties adequately ■.

Member States shall ensure that ■ members of staff *of insurance and reinsurance intermediaries and insurance undertakings, which pursue insurance mediation as principal professional activity, regularly* update their knowledge and ability *appropriate to the function they are performing and the relevant market*.

To ensure that these provisions are complied with a continuing professional development and sufficient and appropriate training to their staff of at least 200 hours in a five-year period, or a proportional number of hours where it is not their principal activity, needs to be fulfilled. Member States shall also make public the criteria they have established in order for staff to meet their competence requirements. Such criteria shall include a list of any qualifications they recognise.

To that end, Member States shall have in place mechanisms to control, assess, and certify the knowledge and skills through independent bodies.

Member States *shall* adjust the required conditions with regard to knowledge and ability in line with the particular activity of insurance or reinsurance mediation and the products mediated, particularly if the principal professional activity of the intermediary is other than insurance mediation. ■ Member States may provide that in the cases referred to in the second subparagraph of Article 3(1) *and with regard to the employees of insurance companies engaged in insurance mediation*, the insurance undertaking or intermediary shall verify that the knowledge and ability of the intermediaries are in conformity with the obligations set out in the first subparagraph of this paragraph and, if need be, shall provide such intermediaries with training which corresponds to the requirements concerning the products sold by the intermediaries.

Member States need not apply the requirement referred to in the first subparagraph of this paragraph to all the natural persons working in an insurance undertaking or insurance or reinsurance intermediary who pursue the activity of insurance or reinsurance mediation. Member States shall ensure that a reasonable proportion of the persons within the management structure of such undertakings who are responsible for mediation in respect

of insurance and reinsurance products and all other persons directly involved in insurance or reinsurance mediation demonstrate the knowledge and ability necessary for the performance of their duties.

2. Insurance and reinsurance intermediaries and members of staff of insurance undertakings carrying out insurance mediation activities shall be of good repute. As a minimum, *those directly involved in the marketing or selling of the product* shall have a clean police record or any other national equivalent in relation to serious criminal offences linked to crimes against property or other crimes related to financial activities ■.

Member States may, in accordance with the provisions of the second subparagraph of Article 3(1), allow the insurance undertaking to check the good repute of insurance intermediaries.

Member States need not apply the requirement referred to in the first subparagraph of this paragraph to all the natural persons who work in an insurance undertaking or insurance and reinsurance intermediary and who pursue the activity of insurance and reinsurance mediation. Member States shall ensure that the management structure of such undertakings and any staff directly involved in insurance or reinsurance mediation fulfil that requirement.

3. Insurance and reinsurance intermediaries shall hold professional indemnity insurance covering the whole territory of the Union or some other comparable guarantee against liability arising from professional negligence, for at least **EUR 1 250 000** applying to each claim and in aggregate **EUR 1 850 000** per year for all claims, unless such insurance or comparable guarantee is already provided by an insurance undertaking, reinsurance undertaking or other undertaking on whose behalf the insurance or reinsurance intermediary is acting or for which the insurance or reinsurance intermediary is empowered to act or such undertaking has taken on full responsibility for the intermediary's actions.
4. Member States shall take all necessary measures to protect customers against the inability of the insurance intermediary to transfer the premium to the insurance undertaking or to transfer the amount of claim or return premium to the insured.

Such measures shall take any one or more of the following forms:

- (a) provisions laid down by law or contract whereby monies paid by the customer to the intermediary are treated as having been paid to the undertaking, whereas monies paid by the undertaking to the intermediary are not treated as having been paid to the customer until the customer actually receives them;
- (b) a requirement for insurance intermediaries to have financial capacity amounting, on a permanent basis, to 4 % of the sum of annual premiums received, subject to a minimum of **EUR 18 750**;
- (c) a requirement that customers' monies shall be transferred via strictly segregated customer accounts and that these accounts shall not be used to reimburse other creditors in the event of bankruptcy;
- (d) a requirement that a guarantee fund be set up.

5. Pursuit of the activities of insurance and reinsurance mediation shall require that the professional requirements set out in this Article be fulfilled on a permanent basis.
6. Member States may reinforce the requirements set out in this Article or add other requirements for insurance and reinsurance intermediaries registered within their jurisdiction.
7. EIOPA shall review the amounts referred to in paragraphs 3 and 4 regularly in order to take account of changes in the European Index of Consumer Prices as published by Eurostat. The first review shall take place five years after the entry into force of this Directive and the successive reviews every five years after the previous review date.

EIOPA shall develop draft regulatory standards which adapt the base amount in euro referred to in paragraphs 3 and 4 by the percentage change in that Index over the period between the entry into force of this Directive and the first review date or between the last review date and the new review date and rounded up to the nearest euro.

EIOPA shall submit those draft regulatory technical standards to the Commission five years after the entry into force of this Directive and the successive reviews every five years after the previous review date.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

8. **Member States** shall specify
 - (a) the notion of adequate knowledge and ability of the intermediary **and members of staff of insurance undertakings** when carrying on insurance mediation with its customers as referred to in paragraph 1 of this Article;
 - (b) appropriate criteria for determining in particular the level of professional qualifications, experiences and skills required for carrying on insurance mediation;
 - (c) the steps that insurance intermediaries and **member of staff of insurance undertakings** might reasonably be expected to take to update their knowledge and ability through continuing professional development in order to maintain an adequate level of performance.
- 8a. **Where a home Member State registers an insurance intermediary which has obtained professional qualifications or experience in another member state, it shall take into consideration the qualifications and experience, having regard to Directive 2005/36/EC of the European Parliament and ¹of the Council and the level of the qualification as it is defined under the European Qualifications Framework for lifelong learning**

¹ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

established under the Recommendation of the European Parliament and Council¹.

Article 9

Publication of general good rules

1. Member States shall take the necessary steps to ensure appropriate publication by their competent authorities of the relevant national legal provisions protecting the general good which are applicable to the carrying on of insurance and reinsurance mediation business in their territories.
2. A Member State which proposes to apply and applies provisions regulating insurance intermediaries and the sale of insurance products in addition to those set out in this Directive shall ensure that the administrative burden stemming from these provisions is proportionate for consumer protection. The Member State shall continue to monitor these provisions to ensure they remain so.
3. EIOPA shall present a standardised information sheet for general good rules to be completed by the competent authorities in each Member State. It shall include the hyperlinks to the websites of competent authorities where information on general good rules is published. Such information shall be updated by the national competent authorities on a regular basis and EIOPA shall make this information available on its website in the English, French and German languages, with all national general good rules categorised into different relevant areas of law.
4. Member States shall establish a single point of contact responsible for providing information on general good rules in their respective Member State. Such a point of contact should be an appropriate competent authority.
5. EIOPA shall examine in a report and inform the Commission about the general good rules published by Member States as referred to in this Article in the context of the proper functioning of this Directive and the Internal Market before ...* [OJ please insert date: three years after the entry into force of the Directive].

Article 10

Competent authorities

1. Member States shall designate the competent authorities empowered to ensure implementation of this Directive. They shall inform the Commission thereof, indicating any division of those duties.
2. The authorities referred to in paragraph 1 shall be either public authorities or bodies recognised by national law or by public authorities expressly empowered for that purpose by national law. They shall not be insurance or reinsurance undertakings ***or associations whose members directly or indirectly include insurance or reinsurance undertakings or insurance or reinsurance intermediaries.***

¹ Recommendation of the European Parliament and of the Council of 23 April 2008 on the establishment of the European Qualifications Framework for lifelong learning (OJ C 111, 6.5.2008, p.1).

3. The competent authorities shall possess all the powers necessary for the performance of their duties. Where there is more than one competent authority on its territory, a Member State shall ensure that those authorities collaborate closely so that they can discharge their respective duties effectively.

Article 11

Exchange of information between Member States

1. The competent authorities of the various Member States shall cooperate in order to ensure the proper application of the provisions of this Directive.
2. The competent authorities shall exchange information on insurance and reinsurance intermediaries if they have been subject to a *penalty* referred to in Chapter VIII and such information is likely to lead to removal from the register of such intermediaries. The competent authorities may also exchange any relevant information at the request of an authority.
3. All persons required to receive or divulge information in connection with this Directive shall be bound by professional secrecy, in the same manner as is laid down in Article 16 of Council Directive 92/49/EEC¹ and Article 15 of Council Directive 92/96/EEC².

Article 12

Complaints

Member States shall ensure that procedures are set up which allow customers and other interested parties, especially consumer associations, to register complaints about insurance and reinsurance intermediaries and undertakings. In all cases complaints shall receive replies.

Article 13

Out-of-court redress

1. ***In accordance with Directive .../.../EU of the European Parliament and of the Council³ and Regulation .../.../EU of the European Parliament and of the Council⁴*** Member States shall ensure the setting-up of appropriate effective impartial and independent complaints and redress procedures for the out-of-court

¹ Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive) (OJ L 228, 11.8.1992, p. 1).

² Council Directive 92/96/EEC of 10 November 1992 on the coordination of laws, regulations and administrative provisions relating to direct life assurance and amending Directives 79/267/EEC and 90/619/EEC (third life assurance Directive) (OJ L 360, 9.12.1992, p. 1).

³ Directive .../.../EU of the European Parliament and of the Council of ... on alternative dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (Directive on consumer ADR) (OJ ...).

⁴ Regulation .../.../EU of the European Parliament and of the Council of ... on online dispute resolution for consumer disputes (Regulation on consumer ODR) (OJ ...).

settlement of disputes between insurance intermediaries and customers, and between insurance undertakings and customers, using existing bodies where appropriate. Member States shall further ensure that all insurance undertakings and insurance intermediaries participate in the procedures for the out-of-court settlement of disputes where **■** the procedure results in decisions which *may be binding for the intermediary or the insurance undertaking, as appropriate, and the client.*

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2. Member States shall ensure that these bodies cooperate in the resolution of cross-border disputes.
- 2a. *Member States shall ensure that insurance intermediaries established on their territories inform consumers about the name, address and website address of the ADR entities by which they are covered and which are competent to deal with potential disputes between themselves and consumers.*
- 2b. *Insurance intermediaries within the Union engaging in online and cross-border online sales shall inform consumers about the ADR platform, if applicable and about their email address. This information shall be made easily, directly, prominently and permanently accessible on the insurance intermediaries' website and if the offer is made by e-mail or another textual message transmitted by electronic means, in that message. It shall include an electronic link to the ADR platform's homepage. Insurance intermediaries shall also inform consumers about the ADR platform when the consumer submits a complaint to the insurance intermediary, a consumer complaint handling system operated by the insurance intermediary or to a company ombudsman.*
- 2c. *Where a customer initiates a procedure for alternative dispute resolution laid down in national law against an insurance intermediary or insurance undertaking with regard to a dispute concerning rights and obligations established under this Directive, the insurance intermediary or insurance undertaking shall be required to participate in that procedure.*
- 2d. *For the purposes of the application of this Directive the competent authorities shall cooperate with each other and with the entities responsible for out-of-court complaint and redress procedures referred to in this Article and to the extent permitted by Union legislative acts in force.*

Article 14

Restriction on use of intermediaries

Member States shall ensure that, *when using the services of the insurance or reinsurance intermediaries established in the Union*, insurance and reinsurance undertakings and intermediaries use the insurance and reinsurance mediation services only of registered insurance and reinsurance intermediaries or of the persons referred to in Article 1(2) or of the persons who have fulfilled the declaration procedure referred to in Article 4.

