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I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 304/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 9 March 2011****amending Council Regulation (EC) No 708/2007 concerning use of alien and locally absent species in aquaculture**

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 43(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinions of the European Economic and Social Committee ⁽¹⁾,

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

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Council Regulation (EC) No 708/2007 ⁽³⁾ establishes a framework governing aquaculture practices in relation to alien and locally absent species to assess and minimise the possible impact of those species and of associated non-target species on aquatic habitats. It provides that introductions and translocations for use in closed aquaculture facilities may at a future date be exempted from the permit requirement of Chapter III of that Regulation, based on new scientific information and advice.

⁽¹⁾ OJ C 354, 28.12.2010, p. 88, and OJ C 51, 17.2.2011, p. 80.

⁽²⁾ Position of the European Parliament of 23 November 2010 (not yet published in the Official Journal) and decision of the Council of 21 February 2011.

⁽³⁾ OJ L 168, 28.6.2007, p. 1.

- (2) The Community-funded concerted action, entitled 'Environmental impacts of alien species in aquaculture' (IMPASSE), has delivered a new operational definition of 'closed aquaculture facilities'. For facilities according to that definition, the degree of risk associated with alien and locally absent species can be reduced to an acceptable level if the potential for escape of the organisms to be farmed and of non-target organisms is addressed during transportation and if well-defined protocols are applied at the receiving facility. Introductions and translocations for use in closed aquaculture facilities should only be exempted from the permit requirement if those conditions are met.

- (3) It is therefore necessary to amend the definition of 'closed aquaculture facility' in Regulation (EC) No 708/2007 by adding specific features intended to ensure the biosecurity of those facilities.

- (4) Member States should draw up a list of closed aquaculture facilities located in their territory. For reasons of transparency, that list should be published and regularly updated on a website set up in accordance with Commission Regulation (EC) No 535/2008 of 13 June 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 708/2007 concerning use of alien and locally absent species in aquaculture ⁽⁴⁾.

- (5) Following these amendments certain other adaptations are needed to Regulation (EC) No 708/2007, in particular, to remove the references to 'closed aquaculture facilities' in the definition of 'routine movement' and from Annex I.

⁽⁴⁾ OJ L 156, 14.6.2008, p. 6.

- (6) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) in order to adapt Annexes I, II and III to technical and scientific progress, to amend Annex IV in order to add species to that Annex and to adopt specifications for the conditions necessary for adding species to Annex IV. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (7) The measures necessary for the implementation of this Regulation should be adopted by the Commission by means of implementing acts in accordance with Article 291 TFEU.
- (8) The term 'Community' used in the enacting terms of Regulation (EC) No 708/2007 should be changed, following the entry into force of the Treaty of Lisbon on 1 December 2009.
- (9) Regulation (EC) No 708/2007 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 708/2007 is hereby amended as follows:

1. in Article 2(1), in the title of Article 13, in Article 15(2) and in the title of Article 19, the noun 'Community', or the corresponding adjective, is replaced by the noun 'Union', or the corresponding adjective, and any grammatical adjustments needed as a consequence of this replacement shall be made;
2. Article 2 is amended as follows:
 - (a) in paragraph 5, the first sentence is replaced by the following:

'5. This Regulation, except for Article 3, Article 4(1) and Article 4(2)(a), shall not apply to the species listed in Annex IV.;
 - (b) paragraph 7 is replaced by the following:

'7. Chapters III to VI shall not apply to movements of alien or locally absent species to be held in closed aquaculture facilities, provided that the transport is carried out under conditions that prevent the escape of those species and of the non-target species.

Member States shall draw up a list of closed aquaculture facilities in their territory that comply with the definition in Article 3(3) and update that list regularly. By 25 October 2011, the list shall be published on the website set up in accordance with Article 4(2) of

Commission Regulation (EC) No 535/2008 (*) which lays down detailed rules for the implementation of this Regulation.