CHAPTER VI

INFORMATION REQUIREMENTS AND CONDUCT OF BUSINESS RULES

Article 15

General principle

1. Member States shall require that, when carrying out insurance mediation with or for customers, an insurance intermediary or insurance undertaking ***always*** acts honestly, ***fairly, trustworthily, honourably and*** professionally in accordance with ***the best*** interests of its customers.
2. All information, including marketing communications, addressed by the insurance intermediary or insurance undertaking to customers or potential customers shall be ***fair***, clear and not misleading. Marketing communications shall ***always*** be clearly identifiable as such.

Article 16

General information provided by the insurance intermediary or insurance undertaking

Member States shall lay down rules ensuring that

- (a) prior to the conclusion of any insurance contract, ***or if there is any material change in the data in the disclosure to customers related to the intermediary after conclusion of an insurance contract***, an insurance intermediary - including tied ones- shall make the following disclosures to customers:
 - (i) its identity and address and that it is an insurance intermediary;
 - (ii) whether or not it provides any type of advice about the insurance products sold;
 - (iii) the procedures referred to in Article 12 allowing customers and other interested parties to register complaints about insurance and reinsurance intermediaries and about the out-of-court complaint and redress procedures referred to in Article 13;
 - (iv) the register in which it has been included and the means for verifying that it has been registered; and
 - (v) whether the intermediary is representing the customer or is acting for and on behalf of the insurance undertaking;
- (b) prior to the conclusion of any insurance contract, an insurance undertaking shall make the following disclosures to customers:
 - (i) its identity and address and that it is an insurance undertaking;

- (ii) whether or not it provides any type of advice about the insurance products sold;
- (iii) the procedures referred to in Article 12 allowing customers and other interested parties to register complaints about insurance undertakings and about the out-of-court complaint and redress procedures referred to in Article 13.

Article 17

Conflicts of interest and transparency

1. Prior to the conclusion of any insurance contract, an insurance intermediary **■** shall provide the customer with at least the following information:
 - (a) whether it has a holding, direct or indirect, representing more than 10% of the voting rights or of the capital in a given insurance undertaking;
 - (b) whether a given insurance undertaking or parent undertaking of a given insurance undertaking has a holding, direct or indirect, representing more than 10% of the voting rights or of the capital in the insurance intermediary;
 - (c) in relation to the contract proposed, whether:
 - (i) it gives advice on the basis of a fair ***and personal*** analysis, or
 - (ii) it is under a contractual obligation to conduct insurance mediation business exclusively with one or more insurance undertakings. In that case, it shall provide the names of those insurance undertakings, or
 - (iii) it is not under a contractual obligation to conduct insurance mediation business exclusively with one or more insurance undertakings and does not give advice on the basis of a fair ***and personal*** analysis. In that case, it shall provide the names of the insurance undertakings with which it may and does conduct business;
- - (e) whether in relation to the insurance contract, it works:
 - (i) on the basis of a fee, that is the remuneration paid directly by the customer; or
 - (ii) on the basis of a commission of any kind, that is the remuneration included in the insurance premium; or
 - (iii) on the basis of a combination of both (i) and (ii);
 - (ea) ***whether in relation to the insurance contract, the source of remuneration is:***
 - (i) ***the policyholder;***
 - (ii) ***the insurance undertaking;***

- (iii) *another insurance intermediary;*
- (iv) *a combination of points (i), (ii) and (iii);*

Additional information may be required by the Member States in accordance with Article 17a;

- 2. *The consumer has the right to request additional detailed information as referred to in paragraph 1(e a).*
- 3. The insurance undertaking, *when selling insurance directly to customers*, shall inform the customer **■** whether any variable remuneration is paid to employees for distributing and managing the insurance product in question.

- 5a. *In cases of conflict of interest and to stimulate fair competition, the consumer shall be provided with information about relevant quantitative elements as regards, the concepts referred to in the paragraph 1(ea) and paragraph 3 of this Article and on the same conditions. In accordance with Article 16 of Regulation (EU) No 1094/2010, EIOPA shall develop, by 31 December 2015 and update periodically, guidelines to ensure consistent application of this Article.*

Article 17 a *Disclosure of information*

Member States may introduce or retain additional disclosure requirements for insurance mediators and insurance undertakings concerning the amount of remuneration, fees, commissions or non-monetary benefits in relation to the provision of intermediation provided that the Member State upholds a level playing field between all distribution channels, does not distort competition, and complies with Union law, and that the resulting administrative burdens remain proportional to the intended level of consumer protection.

Article 18 *Advice, and standards for sales ■*

- 1. *Where advice is provided* prior to the conclusion of any specific contract, the insurance intermediary – including tied ones – or insurance undertaking shall *specify*, on the basis of information provided by the customer:
 - (a) the demands and the needs of that customer;
 - (b) **■** the underlying reasons for any advice *given* to the customer on a specified insurance product **■**

2. The details referred to in points (a) and (b) of paragraph 1 shall be modulated according to the complexity of the insurance product being proposed and the level of financial risk to the customer ***regardless of the distribution route selected.***
3. When the insurance intermediary or the insurance undertaking gives ***advice on the basis of fair analysis***, it is obliged to give that advice on the basis of ***a fair*** analysis of a sufficiently large number of insurance contracts available on the market, to enable it to make a ***personal*** recommendation ***in the best interest of the consumer***, in accordance with professional criteria, regarding which insurance contract would ***most suitable*** to meet the customer's needs.
4. Prior to the conclusion of a contract, whether or not advice is given, the insurance intermediary or insurance undertaking shall ***provide*** the customer the relevant information about the insurance product in a comprehensible form to allow the customer to make an informed decision, while taking into account the complexity of the insurance product and the type of costumer. ***It shall be provided in a standardised information sheet by way of a product information document (PID) in plain language. It shall contain at least the following information:***
 - (a) ***information about the type of insurance;***
 - (b) ***a description of the risks insured and excluded risks;***
 - (c) ***the means of payment of premiums and the duration of payments;***
 - (d) ***exclusions;***
 - (e) ***obligations at the start of the contract;***
 - (f) ***obligations during the term of the contract;***
 - (g) ***obligations in case of a claim made;***
 - (g) ***the term of the contract including start and end date of the contract;***
 - (i) ***the means of terminating the contract.***
- 4a. ***Paragraph 4 shall not apply to:***
 - (a) ***investment products as defined in Article 4a of Regulation .../.../EU of the European Parliament and of the Council¹; or***
 - (b) ***the sale of insurance investment products referred to in Chapter VII of this Directive.***

¹ ***Regulation .../.../EU of the European Parliament and of the Council on key information documents for investment products (OJ ...).***

Article 19
Information exemptions and flexibility clause

1. The information referred to in Articles 16, 17 and 18 need not be ***provided*** when the insurance intermediary or insurance undertaking mediates in the insurance of large risks, in the case of mediation by reinsurance intermediaries or reinsurance undertakings, or in relation to professional customers as specified in the Annex.
2. Member States may maintain or adopt stricter provisions regarding the information requirements referred to in Articles 16, 17 and 18 provided that such provisions comply with Union law. Member States shall communicate to EIOPA and the Commission such national provisions.
- 2a. Member States which maintain or adopt stricter provisions applying to insurance intermediaries shall ensure that those provisions respect level playing field principles and that the administrative burden stemming from these provisions is proportionate relative to the consumer protection benefits.***
3. In order to establish a high level of transparency by all appropriate means, EIOPA shall ensure that the information it receives relating to national provisions is also communicated to consumers insurance intermediaries and insurance undertakings.

Article 20
Information conditions

1. All information to be provided in accordance with Articles 16, 17 and 18 shall be communicated to the customers:
 - (a) on paper;
 - (b) in a clear and accurate manner, comprehensible to the customer; and
 - (c) in an official language of the Member State in which the risk is situated or the Member State of the commitment or in any other language agreed by the parties. It shall be provided free of charge.
2. By way of derogation from paragraph 1(a), the information referred to in Articles 16, 17 and 18 may be provided to the customer in one of the following media:
 - (a) using a durable medium other than paper, where the conditions laid down in paragraph 4 are met; or
 - (b) by means of a website where the conditions laid down in paragraph 5 are met.
3. However, where the information referred to in Articles 16, 17 and 18 is provided using a durable medium other than paper or by means of a website, a paper copy shall be provided to the customer upon request and free of charge.
4. The information referred to in Articles 16, 17 and 18 may be provided using a durable medium other than paper if the following conditions are met:

- (a) the use of the durable medium is appropriate in the context of the business conducted between the intermediary or insurance undertaking and the customer; and
 - (b) the customer has been given the choice between information on paper and in the durable medium, and has chosen that other medium.
5. The information referred to in Articles 16, 17 and 18 may be provided by the means of a website if it is addressed personally to the customer or if the following conditions are met:
- (a) the provision of the information referred to in Articles 16, 17 and 18 by means of a website is appropriate in the context of the business conducted between the intermediary or insurance undertaking and the customer;
 - (b) the customer has consented to the provision of the information referred to in Articles 16, 17 and 18 by means of a website;
 - (c) the customer has been notified electronically of the address of the website, and the place on the website where the information referred to in Articles 16, 17 and 18 can be accessed;
 - (d) it is ensured that the information referred to in Articles 16, 17 and 18 remains accessible on the website for such period of time as the customer reasonably need to consult it.
6. For the purposes of paragraph 4 and 5, the provision of information using a durable medium other than paper or by means of a website shall be regarded as appropriate in the context of the business conducted between the intermediary or insurance undertaking and the customer, if there is evidence that the customer has regular access to the Internet. The provision by the customer of an e-mail address for the purposes of that business shall be regarded as such evidence.
7. In the case of telephone selling, the prior information given to the customer shall be in accordance with Union rules applicable to the distance marketing of consumer financial services. Moreover, ***after the customer has chosen to obtain information in a medium other than paper in accordance with paragraph 4***, information shall be provided to the customer in accordance with paragraph 1 or 2 immediately after the conclusion of the insurance contract.



Article 21a ***Tying and bundling practices***

1. ***When insurance is offered together with another service or ancillary product as part of a package or the same agreement or package, the insurance intermediary or insurance undertaking shall inform and offer the customer the possibility of buying the different components jointly or separately provide for a separate evidence of the premium or prices of***

each component. This shall not prevent the mediation of insurance products with different levels of insurance coverage or multi insurance risk policies.

2. *Where the risks resulting from such an agreement or package offered to a customer are likely to be different from the risks associated with the components taken separately, the insurance intermediary or insurance undertaking shall, upon the customer's request, provide an adequate description of the different components of the agreement or package and the way in which its interaction alters the risks.*
3. *EIOPA, in cooperation with the European Supervisory Authority (European Banking Authority) ESMA, through the Joint Committee of the European Supervisory Authorities, shall develop by ...* [OJ please insert date: 18 months after the date of entry into force of this Directive], and update periodically, guidelines for the assessment and the supervision of cross-selling practices indicating, in particular, situations in which cross-selling practices do not comply with Article 15(1).*
4. *Member States shall ensure that where an insurance intermediary or insurance undertaking provides advice it ensures that the overall package of insurance products meets the demands and needs of the customer.*
5. *Member States may maintain or adopt additional stricter measures or intervene on a case-by-case basis to prohibit the sale of insurance together with another service or product as part of a package or as a condition for the same agreement or package when they can demonstrate that such practices are detrimental to consumers.*

CHAPTER VII

ADDITIONAL CUSTOMER PROTECTION REQUIREMENTS IN RELATION TO INSURANCE INVESTMENT PRODUCTS

Article 22

Scope

This Chapter applies **■** requirements *additional to those referred to in Articles 15, 16, 17 and 18* to insurance mediation *activities* when *they are* carried on in relation to the sale of insurance investment *based* products by *the following*:

- (a) an insurance intermediary;
- (b) an insurance undertaking.

Article 23

Conflicts of interest

1. Member States shall require insurance intermediaries and insurance undertakings to take all appropriate steps to identify conflicts of interest between themselves, including their managers, employees and tied insurance intermediaries, or any person directly or indirectly linked to them by control and their customers or between one customer and another that arise in the course of carrying *out any* insurance mediation *activities*.

2. Where **organisational or administrative arrangements made** by the insurance intermediary or insurance undertaking in **accordance** with Article 15, 16 and 17 are not sufficient to ensure, with reasonable confidence, that risks of damage to **customer** interests ■ will be prevented, the insurance intermediary or insurance undertaking shall clearly disclose **to the customer** the general nature **and** sources of conflicts of interest, **as appropriate**, to the customer before undertaking business on **its** behalf.
- 2a. **The disclosure referred to in paragraph 2 shall:**
- (a) **be made in a durable medium; and**
 - (b) **include sufficient detail, taking into account the nature of the customer, to enable that customer to take an informed decision with respect to the insurance mediation activities in the context of which the conflict of interest arises.**
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 33 **in order to:**
 - (a) ■ define the steps ■ that insurance intermediaries **or** insurance undertakings might reasonably be expected to take to identify, prevent, manage and disclose conflicts of interest when **carrying out** insurance mediation **activities**;
 - (b) **establish** appropriate criteria for determining the types of conflict of interest whose existence may damage the interests of the customers or potential customers of the insurance intermediary or insurance undertaking.

Article 24

General principles and information to customers

1. Member States shall **ensure** that, when carrying out insurance mediation **activities**, an insurance intermediary or insurance undertaking acts honestly, fairly and professionally in accordance with the best interests of its customers and complies, in particular, with the principles set out in this Article and in Article 25.
2. All information, including marketing communications, addressed by the insurance intermediary or insurance undertaking to customers or potential customers shall be fair, clear and not misleading. Marketing communications shall be clearly identifiable as such.
3. Appropriate information shall be provided to customers or potential customers about **the following**:
 - (a) the insurance intermediary or insurance undertaking and its services: **when** advice is provided, information shall specify whether the advice is provided on an independent basis and whether it is based on a broad or on a more restricted analysis of the market and shall indicate whether the insurance intermediary or insurance undertaking will provide the customer with the on-going assessment of the suitability of the **insurance-based investment** product recommended to **customers**;

- (b) ***insurance-based investment*** products and proposed investment strategies: ***this*** should include appropriate guidance on and warnings of the risks associated with investments in those ***instruments*** or in respect of particular investment strategies; ■

- (ba) ***all costs and associated charges relating to insurance intermediation or ancillary services which must include the cost of advice, where relevant, the cost of the financial instrument recommended or marketed to the client and how the client may pay for it, also encompassing any third-party payments; [Am. 8]3a. The information concerning all costs and charges, including costs and charges in connection with the intermediation service and the insurance product, which are not caused by the occurrence of underlying market risk, shall be aggregated to allow the client to understand the overall cost as well as the cumulative effect on return of the investment, and where the client so requests, an itemised breakdown. Where applicable, such information shall be provided to the client on a regular basis, at least annually, during the life of the investment.***

The information referred to in the first subparagraph and in paragraph 6a shall be provided in a comprehensible form in such a manner that clients or potential clients are reasonably able to understand the nature and risks of the investment service and of the specific type of insurance investment product that is being offered and, consequently, to take investment decisions on an informed basis. Member States may allow that information to be provided in a standardised format. [Am. 9]

4. The information referred to in ***paragraphs 2 and 3*** should be provided in a comprehensible form in such a manner that customers or potential customers are reasonably able to understand the nature and risks of the specific ***type of insurance-based investment*** product that is being offered and, consequently, to take investment decisions on an informed basis. This information may be provided in a standardised format ***in accordance with Article 18(4).***
5. ***Member States shall require that when*** the insurance intermediary or insurance undertaking informs the customer that insurance advice is provided on an independent basis the insurance intermediary or insurance undertaking ***shall disclose to the customer the nature of the remuneration received in relation to the insurance contract:***
- (a) ***the range of insurance products on which the recommendation will be based and, in particular, whether the range is limited to insurance products issued or provided by entities having close links with the intermediary who represents the customer;***
- 5a. ***Member States may additionally prohibit or further restrict the offer or acceptance of fees, commissions or non-monetary benefits from third parties in relation to the provision of insurance advice. That may include requiring any such fees, commissions or non-monetary benefits to be returned to the clients or offset against fees paid by the client.***

*Member States may further require that where an intermediary informs the client that advice is given independently, the intermediary shall assess a sufficiently large number of insurance products available on the market **which are sufficiently** diversified with regard to their type and issuers or product **providers to ensure that the client's objectives can be suitably met and shall** not be limited to insurance products issued or provided by entities having close links with the [] intermediary [].*

- 5b. *An insurance intermediary shall maintain and operate effective organisational and administrative arrangements with a view to taking all reasonable steps designed to prevent conflicts of interest as defined in Article 23 from adversely affecting the interests of its clients.*

An insurance company which manufactures financial instruments for sale to clients shall maintain, operate and review a process for the approval of each insurance product or significant adaptations of existing insurance products before it is marketed or distributed to clients.

The product approval process shall specify an identified target market of end clients within the relevant category of clients for each product and ensure that all relevant risks to such identified target market are assessed and that the intended distribution strategy is consistent with the identified target market.

The insurance company shall also regularly review financial instruments offered or marketed by the firm, taking into account any event that could materially affect the potential risk to the identified target market, to assess at least whether the product remains consistent with the needs of the identified target market and whether the intended distribution strategy remains appropriate. [Am. 11]

6. EIOPA shall develop by ...* [OJ please insert date: 18 months after the date of entry into force of this Directive], and update periodically, guidelines for the assessment and the supervision of cross-selling practices indicating, in particular, situations in which cross-selling practices are not compliant with obligations in paragraph 1.

[]

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 33 *to specify the principles with which* insurance intermediaries and insurance undertakings *must* comply [] when carrying *out* insurance mediation *activities* with their customers. Those delegated acts shall *take into account*:
- (a) the nature of the *services* offered or provided to the customer or potential customer, taking into account the type, object, size and frequency of the transactions;
 - (b) the nature of the products being offered or considered including different types of *insurance-based investment* products;

Article 25

Assessment of suitability and appropriateness and reporting to customers

1. When providing advice the insurance intermediary or insurance undertaking shall obtain the necessary information regarding the customer's or potential customer's knowledge and experience in the **investment** field relevant to the specific type of product **■**, the customer's or potential customer's financial situation and **■** investment objectives **so as to enable** the insurance intermediary or insurance undertaking **to recommend to the customer or potential customer** the insurance **mediation activities or insurance-based investment** products that are suitable for the customer or potential customer.
2. Member States shall ensure that insurance intermediaries and insurance undertakings, when carrying **out** insurance mediation **activities other than those referred to in paragraph 1**, ask the customer or potential customer to provide information regarding **his** knowledge and experience in the investment field relevant to the specific type of **insurance-based investment** product **■** offered or demanded so as to enable the insurance intermediary or insurance undertaking to assess whether the insurance **mediation activity or insurance-based** product envisaged is appropriate for the customer.

Where the insurance intermediary or insurance undertaking considers, on the basis of the information received under the previous subparagraph, that the **insurance-based investment** product **■** is not appropriate to the customer or potential customer, the insurance intermediary or insurance undertaking shall warn the customer or potential customer. This warning may be provided in a standardised format.

Where customers or potential customers do not provide the information referred to **under** the first subparagraph, or where they provide insufficient information regarding their knowledge and experience, the insurance intermediary or insurance undertaking shall warn them that **they are** not in a position to determine whether the **insurance-based investment** product envisaged is appropriate for them. This warning may be provided in a standardised format.

- 2a. **Member States shall allow insurance intermediaries or insurance undertakings when carrying out insurance mediation activities that consist only of executing customer orders, to provide those activities to their customers without the need to obtain the information or make the determination provided for in paragraph 2 where all the following conditions are met:**
 - (a) **the activities refer to either of the following insurance-based investment products:**
 - (i) **contracts which only provide investment exposure to the financial instruments deemed non-complex under Directive .../.../EU [MiFID] and do not incorporate a structure which makes it difficult for the customer to understand the risks involved; or**
 - (ii) **other non-complex insurance-based investments for the purpose of this paragraph;**

- (b) *the insurance mediation activity is carried out at the initiative of the customer or potential customer;*
 - (c) *the customer or potential customer has been clearly informed, whether or not in a standardised format, that in the provision of this insurance mediation activity, the insurance intermediary or insurance undertaking is not required to assess the appropriateness of the insurance-based investment product or insurance mediation activity provided or offered and that the customer or potential customer does not benefit from the corresponding protection of the relevant conduct of business rules;*
 - (d) *the insurance intermediary or insurance undertaking complies with its obligations under Article 23.*
3. The insurance intermediary or insurance undertaking shall establish a record that includes *the* document or documents ■ agreed between *itself* and the customer that set out the rights and obligations of the parties, and the other terms on which the insurance intermediary or insurance undertaking will *carry out insurance mediation activities for* the customer. The rights and duties of the parties to the contract may be incorporated by reference to other documents or legal texts.
4. The ■ insurance intermediary or insurance undertaking *shall provide the customer with* adequate reports on the *insurance mediation activity* provided ■. These reports shall include periodic communications to customers, taking into account the type and the complexity of *insurance-based investment* products involved and the nature of the *insurance mediation activity carried out for* the customer and shall include, where applicable, the costs associated with the *activities* undertaken on behalf of the customer. ■
- When providing advice, the insurance intermediary or insurance undertaking shall, before the insurance-based investment product is arranged with the customer, provide the customer with a statement in a durable medium on suitability specifying the advice given and how that advice meets the preferences, objectives and other characteristics of the customer.*
- Where the agreement is concluded using a means of distance communication which prevents the prior delivery of the suitability assessment, the insurance intermediary or insurance undertaking can provide the written statement on suitability in a durable medium immediately after the customer is bound by any agreement.*
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 33 to *specify the principles with which* insurance intermediaries and insurance undertakings *must* comply ■ when carrying *out* insurance mediation *activities to* their customers. Those delegated acts shall *take into account*:
- (a) the nature of the *services* offered or provided to the customer or potential customer, taking into account the type, object, size and frequency of the transactions;