(*) OJ L 156, 14.6.2008, p. 6.;

3. Article 3 is amended as follows:

(a) point 3 is replaced by the following:

'3. "Closed aquaculture facility" means a land-based facility:

(a) where:

- (i) aquaculture is conducted in an aquatic medium which involves recirculation of water; and
- (ii) discharges do not connect in any way to open waters before screening and filtering or percolation and treatment to prevent the release of solid waste into the aquatic environment and the escape from the facility of farmed species and non-target species that might survive and subsequently reproduce;

(b) and which:

- (i) prevents losses of reared specimens or non-target species and other biological material, including pathogens, due to factors such as predators (e.g. birds) and flooding (e.g. the facility must be situated at a safe distance from open waters following a proper assessment made by the competent authorities);
- (ii) prevents, in a reasonable way, losses of reared specimens or non-target species and other biological material, including pathogens, due to theft and vandalism; and
- (iii) ensures appropriate disposal of dead organisms;;

(b) point 16 is replaced by the following:

'16. "routine movement" means the movement of aquatic organisms from a source which has a low risk of transferring non-target species and which, on account of the characteristics of the aquatic organisms and/or the method of aquaculture to be used, does not give rise to adverse ecological effects;';

4. in Article 4, the existing paragraph is numbered as '1' and the following paragraph is added:

'2. The competent authorities in the Member States shall monitor and supervise aquaculture activities so as to ensure that:

(a) closed aquaculture facilities comply with the requirements laid down in Article 3(3); and

(b) transport from or to closed aquaculture facilities takes place in conditions that are such as to prevent the escape of alien or non-target species;'

5. Article 14 is replaced by the following:

'Article 14

Release into aquaculture facilities in the case of routine introductions

In the case of routine introductions, the release of aquatic organisms into aquaculture facilities shall be allowed without quarantine or pilot release, unless, in exceptional cases, the competent authority decides otherwise on the basis of specific advice given by the advisory committee. Movements from a closed aquaculture facility to an open aquaculture facility shall be considered to be routine or non-routine movements in line with Articles 6 and 7;'

6. Article 24 is replaced by the following:

'Article 24

Amendments of Annexes and detailed rules

1. The Commission may, by means of delegated acts in accordance with Article 24a and subject to the conditions laid down in Articles 24b and 24c:

(a) amend Annexes I, II and III to this Regulation in order to adapt them to technical and scientific progress;

(b) adopt specifications for the conditions necessary for adding species to Annex IV, as provided for in paragraph 3; and

(c) add species to Annex IV where the conditions provided for in paragraph 3 and their further specifications are complied with.

2. When adopting delegated acts as referred to in paragraph 1, the Commission shall act in accordance with this Regulation.

3. In order for its species to be added to Annex IV, an aquatic organism must have been used in aquaculture in certain parts of the Union for a long time (with reference to its life cycle) with no adverse effect, and its introduction and translocation must be possible without the coincident movement of potentially harmful non-target species.

4. Member States may request the Commission to add species to Annex IV. Member States may provide scientific data to prove coherence with relevant criteria for adding species to Annex IV. The Commission shall decide on the suitability of a request within 5 months of its receipt, excluding the time for the Member State to provide additional information if the Commission so requests.

5. Member States concerned may, in respect of their outermost regions as referred to in Article 349 of the Treaty on the Functioning of the European Union, propose the addition of species to be included in a separate part of Annex IV.

6. The Commission may adopt detailed rules for the implementation of paragraphs 4 and 5, and in particular the formats, the contents and the particulars of Member States' requests for the addition of species and the information to be provided in support of such requests, in accordance with the procedure referred to in Article 30(2) of Regulation (EC) No 2371/2002;'

7. the following Articles are inserted:

'Article 24a

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 24 shall be conferred on the Commission for a period of 5 years from 24 April 2011. The Commission shall make a report in respect of the delegated power at the latest 6 months before the end of the 5-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 24b.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 24b and 24c.