- (b) the nature of the products being offered or considered, including different types of *financial instruments and banking deposits referred to in Article 1(2) of Directive .../.../EU [MiFID]*;

(ba) *the retail or professional nature of the customer or potential customer.*

- 5a. *EIOPA shall develop by ...* [OJ please insert date: 18 months after the date of entry into force of this Directive], and update periodically, guidelines for the assessment of insurance-based investment products incorporating a structure which makes it difficult for the customer to understand the risk involved in accordance with paragraph 3(a).*

CHAPTER VIII

PENALTIES AND OTHER MEASURES

Article 26

Administrative penalties and other measures

1. Member States shall ensure that their administrative *penalties* and *other* measures are effective, proportionate and dissuasive.
2. Member States shall ensure that where obligations apply to insurance or reinsurance undertakings or insurance or reinsurance intermediaries, in case of a breach, administrative *penalties* and *other* measures can be applied to the members of their management body, and any other natural or legal persons who, under national law, are responsible for a breach.
3. The competent authorities shall be given all investigatory powers that are necessary for the exercise of their functions. In the exercise of their [...] powers *to impose penalties*, the competent authorities shall cooperate closely to ensure that *penalties* or *other* measures produce the desired results and coordinate their action when dealing with cross border cases, *while ensuring that conditions are met for legitimate data processing in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001. The competent authorities may request documents or other information under a formal decision, which shall indicate the legal basis for the request for information, the deadline for compliance and the right of the recipient to seek a judicial review of the decision.*

Article 27
Publication of penalties

Member States shall provide that the competent authority publishes any *penalty* or *other* measure that has been imposed for breaches of the provisions of the national provisions adopted in the implementation of this Directive ■ including information on the type and nature of the breach and the identity of persons responsible for it, ***only if the penalty or other measure has become final and is not subject to appeal or judicial review***. Where the publication would cause a disproportionate damage to the parties involved, the competent authorities shall publish the *penalties* on an anonymous basis.

Article 28
Breaches

1. This article shall apply to the following:
 - (a) an insurance or reinsurance intermediary who is not registered in a Member State and who does not fall within Article 1(2) or Article 4;
 - (b) a person providing ancillary insurance activities without having submitted a declaration as laid down in Article 4, or who has submitted such a declaration but in respect of whom the requirements set out in Article 4 are not met;
 - (c) an insurance or reinsurance undertaking or insurance or reinsurance intermediary using the insurance or reinsurance mediation services of persons who are neither registered in a Member State nor referred to in Article 1(2), and who have not submitted a declaration under Article 4;
 - (d) an insurance or reinsurance intermediary having obtained a registration through false statements or any other irregular means in breach of Article 3;
 - (e) an insurance or reinsurance intermediary or insurance undertaking failing to meet the provisions of Article 8;
 - (f) an insurance undertaking or insurance or reinsurance intermediary failing to comply with conduct of business requirements in accordance with Chapter VI and VII.
2. Member States shall ensure that in the cases referred to in paragraph 1, the administrative *penalties* and *other* measures that can be applied include at least the following:
 - (a) a public statement, which indicates the natural or legal person and the nature of the breach;
 - (b) an order requiring the natural or legal person to cease the conduct and to desist from a repetition of that conduct;
 - (c) in case of an insurance or reinsurance intermediary, withdrawal of registration in accordance with Article 3;

- (d) a **temporary** ban against any member of the management body of the insurance or reinsurance intermediary or insurance or reinsurance undertaking **I**, who is held responsible, to exercise functions in insurance intermediaries or reinsurance intermediaries, or insurance or reinsurance undertakings;
- (e) in case of a legal person, administrative pecuniary *penalties* of up to 10 % of the total annual turnover of the legal person in the preceding business year; where the legal person is a subsidiary of a parent undertaking, the relevant total annual turnover shall be the total annual turnover resulting from the consolidated accounts of the ultimate parent undertaking in the preceding business year;
- (f) in case of a natural person, administrative pecuniary *penalties* of up to 5 000 000 EUR, or in the Member States where the Euro is not the official currency, the corresponding value in the national currency on the date of entry into force of this Directive; and

Where the benefit derived from the breach can be determined, Member States shall ensure that the maximum level is no lower than twice the amount of that benefit.

Article 29 *Effective application of penalties*

1. Member States shall ensure that when determining the type of administrative *penalties* or *other* measures and the level of administrative pecuniary *penalties*, the competent authorities shall take into account all relevant circumstances, including, **where appropriate**:
 - (a) the gravity and the duration of the breach;
 - (b) the degree of responsibility of the responsible natural or legal person;
 - (c) the financial strength of the responsible natural or legal person, as indicated by the total turnover of the responsible legal person or the annual income of the responsible natural person;
 - (d) the importance of profits gained or losses avoided by the responsible natural or legal person, insofar as they can be determined;
 - (e) the losses for third parties caused by the breach, insofar as they can be determined;
 - (f) the level of cooperation of the responsible natural or legal person with the competent authority; and
 - (g) previous breaches by the responsible natural or legal person.

- I**

3. This Directive shall not affect the power of the host Member States to take appropriate measures to prevent or to penalise irregularities committed within their territories

which are contrary to legal or regulatory provisions adopted in the interest of the general good. This shall include the possibility of preventing offending insurance or reinsurance intermediaries from initiating any further activities within their territories. ■

Article 30
Reporting of breaches

1. Member States shall ensure that the competent authorities establish effective mechanisms to encourage reporting of breaches of national provisions implementing this Directive to the competent authorities.
2. Those arrangements shall include at least:
 - (a) specific procedures for the receipt of reports and their follow-up;
 - (b) appropriate protection, ***including anonymity where appropriate, for those who report the commission of*** breaches committed within them; and
 - (c) protection of personal data concerning both the person who reports the breaches and the natural person who is allegedly responsible for a breach, in compliance with the principles laid down in Directive 95/46/EC.

The identity of the persons reporting and allegedly responsible for the breach shall remain confidential at every stage, unless the disclosure thereof is required under national law for the purpose of subsequent inquiries or legal proceedings.

Article 31
Submitting information to EIOPA in relation to penalties

1. Member States shall provide EIOPA annually with aggregated information regarding all administrative measures or administrative *penalties* imposed in accordance with Article 26.

Competent authorities shall provide EIOPA annually with aggregated information regarding all administrative measures or administrative *penalties* imposed in accordance with Article 26.
2. Where the competent authority has disclosed an administrative measure or administrative *penalty* to the public, it shall contemporaneously report that fact to EIOPA.
3. EIOPA shall develop draft implementing technical standards on procedures and forms for submitting information as referred to in this Article.

EIOPA shall submit those draft implementing technical standards to the Commission by ... **[OJ please insert date: six months after entry into force of this Directive]*.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

CHAPTER IX

FINAL PROVISIONS

Article 32 *Data Protection*

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Directive.
2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by EIOPA pursuant to this Directive.

Article 33 *Delegated acts*

The Commission shall be empowered to adopt delegated acts in accordance with Article 34 concerning Articles 23, 24 and 25.

Article 34 *Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 23, 24 and 25 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Directive.
3. The delegation of powers referred to in Articles 23, 24 and 25 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 23, 24 and 25 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three months* of notification of that act to the European Parliament

and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *three months* at the initiative of the European Parliament or the Council.

Article 34a

Further provisions for draft regulatory technical standards

1. *Notwithstanding any time limit provided for the submission of draft regulatory technical standards to the Commission, the Commission shall submit its drafts in intervals of 12, 18 or 24 months.*
2. *The Commission shall not adopt regulatory technical standards where the scrutiny time of the European Parliament is reduced to less than two months, including any extension, because of recess.*
3. *The European Supervisory Authorities may consult the European Parliament during the drafting stages of the regulatory technical standards, particularly where there are concerns regarding the scope of this Directive.*
4. *Where the competent committee of the European Parliament has rejected regulatory technical standards and there are less than two weeks before the following plenary part-session, the European Parliament may extend its time for scrutiny until the plenary part-session thereafter.*
5. *Where regulatory technical standards have been rejected and the identified issues are of limited scope, the Commission may adopt an expedited timetable for delivering a revised draft regulatory technical standard.*
6. *The Commission shall ensure that all queries of the European Parliament that are formally raised formally via the Chair of the competent committee are answered promptly before the adoption of the draft regulatory technical standards.*

Article 35

Review and evaluation

1. *By ...* [OJ please insert date: five years after the date of entry into force of this Directive.], the Commission shall review [] the practical application of rules laid down in this Directive taking due account of developments in the retail investment products markets as well as experiences acquired in practical application of this Directive and Regulation .../.../EU [on key information documents for investment products] and Directive .../.../EU [MIFID II]. [] This **examination** shall also include a specific analysis of the impact of Article 17(2), taking into account the situation of competition on the market of intermediation services for contracts other than contracts in any of the classes specified in Annex I of Directive 2002/83/EC and the impact of the obligations referred to in Article 17(2) on insurance intermediaries which are small and medium sized enterprises.*

2. After consulting the Joint Committee of European Supervisory Authorities, the Commission shall submit *its findings* to the European Parliament and *to* the Council.

5. **The Commission** shall examine whether the competent authorities referred to in Article 10(1) are sufficiently empowered and have adequate resources to carry out their tasks.

Article 36 Transposition

1. Member States shall *adopt and publish, by ...*[OJ please insert date: 18 months after the date of entry into force of this Directive]*, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those measures.

Where the documents accompanying notification of transposition measures provided by the Member States are not sufficient to assess fully the compliance of those measures with certain provisions of this Directive, the Commission may, upon EIOPA's request and with a view to carrying out its tasks under Regulation (EU) No 1094/2010, or on its own initiative, require Member States to provide more detailed information regarding the transposition of this Directive and the implementation of those measures.

- 1a. *Member States shall apply the measures referred to in paragraph 1 from ...*[OJ please insert date: 18 months after the date of entry into force of this Directive].*

When Member States adopt those *measures*, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 37 Repeal

Directive 2002/92/EC is repealed with effect from ...* *[OJ please insert date: 18 months after the date of entry into force of this Directive.]*, without prejudice to obligations of the Member States relating to the time-limit for transposition into national law of that Directive.

References to the repealed Directive shall be construed as references to this Directive.

Article 38
Entry into force

This Directive shall enter into force on the twentieth day of *that of* its publication in the Official Journal of the European Union.