Article 24b

Revocation of the delegation

1. The delegation of power referred to in Article 24 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 24c

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council, that period shall be extended by 2 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If either the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.;

8. Annex I is amended as follows:

(a) the first paragraph is replaced by the following:

‘Wherever possible, information is to be supported with references from the scientific literature, and notations to personal communications with scientific authorities and fisheries experts.’;

(b) Section D (Interaction with native species) is amended as follows:

(i) point 1 is replaced by the following:

‘(1) What is the potential for survival and establishment of the introduced organism if it escapes?’;

(ii) point 6 is replaced by the following:

‘(6) Will the introduced organisms survive and successfully reproduce in the proposed area of introduction or will annual stocking be required?’.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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

Done at Strasbourg, 9 March 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
GYŐRI E.

**REGULATION (EU) No 305/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 9 March 2011**

**laying down harmonised conditions for the marketing of construction products and repealing
Council Directive 89/106/EEC**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European
Union, and in particular Article 114 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and
Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

(1) The rules of Member States require that construction
works be designed and executed so as not to endanger
the safety of persons, domestic animals or property nor
damage the environment.

(2) Those rules have a direct influence on the requirements
of construction products. Those requirements are
consequently reflected in national product standards,
national technical approvals and other national
technical specifications and provisions related to
construction products. Due to their disparity, those
requirements hinder trade within the Union.

(3) This Regulation should not affect the right of Member
States to specify the requirements they deem necessary to
ensure the protection of health, the environment and
workers when using construction products.

(4) Member States have introduced provisions, including
requirements, relating not only to safety of buildings
and other construction works but also to health, dura-
bility, energy economy, protection of the environment,
economic aspects, and other important aspects in the
public interest. Laws, regulations, administrative
measures or case-law, established either at Union or
Member State level, concerning construction works may
have an impact on the requirements of construction
products. Since their effect on the functioning of the
internal market is likely to be very similar, it is appro-
priate to consider such laws, regulations, administrative
measures or case-law as 'provisions' for the purposes of
this Regulation.

(5) Where applicable, provisions for an intended use or uses
of a construction product in a Member State, aimed at
fulfilling basic requirements for construction works,
determine the essential characteristics the performance
of which should be declared. In order to avoid an
empty declaration of performance, at least one of the
essential characteristics of a construction product which
are relevant for the declared use or uses should be
declared.

(6) Council Directive 89/106/EEC of 21 December 1988 on
the approximation of laws, regulations and administrative
provisions of the Member States relating to construction
products ⁽³⁾ aimed to remove technical barriers to trade
in the field of construction products in order to enhance
their free movement in the internal market.

(7) In order to achieve that objective, Directive 89/106/EEC
provided for the establishment of harmonised standards
for construction products and provided for the granting
of European technical approvals.

(8) Directive 89/106/EEC should be replaced in order to
simplify and clarify the existing framework, and
improve the transparency and the effectiveness of the
existing measures.

⁽¹⁾ OJ C 218, 11.9.2009, p. 15.

⁽²⁾ Position of the European Parliament of 24 April 2009 (OJ C 184 E, 8.7.2010, p. 441), position of the Council at first reading of 13 September 2010 (OJ C 282 E, 19.10.2010, p. 1), position of the European Parliament of 18 January 2011 (not yet published in the Official Journal) and decision of the Council of 28 February 2011.

⁽³⁾ OJ L 40, 11.2.1989, p. 12.