Article 39
Addressees

This Directive is addressed to the Member States.

Done at ...,

For the European Parliament

For the Council

ANNEX I
PROFESSIONAL CUSTOMERS

A professional customer is a customer who possesses the experience, knowledge and expertise to make his own decisions and properly assess the risks that he incurs. The following should all be regarded as professionals in all insurance services and activities and insurance products for the purposes of the Directive.

1. ***Insurance and reinsurance undertakings;***

■

1a. Insurance and reinsurance intermediaries.

2. Large undertakings meeting two of the following size requirements on a company basis:

- balance sheet total: EUR 20,000,000
- net turnover: EUR 40,000,000
- own funds: EUR 2,000,000.

3. National ■ governments ■.

■

ANNEX II

EXPLANATORY DOCUMENTS

In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

With regard to this Directive, the Commission considers the transmission of such documents to be justified for the following reasons:

Complexity of the Directive and of the sector concerned:

The field of insurance and distribution of insurance products is particularly complicated and can be very technical from the point of view of professionals who are not specialised in it. In the absence of well-structured explanatory documents, the task of overseeing the transposition would be disproportionately time-consuming. The current proposal represents a review where the text of the Insurance Mediation Directives (IMD) was recasted. Even though many of the provisions have not changed as to their substance, a number of new provisions have been introduced, and a number of existing provisions have been revised or deleted. The structure, form, and presentation of the texts are completely new. The new structure has been necessary to give a clearer and more logical order to the legal provisions but it will result in the need for a structured approach during the transposition supervision.

Some of the provisions of the proposed Directive may potentially have an impact on a number of areas of the national legal order such as the company, commercial or tax law or other legislative areas in the Member States. It may also affect secondary national law including Acts and general conduct of business rules for Financial or Insurance Intermediaries. The interrelation of matters with all these neighbouring fields may mean, depending on the system in the Member States, that some provisions are implemented by means of new or already existing rules from those fields, a clear view of which should be available.

Consistency and interrelation with other initiatives:

The current proposal is tabled for adoption as part of a 'Consumer Retail Package' together with the PRIIPs proposal on product disclosures (Regulation on key information documents on investment products and amending Directives 2003/71/EC and 2009/65/EC) and UCITS V. The PRIIPs initiative aims at ensuring a coherent horizontal approach to product disclosure with regard to investment products and insurance products with investment elements (so-called insurance investments), and provisions on selling practices will be included in the revisions of the IMD and MiFID (Markets in Financial Instruments Directive). The proposal is furthermore consistent with, and complementary to, other EU legislation and policies, particularly in the areas of consumer protection, investor protection and prudential supervision, such as Solvency II (Directive 2009/138/EC), MiFID II (the recast of MiFID), and the above mentioned PRIIPs initiative.

The new IMD would continue to have the features of a "minimum harmonisation" legal instrument. This means that Member States may decide to go further if necessary for the purposes of consumer protection. However, the minimum standards of IMD will be raised

significantly. ■ Moreover, a revision clause is considered in the directive and, in order to be able to collect all relevant information on the functioning of those rules, the Commission will need to be able to monitor their implementation from the outset.

Chapter on insurance investment: The text of the proposal features a Chapter introducing additional customer protection requirements in relation to insurance investment products.

There is a strong political will to put such provisions in place but, at the same time, there is very little experience as this is a new area. Therefore, it is of high importance that the Commission receives transposition documents on how the Member States have given effect to such provisions.

The specificities of non-life insurance products must however be taken into account in the Level 2 guidelines. In line with the analogous principle in MIFID II Article 3, there should be considered an analogous regime for insurances when implementing the Directive at national level and in the joint committee's guidelines. Persons carrying out insurance mediation in relation to insurance investment products should comply with the conduct standards applicable to all insurance contracts as well as to the enhanced standards applicable to insurance investment products. Anyone intermediating in insurance investment products must be registered as an insurance intermediary.

Low estimated additional administrative burden stemming from requesting explanatory documents from Member States: As mentioned above, the current text has been in place since 2002 (when the original Directive was adopted). Therefore, it will not be burdensome for Member States to notify their implementing provisions as they have normally been notifying most of them for quite some time already. The estimated low additional administrative burden of requesting explanatory documents from Member States regarding the new parts of the Directive is proportionate and necessary for the Commission to carry out its task of overseeing the application of Union law.

On the basis of the above, the Commission believes that the requirement to provide explanatory documents in the case of the proposed Directive is proportionate and does not go beyond what is necessary to achieve the objective to carry out efficiently the task of overseeing accurate transposition.

Third programme for the Union's action in the field of health (2014-2020)

*****I**

European Parliament legislative resolution of 26 February 2014 on the proposal for a regulation of the European Parliament and of the Council establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 (COM(2011)0709 – C7-0399/2011 – 2011/0339(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0709),
- having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0399/2011),
- having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 35 thereof,
- having regard to its resolution of 9 October 2008 on "Together for Health: A Strategic approach for the EU 2008-2013"¹,
- having regard to the White paper - Together for Health: A strategic Approach for the EU 2008-2013 (COM (2007)0630),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 23 February 2012²,
- having regard to the opinion of the Committee of the Regions of 4 May 2012³,
- having regard to its resolution of 8 March 2011 on reducing health inequalities in the EU⁴,
- having regard to the undertaking given by the Council representative by letter of 20 November 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
- having regard to Rule 55 of its Rules of Procedure,

¹ OJ C 9 E, 15.1.2010, p. 56.

² OJ C 143, 12.5.2012, p. 102.

³ OJ C 225, 27.7.2012, p. 223.

⁴ OJ C 199 E, 7.7.2012, p. 25.

- having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Budgets and the Committee on Industry, Research and Energy (A7-0224/2012),
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.

Position of the European Parliament adopted at first reading on 26 February 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on *the establishment of a third Programme for the Union's action in the field of health* (2014-2020) and repealing Decision No 1350/2007/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 168 (5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national *parliaments*,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure³,

¹ OJ C 143, 22.5.2012, p. 102.

² OJ C 225, 27.7.2012, p. 223.

³ Position of the European Parliament of 26 February 2014.

Whereas:

- (1) ***In accordance with Article 168 of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities*** . The Union ***is to*** complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of the ***Member States for the definition of*** their health policies and the organisation and delivery of health services and medical care.
- (2) Continued effort is required in order to meet the requirements set out in Article 168 TFEU. ***The promotion of*** good health at ***Union*** level is ***also*** an integral part of ‘Europe 2020: A strategy for smart, sustainable and inclusive growth’ (“the Europe 2020 Strategy”). Keeping people healthy and active longer ***and empowering them to take an active role in managing their health,*** will have positive overall effects ***on health,*** ***including a reduction of health inequalities,*** and a positive impact ***on quality of life,*** on productivity and competitiveness, while reducing pressures on national budgets. ***Support for, and recognition of, innovation, which has an impact on*** health, helps ***to*** take up the challenge of sustainability in the health sector in the context of demographic change; and action to reduce inequalities in health is important for the purposes of achieving ‘inclusive growth’. It is appropriate in that context to establish the third ***Programme for the Union's action in the field of*** health (2014-2020) (the Programme’).

- (3) *According to the definition of the World Health Organisation (WHO), “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”. In order to improve the health of the population in the Union and reduce health inequalities, it is essential not to focus only on physical health. According to the WHO, mental health problems account for almost 40% of years lived with disability. Mental health problems are also wide-ranging, long-lasting and a source of discrimination, and contribute significantly to inequality in health. Moreover, the economic crisis affects factors determining mental health, as protective factors are weakened and risk factors increased.*

- (4) The previous programmes of Community action in the field of public health (2003-2008) and in the field of health (2008-2013), adopted respectively by Decisions *No* 1786/2002/EC¹ and 1350/2007/EC of the European Parliament and of the Council² (*"the previous health programmes"*), have been positively assessed as resulting in a number of important developments and improvements. The Programme should build on the achievements of the previous health programmes. It should also take into account the recommendations of the external audits and evaluations carried out, in particular recommendations of the Court of Auditors in its Special Report No 2/2009, according to which for the period after 2013, the European Parliament, the Council and the Commission should reconsider the scope for Union public health activities and the approach of Union funding in that area. This should be done bearing in mind the budgetary means available and the existence of other cooperation mechanisms ■ as a means of facilitating collaboration and the exchange of information among stakeholders throughout Europe.

¹ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (OJ L 271, 9.10.2002, p. 1).

² Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (OJ L 301, 20.11.2007, p. 3).

- (5) In line with the objectives of the Europe 2020 Strategy, the Programme should focus on a set of well-defined objectives and actions with clear, proven **Union** added value, and concentrate support on a smaller number of activities in priority areas. The emphasis **should** be placed, in accordance with the principle of subsidiarity, on areas where ■ there are clear cross-border or internal market issues at stake, or where there are significant advantages and efficiency gains from collaboration at **Union** level.
- (6) The **Programme should** be a means of promoting actions in areas where there is **a Union** added-value **that can be demonstrated** on the basis of the following ■ : **exchanging good** practices ■ between Member States; supporting networks for knowledge sharing or mutual learning; addressing cross-border threats to reduce their risks and mitigate their consequences; addressing certain issues relating to the **internal market** where the **Union** has substantial legitimacy to ensure high-quality solutions across Member States; unlocking the potential of innovation in health; actions that could lead to a system for benchmarking to allow informed decision-making at **Union** level; improving efficiency by avoiding a waste of resources due to duplication and optimising the use of financial resources.

- (7) *The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.*
- (8) The ■ WHO ■ European Health Report 2009 identifies scope for increasing investment in public health and health systems. In that regard, Member States are encouraged to identify health improvement as a priority in their national programmes and to benefit from better awareness of the possibilities of *Union* funding for health. Therefore, the Programme should facilitate the uptake of its results into national health policies.
- (9) Innovation in health *should be understood as a public health strategy which is not limited to technological advances* in terms of products and services ■ . *Fostering innovation in the field of public health interventions, prevention strategies, health system management and in the organisation and provision of health services and medical care, including health promotion and disease prevention interventions*, has the potential to *improve public health outcomes*, enhance the quality of care to patients and respond to unmet needs, *and also to foster the competitiveness of stakeholders and to improve* the cost-efficiency and sustainability of *health services and medical care*. Therefore, the Programme should facilitate the *voluntary* uptake of innovation in *health, taking into account the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006*¹.

¹ Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

- (10) The Programme should, *in particular in the context of the economic crisis*, contribute to addressing health inequalities *and the promotion of equity and solidarity* through *actions* under the different objectives and by encouraging and facilitating the exchange of good practices ■ .
- (11) *Pursuant to Articles 8 and 10 TFEU, the Union is to promote equality between men and women and aim to combat discrimination. Accordingly, the Programme should support the mainstreaming of gender equality and anti-discrimination objectives in all its actions.*
- (12) ■ Patients need to be empowered, *inter alia by enhancing health literacy*, to manage their health and their healthcare more pro-actively, *to prevent poor health and make informed choices*. The transparency of healthcare activities and systems and the availability of *reliable, independent and user-friendly* information to patients should be optimised. Healthcare practices should be informed by feedback from, and communication with, patients. Support for Member States, patient organisations and stakeholders is essential and should be coordinated at *Union* level in order to help patients in an effective manner, in particular those affected by rare diseases, to benefit from cross-border healthcare.