- (9) This Regulation should take account of the horizontal legal framework for the marketing of products in the internal market, established by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products ⁽¹⁾ as well as by Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products ⁽²⁾.
- (10) The removal of technical barriers in the field of construction may only be achieved by the establishment of harmonised technical specifications for the purposes of assessing the performance of construction products.
- (11) Those harmonised technical specifications should include testing, calculation and other means, defined within harmonised standards and European Assessment Documents for assessing performance in relation to the essential characteristics of construction products.
- (12) The methods used by the Member States in their requirements for construction works, as well as other national rules relating to the essential characteristics of construction products, should be in accordance with harmonised technical specifications.
- (13) Where appropriate, classes of performance in relation to the essential characteristics of construction products should be encouraged to be used in harmonised standards, so as to take account of different levels of basic requirements for construction works for certain construction works as well as of the differences in climate, geology and geography and other different conditions prevailing in the Member States. On the basis of a revised mandate, the European standardisation bodies should be entitled to establish such classes in cases where the Commission has not already established them.
- (14) Where an intended use requires threshold levels in relation to any essential characteristic to be fulfilled by construction products in Member States, those levels should be established in the harmonised technical specifications.
- (15) When assessing the performance of a construction product, account should also be taken of the health and safety aspects related to its use during its entire life cycle.
- (16) Threshold levels determined by the Commission pursuant to this Regulation should be generally recognised values for the essential characteristics of the construction product in question with regard to the provisions in Member States and should ensure a high level of protection within the meaning of Article 114 of the Treaty on the Functioning of the European Union (TFEU).
- (17) Threshold levels can be of a technical or regulatory nature, and may be applicable to a single characteristic or to a set of characteristics.
- (18) The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are recognised as the competent organisations for the adoption of harmonised standards in accordance with the general guidelines for cooperation between the Commission and those two organisations signed on 28 March 2003. Manufacturers should use those harmonised standards when the references to them have been published in the *Official Journal of the European Union* and in accordance with the criteria established under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ⁽³⁾. Once a sufficient level of technical and scientific expertise on all the relevant aspects is attained, recourse to harmonised standards with regard to construction products should be increased, including, where appropriate, and after consultation of the Standing Committee on Construction, by requiring, by means of mandates, that those standards be developed on the basis of existing European Assessment Documents.
- (19) The procedures under Directive 89/106/EEC for assessing performance in relation to the essential characteristics of construction products not covered by a harmonised standard should be simplified in order to make them more transparent and to reduce costs to manufacturers of construction products.
- (20) In order to allow a manufacturer of a construction product to draw up a declaration of performance for a construction product which is not covered or not fully covered by a harmonised standard, it is necessary to provide for a European Technical Assessment.
- (21) Manufacturers of construction products should be allowed to request European Technical Assessments to be issued for their products on the basis of the guidelines for European technical approval established under Directive 89/106/EEC. The right to use those guidelines as European Assessment Documents should therefore be ensured.

⁽¹⁾ OJ L 218, 13.8.2008, p. 30.

⁽²⁾ OJ L 218, 13.8.2008, p. 82.

⁽³⁾ OJ L 204, 21.7.1998, p. 37.

- (22) The establishment of draft European Assessment Documents and the issuing of European Technical Assessments should be entrusted to Technical Assessment Bodies (hereinafter referred to as 'TABs') designated by Member States. In order to ensure that TABs have the necessary competence for carrying out those tasks, the requirements for their designation should be set out at Union level.
- (23) TABs should establish an organisation (hereinafter referred to as an 'organisation of TABs'), supported, where applicable, through Union financing, to coordinate procedures for the establishment of draft European Assessment Documents and for the issuing of the European Technical Assessments, ensuring the transparency and the necessary confidentiality of those procedures.
- (24) Except in the cases laid down in this Regulation, the placing on the market of a construction product which is covered by a harmonised standard or for which a European Technical Assessment has been issued should be accompanied by a declaration of performance in relation to the essential characteristics of the construction product in accordance with the relevant harmonised technical specifications.
- (25) Where applicable, the declaration of performance should be accompanied by information on the content of hazardous substances in the construction product in order to improve the possibilities for sustainable construction and to facilitate the development of environment-friendly products. Such information should be provided without prejudice to the obligations, particularly with regard to labelling, laid down in other instruments of Union law applicable to hazardous substances and should be made available at the same time and in the same form as the declaration of performance so as to reach all potential users of construction products. Information on the content of hazardous substances should initially be limited to substances referred to in Articles 31 and 33 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency⁽¹⁾. However, the specific need for information on the content of hazardous substances in construction products should be further investigated with a view to completing the range of substances covered so as to ensure a high level of protection of the health and safety of workers using construction products and of users of construction works, including with regard to recycling and/or reuse requirements of parts or materials. This Regulation is without prejudice to Member States' rights and obligations pursuant to other instruments of Union law that may apply to hazardous substances, in particular, Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽²⁾, Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy⁽³⁾, Regulation (EC) No 1907/2006, Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste⁽⁴⁾ and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁽⁵⁾.
- (26) It should be possible for the declaration of performance to be numbered in accordance with the product-type reference number.
- (27) It is necessary to provide for simplified procedures for the drawing up of declarations of performance in order to alleviate the financial burden of enterprises, in particular small and medium-sized enterprises (SMEs).
- (28) In order to ensure that the declaration of performance is accurate and reliable, the performance of the construction product should be assessed and the production in the factory should be controlled in accordance with an appropriate system of assessment and verification of constancy of performance of the construction product. Several systems could be chosen to be applied for a given construction product, in order to take into account the specific relationship of some of its essential characteristics to the basic requirements for construction works.
- (29) Given the specificity of construction products and the particular focus of the system for their assessment, the procedures for the conformity assessment provided for in Decision No 768/2008/EC, and the modules set out therein, are not appropriate. Specific methods should therefore be established for the assessment and verification of constancy of performance in relation to the essential characteristics of construction products.
- (30) Due to the difference in the meaning of the CE marking for construction products, when compared to the general principles set out in Regulation (EC) No 765/2008, specific provisions should be put in place to ensure the clarity of the obligation to affix the CE marking to construction products and the consequences thereof.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 123, 24.4.1998, p. 1.

⁽³⁾ OJ L 327, 22.12.2000, p. 1.

⁽⁴⁾ OJ L 312, 22.11.2008, p. 3.

⁽⁵⁾ OJ L 353, 31.12.2008, p. 1.

- (31) By affixing the CE marking or having such marking affixed to a construction product, manufacturers should indicate that they take responsibility for the conformity of that product with its declared performance.
- (32) The CE marking should be affixed to all construction products for which the manufacturer has drawn up a declaration of performance in accordance with this Regulation. If a declaration of performance has not been drawn up, the CE marking should not be affixed.
- (33) The CE marking should be the only marking of conformity of the construction product with the declared performance and compliance with applicable requirements relating to Union harmonisation legislation. However, other markings may be used, provided that they help to improve the protection of users of construction products and are not covered by existing Union harmonisation legislation.
- (34) To avoid the unnecessary testing of construction products for which performance has already been sufficiently demonstrated by stable test results or other existing data, the manufacturer should be allowed, under conditions set up in the harmonised technical specifications or in a Commission decision, to declare a certain level or class of performance without testing or without further testing.
- (35) To avoid duplicating tests already carried out, a manufacturer of a construction product should be allowed to use the test results obtained by a third party.
- (36) Conditions should be defined for the use of simplified procedures for the assessment of the performance of construction products, in order to reduce as far as possible the cost of placing them on the market, without reducing the level of safety. The manufacturers using such simplified procedures should demonstrate appropriately the fulfilment of those conditions.
- (37) In order to enhance the impact of market surveillance measures, all simplified procedures provided for in this Regulation for the assessment of the performance of construction products should apply only to natural or legal persons which manufacture the products they place on the market.
- (38) To further decrease the cost to micro-enterprises of placing construction products, which they have manufactured, on the market, it is necessary to provide for simplified procedures for the assessment of performance when the products in question do not imply significant safety concerns while complying with the applicable requirements, whatever the origin of those requirements. Enterprises applying those simplified procedures should, in addition, demonstrate that they qualify as micro-enterprises. Moreover, they should follow the applicable procedures for verification of constancy of performance provided for in the harmonised technical specifications for their products.
- (39) For an individually designed and manufactured construction product, the manufacturer should be allowed to use simplified procedures for the assessment of performance, where it can be demonstrated that the product placed on the market complies with the applicable requirements.
- (40) The interpretative framework for the definition of 'non-series process', to be applied to different construction products covered by this Regulation, should be established by the Commission in consultation with the Standing Committee on Construction.
- (41) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they place or make available on the market only construction products which are in compliance with the requirements of this Regulation, which aim to ensure the performance of construction products and fulfil basic requirements for construction works. In particular, importers and distributors of construction products should be aware of the essential characteristics for which there are provisions on the Union market, and of the specific requirements in Member States in relation to the basic requirements for construction works, and should use this knowledge in their commercial transactions.
- (42) It is important to ensure the accessibility of national technical rules so that enterprises, and in particular SMEs, can gather reliable and precise information about the law in force in the Member State where they intend to place or make available on the market their products. Member States should therefore designate Product Contact Points for Construction for this purpose. In addition to the tasks defined in Article 10(1) of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State ⁽¹⁾, Product Contact Points for Construction should also provide information on rules applicable to the incorporation, assembling or installation of a specific type of construction product.