- (13) *Reducing the burden of resistant infections and healthcare associated infections and securing the availability of effective antimicrobials is essential for the efficiency of health systems and for the safety of patients. The Programme should support sustained efforts to improve methods of analysis to detect and prevent antimicrobial resistance and improve networking among all healthcare actors, including the veterinary sector, in relation to dealing with antimicrobial resistance.*
- (14) In the context of an ageing society, well-directed investments to promote health and prevent diseases can increase the number of ‘healthy life years’ and thus enable the elderly to *enjoy a healthy and active life* as they *get* older. Chronic diseases are responsible for over 80 % of premature mortality in the *Union*. *The Programme should identify, disseminate and promote* the uptake of *evidence-based and good* practices for cost-effective *health promotion and disease* prevention measures focused *in particular* on the key risk factors, such as *tobacco use, drug use, harmful use* of alcohol and *unhealthy dietary habits*, obesity *and physical inactivity*, as well as on HIV/AIDS, *tuberculosis and hepatitis*. Effective prevention would contribute to increasing the financial sustainability of healthcare systems. *Operating within a gender sensitive framework, the Programme should contribute to disease prevention in all its aspects (primary, secondary and tertiary prevention) and throughout the lifetime of the Union's citizens, to health promotion and the fostering of supportive environments for healthy lifestyles, taking into account* underlying factors of a social and environmental nature *as well as the impact on health of certain disabilities*.

- (15) In order to minimise the public health consequences of cross-border threats to health as set out in Decision No 1082/2013/EU of the European Parliament and of the Council¹, which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E. coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome), *or health effects resulting from increasing population movements*, the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect, assess and manage major cross-border health threats. Due to the nature of *those* threats, the Programme should support coordinated public health measures at *Union* level to address different aspects of cross-border health threats, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In that context, it is important that the *Programme* benefit from complementarity with the work programme of the European Centre for disease prevention and control, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council², in the fight against communicable diseases and the activities supported under the *Union* programmes for research and innovation. Special efforts should be undertaken to ensure coherence and synergies between the Programme and global health work carried out under other *Union* programmes and instruments that address, in particular, the areas of influenza, HIV/AIDS, tuberculosis and other cross-border health threats in third countries.

¹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

² Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

- (16) It should be possible for action under the Programme to also cover cross-border health threats caused by biological and chemical incidents, environment and climate change. As stated in the Commission's Communication "A Budget for Europe 2020", the Commission has committed to mainstreaming climate change into overall Union spending programmes and to direct at least 20 % of the Union budget to climate-related objectives. Spending in the ■ Programme under the specific objective *related to serious cross-border health threats should* contribute in a general manner to *those* objectives by addressing health threats associated with climate change. The Commission *should* provide information on climate change expenditure within the ■ Programme.
- (17) In accordance with *Article 114 TFEU*, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. In line with that objective, the Programme should undertake special efforts to support actions required by, and contributing to, the aims of *Union* legislation in the fields of communicable diseases and other health threats, human tissues and cells, blood, human organs, medical devices, medicinal products, patients' rights in cross-border healthcare, and tobacco products and tobacco advertising.
- (18) The Programme *should* contribute to evidence-based decision-making by fostering a health information and knowledge system, *taking into account relevant activities carried out by international organisations, such as the WHO and the Organisation for Economic Cooperation and Development (OECD). That system should consist of, inter alia, the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, support to the Scientific* Committees set up in accordance with Commission Decision 2008/721/EC¹ and ■ -the wide dissemination of the results of the Programme.

¹ Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (OJ ■-L 241, 10.9.2008, p. 21).

- (19) *Union policy in the field of health is aimed at complementing and supporting national health policies, encouraging cooperation between Member States and promoting the coordination between their programmes. The exchange of good practices is a key instrument of that policy. Such exchange should enable national authorities to benefit from efficient solutions developed in other Member States, reduce duplication of efforts and increase value for money by promoting innovative solutions in the field of health. Therefore, the Programme should focus mainly on cooperation with **the** competent authorities that are responsible for health in **the Member States** and provide incentives for **a wider** participation of all Member States as recommended in the evaluations of the previous health programmes.* In particular, **█** *Members States whose Gross National Income (GNI) per inhabitant is lower than 90 % of the Union average should be actively encouraged to participate in actions co-financed by the competent authorities that are responsible for health in **the Member States** or by bodies mandated by those competent authorities. Such actions should be considered to be of exceptional utility and, in particular, respond to the objective of facilitating the participation of Member States whose GNI per inhabitant is lower than 90 % of the Union average and making that participation wider. Further and appropriate non-financial support for the participation of those Member States in such actions, for example in terms of the application process, transfer of knowledge and uptake of expertise, should also be considered.*

- (20) Non-governmental bodies and health stakeholders, in particular patients' organisations and health professionals' associations, play an important role in providing the Commission *with* the information and advice necessary to implement the *Programme*. In *doing so*, it is possible that they would require contributions from the Programme to enable them to function. That is why the *Programme should* be accessible to *non-governmental bodies* and patient organisations working in the public health area, which play an effective role in civil dialogue processes at *Union* level, such as participation in consultative groups, and in that way contribute to pursuing the specific objectives *of the Programme*.
- (21) The Programme should promote synergies, while avoiding duplication with related Union programmes and actions, *by promoting, where relevant, the uptake of innovative breakthroughs resulting from research in the health sector*. Appropriate use should be made of other Union funds and programmes, in particular the Framework Programme for Research and Innovation 2014-2020 (*Horizon 2020*), established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council¹, and its outcomes, the Structural Funds, the Programme for Employment and Social Innovation, established by Regulation (EU) No 1296/2013 of the European Parliament and of the Council², the European Union Solidarity Fund, established by Council Regulation (EC) No 2012/2002³, the Union strategy on health and safety at work (2007-2012), the Programme for the Competitiveness of Enterprises and small and medium sized enterprises (COSME), established by Regulation (EU) No 1287/2013 of the European Parliament and of the Council⁴, the Programme for Environment and Climate Action (LIFE), established by Regulation (EU) No

¹ Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014–2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

² Regulation (EU) No 1296/2013 of the European Parliament and of the Council of 11 December 2013 on a European Union Programme for Employment and Social Innovation ("EaSI") and amending Decision No 283/2010/EU establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 347, 20.12.2013, p. 238).

³ Council Regulation (EC) No 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund (OJ L 311, 14.11.2002, p. 3).

⁴ Regulation (EU) No 1287/2013 of the European Parliament and of the Council of 11 December 2013 establishing a Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (COSME) (2014 - 2020) and repealing Decision No 1639/2006/EC (OJ L 347, 20.12.2013, p. 33).

1293/2013 of the European Parliament and of the Council¹, the Consumer Programme, the Justice Programme, established by Regulation (EU) 1382/2013 of the European Parliament and of the Council², the Ambient Assisted Living Joint Programme, the programme for education, training, youth and sport (Erasmus+), established by Regulation (EU) No 1288/2013 of the European Parliament and of the Council³, the European Statistical Programme, established by Regulation (EU) No 99/2013 of the European Parliament and of the Council⁴ **and the European Innovation Partnership on Active and Healthy Ageing**, within their respective activities.

¹ Regulation (EU) No 1293/2013 of the European Parliament and of the Council of 11 December 2013 on the establishment of a Programme for the Environment and Climate Action (LIFE) and repealing Regulation (EC) No 614/2007 (OJ L 347, 20.12.2013, p. 185).

² Regulation (EU) No 1382/2013 of the European Parliament and of the Council of 17 December 2013 establishing a Justice Programme for the period 2014 to 2020 (OJ L 354, 28.12.2013, p. 73).

³ Regulation (EU) No 1288/2013 of the European Parliament and of the Council of 11 December 2013 establishing "Erasmus+": the Union programme for education, training, youth and sport and repealing Decisions No 1719/2006/EC, No 1720/2006/EC and No 1298/2008/EC (OJ L 347, 20.12.2013, p. 50).

⁴ Regulation (EU) No 99/2013 of the European Parliament and of the Council of 15 January 2013 on the European statistical programme 2013-17 (OJ L 39, 9.2.2013, p. 12).

- (22) In accordance with Article 168(3) *TFEU*, the Union and the Member States are to foster cooperation with third countries and the competent international organisations in the sphere of public health. The ***Programme*** should therefore be open to the participation of third countries, in particular of acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, European Free Trade Association (EFTA)/European Economic Area (EEA) countries, neighbouring countries and the countries to which the European Neighbourhood Policy (ENP) applies, and other countries in accordance with the conditions laid down by any relevant bilateral or multilateral agreement.
- (23) Appropriate relations with third countries not participating in the ***Programme*** should be facilitated in order to help achieve the objectives of the Programme, taking *into* account any relevant agreements between those countries and the Union. This could involve ***the Union organising*** health events or third countries undertaking activities, which are complementary to those financed under the ***Programme***, in areas of mutual interest, but should not involve a financial contribution under the Programme.

- (24) In order to maximise the effectiveness and efficiency of actions at Union and international level, *and with a view to implementing the Programme*, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the **WHO**, as well as with the Council of Europe and the **OECD**.
- (25) The Programme should run for a period of seven years to align its duration with that of the Multiannual Financial Framework as set out in ■ Council Regulation (EU, Euratom) No 1311/2013¹. This Regulation lays down ■ a financial envelope *for the entire duration of the Programme which is to constitute* the prime reference amount, within the meaning of Point 17 of the *Interinstitutional* Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management² ■ , for the European Parliament and the Council during the annual budgetary procedure.

¹ Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884).

² OJ C 373, 20.12.2013, p. 1.

- (26) In accordance with Article **54** of Regulation (*EU, Euratom*) No **966/2012** of the European *Parliament and of the Council*¹, this Regulation provides the legal basis for the action and for the implementation of the ■ Programme.
- (27) In order to ensure continuity in the financial support provided under the Programme to the functioning of bodies, the Commission should be able, in the annual work programme for 2014, to consider the costs directly linked to the implementation of the supported activities to be eligible for financing, even if they were incurred by the beneficiary before the financing application was submitted.
- (28) In order to ensure uniform conditions for the implementation of this Regulation by means of annual work programmes, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council².

¹ *Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. ■-1).*

² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p 13).

- (29) The Programme should be implemented in full respect of the principle of transparency **■**. *Budgetary resources should be shared between the different objectives of the Programme in a balanced way throughout the duration of the Programme, taking into account the probable advantages for promoting health.* Appropriate actions covered by the **■** specific objectives *of the Programme* and with a clear **■-Union** added value should be selected and funded by the Programme. The annual work programmes should set out, in particular, the essential selection criteria applicable to the potential beneficiaries, in accordance with **■** Regulation (EU, Euratom) No **966/2012**, in order to ensure they have the financial and operational capacity to undertake actions financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.
- (30) The value and impact of the Programme should be regularly monitored and evaluated. Its evaluation should take into account the fact that the achievement of the Programme's objectives could require a longer time period than its duration. *Half way through the duration of the Programme, but not later than 30 June 2017, the mid-term evaluation report should be drawn up in order to assess the state-of-play of the implementation of thematic priorities of the Programme.*

- (31) In order for the Programme to benefit fully from the findings of the mid-term evaluation report on its implementation and to allow for possible adjustments necessary for achieving its objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in order to remove any of the thematic priorities set out in this Regulation or to include new thematic priorities in this Regulation. It is of particular importance that the Commission carry out appropriate consultations during *its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.*
- (32) The cooperation of national authorities is essential in sharing information with potential applicants to allow equitable participation in the Programme, and knowledge produced by the Programme with the different national health sector stakeholders.
■ Thus, National Focal Points should be designated by the Member States in order to support *those* activities.
- (33) *In the application of the Regulation, the Commission should consult the relevant experts, including National Focal Points.*
- (34) The financial interests of the ■ Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, penalties.

- (35) A transition should be ensured between the **Programme** and the previous programme it replaces, in particular regarding the continuation of multiannual arrangements for its management, such as the financing of technical and administrative assistance. As of 1 January 2021, the technical and administrative assistance appropriations should cover, if necessary, the expenditure related to the management of actions not yet completed by the end of 2020.
- (36) *Since the general objectives of this Regulation, namely to complement, support and add value to the policies of the Member States to improve the health of the population in the Union and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems, and protecting Union citizens from serious cross-border health threats, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of this Regulation, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.*
- (37) This Regulation replaces Decision No 1350/2007/EC. That Decision should therefore be repealed ■ .

- (38) *It is appropriate to ensure a smooth transition without interruption between the previous programme in the field of health (2008-2013) and the Programme and to align the duration of the Programme with Regulation (EU, Euratom) No 1311/2013. Therefore, the Programme should apply as from 1 January 2014,*

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Establishment of the Programme

This Regulation establishes *the* third multi-annual programme for Union action in the field of health ■ for ■ the period from 1 January 2014 to 31 December 2020 (■ "the Programme").

Article 2

General objectives

The general objectives of the ■ Programme shall be to *complement, support and add value to the policies of* the Member States to *improve the health of Union citizens and reduce health inequalities by promoting health, encouraging* innovation in *health, increasing* the sustainability of health systems ■ *and protecting Union* citizens from *serious* cross-border health threats.

Chapter II

Objectives and actions

Article 3

Specific objectives and indicators

The general objectives referred to in Article 2 shall be pursued through the following specific objectives:

- (1) *In order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles: identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value.*

This objective shall be measured, in particular, through the increase in the number of Member States involved in health promotion and disease prevention, using evidence-based and good practices through measures and actions taken at the appropriate level in Member States.

- (2) *In order to protect Union citizens from serious cross-border health threats: identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies.*

This objective shall be measured, in particular, through the increase in the number of Member States integrating coherent approaches in the design of their preparedness plans.

- (3) *In order to support public health capacity-building and contribute to innovative, efficient and sustainable health systems: identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and to facilitate the voluntary uptake of innovations in public health intervention and prevention strategies.*

This objective *shall* be measured, in particular, through the increase *in the advice produced and the* number of Member States using the ■ tools and mechanisms *identified in order to contribute to effective results in their health systems.*

- (4) ***In order to facilitate access to better and safer healthcare for Union citizens: increase*** access to medical expertise and information for specific conditions beyond national borders, ***facilitate the application of the results of research*** and **■** develop ***tools for the improvement of*** healthcare quality and patient safety ***through, inter alia, actions contributing to the improvement of health literacy.***

This objective shall be measured, in particular, through the increase ***in the*** number of **■** European reference networks ***established in accordance with*** Directive 2011/24/EU ***of the European Parliament and of the Council***¹ ("European reference networks"), the increase ***in the number of healthcare providers and centres of expertise joining European reference networks***, and the increase ***in the*** number of Member States using the ***tools*** developed.

■

Article 4

Eligible actions

The ***specific*** objectives of the Programme shall be achieved through actions ***in line with the thematic priorities listed in Annex I and implemented via the annual work programmes*** referred to in Article ***11***.

■

¹ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (***OJ L 88, 4.4.2011, p. 45***).

Chapter III

Financial provisions

Article 5

Funding

The financial *envelope* for the implementation of the Programme for the period from 1 January 2014 to 31 December 2020 shall be EUR **449 394 000** in current prices.

The annual appropriations shall be authorised by the European Parliament and the Council within the limits of the multiannual financial framework.

Article 6

Participation of third countries

■ The Programme shall be open, on a cost basis, to the participation of third countries, in particular:

- (a) acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, in accordance with the general principles and general terms and conditions for their participation in Union programmes established in the respective Framework Agreements, Association Council Decisions or similar agreements;
- (b) EFTA/EEA countries in accordance with the conditions established in the EEA Agreement;

- (c) neighbouring countries and the countries to which, in accordance with the conditions laid down by a relevant bilateral or multilateral agreement, the ENP applies;
- (d) other countries in accordance with the conditions laid down by a relevant bilateral or multilateral agreement.

Article 7

Types of intervention

1. In accordance with Regulation (EU, Euratom) No 966/2012, financial contributions by the Union *shall* take the form of grants, public procurement or any other form of intervention necessary for achieving the objectives of the Programme.
2. Grants may be awarded to fund:
 - (a) actions having a clear *Union* added value co-financed by the competent authorities that are responsible for health in the Member States or in the third countries participating in the Programme pursuant to Article 6, or by *public sector bodies and non-governmental bodies, as referred to in Article 8(1), acting individually or as a network*, mandated by *those* competent authorities;
 - (b) actions having a clear *Union* added value *explicitly provided for and duly justified in the annual work programmes* co-financed by other public, *non-governmental* or private bodies, as referred to in Article 8(1), including international organisations active in the area of health and, *in the latter case*, where appropriate, without *a* previous call for *proposals*;
 - (c) the functioning of non-governmental bodies as referred to in Article 8(2), where financial support is necessary *for* the pursuit of one or more of the specific objectives of the Programme.

3. Grants paid by the Union shall not exceed ■ 60 % of eligible costs for an action relating to an objective of the Programme *or* for the functioning of a non-governmental body. In cases of exceptional utility, *the* contribution *by the Union may be* up to ■ 80 % of eligible costs ■ .

For the actions referred to in point (a) of paragraph 2, *exceptional utility is achieved, inter alia, where:*

- (a) *at least 30 % of the budget of the proposed action is allocated to* Member States whose GNI per inhabitant is less *than* 90 % *of the Union average; and*
- (b) *bodies from at least 14 participating countries participate in the action, out of which at least four are countries whose GNI per inhabitant is less than 90 % of the Union average.*
4. *By way of derogation from Article 130(2) of Regulation (EU, Euratom) No 966/2012 and in duly justified cases, the Commission may, in the annual work programme for 2014, consider the costs directly linked to the implementation of supported actions to be eligible for financing from 1 January 2014, even if they were incurred by the beneficiary before the grant application was submitted.*

Article 8

Beneficiaries eligible for grants

1. The grants for actions referred to under Article 7(2)(a) and (b) may be awarded to legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments ■ .
2. The grants for the functioning of bodies referred to under Article 7(2)(c) may be awarded to bodies which fulfil all the following criteria:
 - (a) *they* are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;
 - (b) *they* work in the public health area, play an effective role in civil dialogue processes at *Union* level and pursue at least one of the specific objectives of the Programme;
 - (c) *they* are active at Union level and in at least half of the Member States, and have a balanced geographical coverage of the Union.

Article 9

Administrative and technical assistance

The financial *envelope* for the Programme may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities required directly for the management of the Programme and the achievement of its objectives, in particular studies, meetings, information and communication actions, including corporate communication of the political priorities of the Union in so far as they are related to the general objectives of the *Programme*, expenses pertaining to IT networks focusing on information exchange, as well as all other technical and administrative assistance expenses incurred by the Commission for the management of the Programme.

Chapter IV

Implementation

Article 10

Methods of implementation

The Commission shall be responsible for the implementation of the Programme in compliance with the management modes set out in ■ -Regulation (*EU, Euratom*) No 966/2012.

Article 11

Annual work programmes

1. The Commission shall implement the Programme by establishing annual work programmes *in accordance with Regulation (EU, Euratom) No 966/2012 and the criteria set out in Annex II to this Regulation.*
-
2. *The Commission shall adopt, by means of implementing acts, annual work programmes which shall set out, in particular, actions to be undertaken, including the indicative allocation of financial resources.* Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17(2).
3. In implementing the Programme, the Commission, together with the Member States, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

Article 12

Consistency and complementarity with other policies

The Commission shall, in cooperation with the Member States, ensure overall consistency and complementarity between the Programme and other policies, instruments and actions of the Union, *including those of the relevant Union agencies*.

Article 13

Monitoring, evaluation and dissemination of results

1. The Commission shall, in close cooperation with the Member States, monitor the implementation of the actions under the **Programme** in the light of its objectives and indicators, including **available** information on the amount of climate-related expenditure. It shall report thereon to the committee referred to in Article **17(1)**, and shall keep the European Parliament and the Council informed.
2. At the request of the Commission, **Member States shall submit available information** on the implementation and impact of the Programme. ***Such requests for information shall be proportionate and shall avoid imposing any unnecessary increase in the administrative burden on Member States.***

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3. *Half way through the duration of the Programme, but not later than 30 June 2017, the Commission shall draw up and present to the European Parliament and to the Council a mid-term evaluation report [] on the achievement of the objectives of the Programme [], the state-of-play regarding the implementation of the thematic priorities set out in Annex I, and the efficiency of the use of resources and the Union added value of the Programme, in view of a decision on the renewal, modification or suspension of its thematic priorities. The mid-term evaluation report shall, additionally, address the scope for simplification, the internal and external coherence of the Programme, the continued relevance of all objectives, as well as the contribution of the actions to the achievement of the objectives set out in Article 168 TFEU. It shall take into account evaluation results on the long-term impact of the previous programme.*

In the mid-term evaluation report, the Commission shall, in particular, indicate the following:

- (a) if it is not possible to implement and achieve one or more of the thematic priorities listed in Annex I in line with the objectives of the Programme and within the remaining duration of the Programme;*
- (b) whether the evaluation identified one or more specific, significant thematic priorities which are not listed in Annex I, but which have become necessary to achieve the general and specific objectives of the Programme;*

(c) *the reasons for the conclusions referred to in points (a) and (b).*

The long-term impact and the sustainability of effects of the ■ Programme *shall* be evaluated with a view to feeding into a decision on *the* possible renewal, modification or suspension of a subsequent programme.

4. The Commission shall make the results of actions undertaken pursuant to this Regulation publicly available and shall ensure that they are widely disseminated *in order to contribute to improving health in the Union.*

Article 14

Follow-up to the mid-term evaluation report

1. *Where the mid-term evaluation report identifies that one or more thematic priorities cannot be implemented and achieved in line with the objectives of the Programme and within the duration of the Programme, the Commission shall be empowered to adopt, by 31 August 2017, delegated acts in accordance with Article 18 in order to remove the thematic priority or priorities concerned from Annex I. Only one delegated act removing one or more thematic priorities may enter into force pursuant to Article 18 throughout the duration of the Programme.*

2. *Where the mid-term evaluation report identifies one or more specific, significant thematic priorities which are not listed in Annex I, but which have become necessary to achieve the general and specific objectives of the Programme, the Commission shall be empowered to adopt, by 31 August 2017, delegated acts in accordance with Article 18 in order to add the thematic priority or priorities concerned to Annex I. A thematic priority shall be achievable within the duration of the Programme. Only one delegated act adding one or more thematic priorities may enter into force pursuant to Article 18 throughout the duration of the Programme.*
3. *Any such removal or addition of thematic priorities shall be in line with the general objectives and with the relevant specific objectives of the Programme.*

Article 15

National Focal Points

Member States shall designate National Focal Points which shall assist the Commission in the promotion of the Programme *and, as appropriate*, the dissemination of the results of the Programme and the available information on the impact *of* the Programme ■ as referred to in Article 13(2).

Article 16

Protection of the financial interests of the ■ Union

1. The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the ■ Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by *dissuasive administrative and financial* penalties.
2. The Commission, or its representatives, and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds *under this Regulation*.

3. The European Anti-Fraud Office (OLAF) may carry out *investigations, including* on-the-spot checks and inspections ■ in accordance with the *provisions and* procedures laid down in Regulation (EU, Euratom) No 883/2013 *of the European Parliament and of the Council*¹ and Council Regulation (Euratom, EC) No 2185/96² with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the ■ Union in connection with a grant agreement or grant decision or a contract *funded under this Regulation*.
4. Without prejudice to *paragraphs 1, 2* and *3*, cooperation agreements with third countries and *with* international organisations, *contracts*, grant agreements and grant decisions ■ resulting from the implementation of this Regulation shall *contain provisions* expressly *empowering* the Commission, the Court of Auditors and OLAF to conduct such audits and *investigations, in accordance with their respective competences*.

¹ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

² Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (*OJ L 292, 15.11.1996, p. 2*).

Chapter V

Procedural provisions

Article 17

Committee procedure

1. The Commission shall be assisted by a committee. *That committee shall be a committee* within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to *this* paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. *Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.*

Article 18

Exercise of the delegation

1. *The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.*

2. *The power to adopt delegated acts referred to in Article 14(1) and (2) shall be conferred on the Commission for the duration of the Programme.*
3. *The delegation of power referred to in Article 14(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated act already in force.*
4. *As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*
5. *A delegated act adopted pursuant to Article 14(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.*

Chapter VI

Transitional and final provisions

Article 19

Transitional provisions

1. The financial *envelope* for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the Programme and the measures adopted under Decision No 1350/2007/EC.
2. If necessary, appropriations may be entered in the budget beyond 2020 to cover the expenses provided for in Article 9, to enable the management of actions not completed by 31 December 2020.

Article 20

Repeal

Decision No 1350/2007/EC shall be repealed with effect from 1 January 2014.

Article 21

Entry into force

This Regulation shall enter into force on the ■ day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

ANNEX I

THEMATIC PRIORITIES


1. ***Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle***
- 1.1. ***Cost-effective promotion and prevention measures in line, in particular, with the Union strategies on alcohol and nutrition, and including actions to support the exchange of evidence-based and good practices for addressing risk factors such as tobacco use and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity, taking into account the public health aspects of underlying factors, such as those of a social and environmental nature, with a focus on Union added value.***
- 1.2. ***Measures to complement the Member States' action in reducing drug-related health damage, including information and prevention.***
- 1.3. ***Support effective responses to communicable diseases such as HIV/AIDS, tuberculosis and hepatitis by identifying, disseminating and promoting the uptake of evidence-based and good practices for cost effective prevention, diagnosis, treatment and care.***

- 1.4. Support cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases including cancer, ***age-related diseases and neurodegenerative diseases***, by sharing knowledge, good practices and developing joint activities on prevention, ***early detection and management (including health literacy and self management)***. ***Follow up*** work on ***cancer which has*** already been undertaken, ***including relevant actions suggested by the European Partnership Action against Cancer***.
- 1.5. Actions required by, or contributing to, the implementation of Union legislation in the field of tobacco products, advertising ***and marketing***. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.
- 1.6. Foster a health ***information and knowledge*** system to contribute to evidence-based decision-making, including ***the use of existing instruments and, where appropriate, further development of standardised health information and tools for monitoring health***, collection and analysis of health data, and the wide dissemination of the results of the Programme.
2. ***Protect Union citizens from serious cross-border health threats***
- 2.1. ***Improve risk assessment and*** close gaps in risk assessment capacities by providing additional capacities for scientific expertise, and map existing assessments ■ .

- 2.2. Support capacity-building against health threats in Member States, *including, where appropriate, cooperation with neighbouring countries*; develop preparedness and response planning *taking into account, and coordinating with, global initiatives, components of generic and specific preparedness planning*, public health response coordination, *non-binding* approaches on vaccination; *address the increasing health threats resulting from global population movements*; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; *contribute to the framework for a voluntary mechanism, including the introduction of optimal vaccination coverage to effectively combat the resurgence in infectious diseases and for* joint procurement of medical countermeasures; develop *coherent* communication strategies.
- 2.3. Actions required by, or contributing to, the implementation of Union legislation in the fields of communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change. Such action may include activities aimed at *facilitating* the implementation, application, monitoring and review of that legislation.
- 2.4. Foster a health *information and* knowledge system to contribute to evidence-based decision-making, including *the use of existing instruments and, where appropriate, further development of standardised health information and tools for monitoring health*, collection and analysis of health data, and the wide dissemination of the results of the Programme.

3. ***Contribute to innovative, efficient and sustainable health systems***
- 3.1. ***Support voluntary cooperation between Member States*** on health technology assessment under the **■** network on health technology assessment set up by Directive 2011/24/EU. Facilitate the uptake of the results streaming from research projects supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), adopted by Decision No 1982/2006/EC of the European Parliament and of the Council¹, and, in the long term, the activities which will be undertaken in the Framework Programme for Research and Innovation (Horizon 2020).
- 3.2. ***Promote the voluntary uptake of health innovation and e-Health*** by increasing the interoperability of patient ***registries*** and other e-Health solutions; support cooperation on e-Health in the Union, in particular on registries, and its uptake by health professionals. This will serve the voluntary network on e-Health set up by Directive 2011/24/EU.
- 3.3. ***Support the sustainability of the health workforce by developing*** effective health workforce forecasting and planning in terms of numbers, ***gender equality***, scope of practice and ***the extent to which training matches the requisite skills, including the ability to make use of new information systems and other advanced technologies***, monitor mobility (within the Union) and migration of health professionals, ***foster*** efficient recruitment and retention strategies and capacity development, ***taking due account of issues of dependency and population ageing***.

¹ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

- 3.4. *Provide expertise and share good practices to assist Member States undertaking* health system reforms *by setting* up a mechanism for pooling expertise at Union level, to provide sound and evidence-based advice on effective and efficient investment *and innovation* in public health and health systems. Facilitate the uptake of the results streaming from research projects supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and, in the long term, the activities which will be undertaken in the Framework Programme for Research and Innovation (Horizon 2020).
- 3.5. *Support actions which address health issues in an ageing society, including relevant actions suggested by* the European Innovation Partnership on Active and Healthy Ageing in its three themes: innovation in awareness, prevention and early diagnosis innovation in cure and care and innovation in active ageing and independent living.
- 3.6. Actions required by or contributing to the implementation of Union legislation in the field of medical devices, *medicinal products* and cross-border healthcare . Such action may include activities aimed at *facilitating* the implementation, application, monitoring and review of that legislation.

- 3.7. Foster a health *information and* knowledge system to contribute to evidence-based decision-making, *including the use of existing instruments, further development, where appropriate, of standardised health information and tools for monitoring health, collection and analysis of health data, the wide* dissemination of the results of the Programme, and support to the Scientific Committees set up in accordance with Decision 2008/721/EC.
4. *Facilitate* access to better and safer healthcare for *Union* citizens
- 4.1. *Support* the establishment of a system of European reference networks ■ for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, as in the case of rare diseases, on the basis of criteria to be established under Directive 2011/24/EU.
- 4.2. *Support* Member States, patient organisations and stakeholders by coordinated action at Union level in order to effectively help patients affected by rare diseases. This includes the creation of reference networks (in compliance with point 4.1), *Union wide* information *databases* and registries for rare diseases based on ■ common criteria ■ .

- 4.3. ***Strengthen*** collaboration on patient safety and quality of healthcare, through, *inter alia*, implementing the Council Recommendation of 9 June 2009 on patient safety, ***including*** the prevention and control of healthcare-associated infections¹; exchange good practices on quality assurance systems; develop guidelines and tools to promote ***quality and*** patient safety ■ ; increase the availability of information to patients on safety and quality, improve feedback and interaction between health providers and patients ■ .
- 4.4. ***In line with the Action Plan against the rising threats from antimicrobial resistance***, improve the prudent use of antimicrobial agents ■ and reduce the practices that increase antimicrobial resistance, ***particularly in hospitals; promote effective prevention and hygiene measures to prevent and control infections***; reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials.
- 4.5. Actions required by, or contributing to, the implementation of Union legislation in the fields of human tissues and cells, blood, human organs, ***medical devices***, medicinal products, and patients' rights in cross-border healthcare, ***while fully respecting the competences and ethical choices of Member States in those fields***. Such action may include activities aimed at ***facilitating*** the implementation, application, monitoring and review of that legislation.
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- 4.6. ***Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, and the wide dissemination of the results of the Programme.***

¹ ***OJ C 151, 3.7.2009. p. 1.***

ANNEX II

CRITERIA FOR ESTABLISHING ANNUAL WORK PROGRAMMES

The annual work programmes shall be established in accordance with the following criteria for the duration of the Programme:

- the relevance of proposed actions for the objectives set out in Articles 2 and 3 and for the thematic priorities set out in Annex I and for the EU Health Strategy "Together for Health";*
- the Union added value of the proposed actions in line with the thematic priorities in Annex I;*
- the public health relevance of proposed actions, in terms of promoting health and preventing diseases, protecting Union citizens from health threats and in terms of improving the performance of health systems;*
- the relevance of the proposed actions to supporting the implementation of Union health legislation;*
- the pertinence of the geographical coverage of the proposed actions;*
- the balanced distribution of budgetary resources between the different objectives of the Programme, taking into account the probable advantages for promoting health;*
- the adequate coverage of the thematic priorities set out in Annex I.*