⁽¹⁾ OJ L 218, 13.8.2008, p. 21.

- (43) In order to facilitate the free movement of goods, Product Contact Points for Construction should provide, free of charge, information about provisions aimed at fulfilling basic requirements for construction works applicable to the intended use of each construction product in the territory of each Member State. Product Contact Points for Construction may also provide economic operators with additional information or observations. For additional information, Product Contact Points for Construction should be allowed to charge fees that are proportionate to the costs of providing such information or observations. Member States should furthermore ensure that sufficient resources are allocated to the Product Contact Points for Construction.
- (44) Since the creation of Product Contact Points for Construction should not interfere with the allocation of functions among competent authorities within the regulatory systems of the Member States, it should be possible for Member States to set up Product Contact Points for Construction in accordance with regional or local competences. Member States should be able to entrust the role of Product Contact Points for Construction to existing contact points established in accordance with other Union instruments, in order to prevent the unnecessary proliferation of contact points and to simplify administrative procedures. In order not to increase administrative costs for enterprises and competent authorities, Member States should also be able to entrust the role of Product Contact Points for Construction not only to existing services within the public administration, but also to national SOLVIT centres, chambers of commerce, professional organisations and private bodies.
- (45) The Product Contact Points for Construction should be able to carry out their functions in a manner that avoids conflicts of interest, particularly in respect of the procedures for obtaining the CE marking.
- (46) For the purposes of ensuring an equivalent and consistent enforcement of Union harmonisation legislation, effective market surveillance should be operated by the Member States. Regulation (EC) No 765/2008 provides the basic conditions for the functioning of such market surveillance, notably for programmes, financing and penalties.
- (47) The responsibility of Member States for safety, health and other matters covered by the basic requirements for construction works on their territory should be recognised in a safeguard clause providing for appropriate protective measures.
- (48) Since it is necessary to ensure throughout the Union a uniform level of performance of bodies carrying out the assessment and verification of constancy of performance of construction products, and since all such bodies should perform their functions to the same level and under conditions of fair competition, requirements should be set for those bodies seeking to be notified for the purposes of this Regulation. Provision should also be made for the availability of adequate information about such bodies and for their monitoring.
- (49) In order to ensure a coherent level of quality in the assessment and verification of constancy of performance of construction products, it is also necessary to establish requirements applicable to the authorities responsible for notifying the bodies carrying out those tasks to the Commission and the other Member States.
- (50) In accordance with Article 291 TFEU, rules and general principles for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾ continues to apply, with the exception of the regulatory procedure with scrutiny, which is no longer applicable.
- (51) For the purposes of achieving the objectives of this Regulation, the Commission should be empowered to adopt certain delegated acts in accordance with Article 290 TFEU. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (52) In particular, the Commission should be empowered to adopt delegated acts outlining the conditions for the use of websites to make available the declaration of performance.
- (53) Since a period of time is required to ensure that the framework for the proper functioning of this Regulation is in place, its application should be deferred with the exception of the provisions concerning the designation of TABs, notifying authorities and notified bodies, the establishment of an organisation of TABs and the establishment of the Standing Committee on Construction.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

- (54) The Commission and the Member States should, in collaboration with stakeholders, launch information campaigns to inform the construction sector, particularly economic operators and users of construction products, of the establishment of a common technical language, the distribution of responsibilities between individual economic operators and users, the affixing of the CE marking on construction products, the revision of the basic requirements for construction works and the systems of assessment and verification of constancy of performance.
- (55) The basic requirement for construction works on sustainable use of natural resources should notably take into account the recyclability of construction works, their materials and parts after demolition, the durability of construction works and the use of environmentally compatible raw and secondary materials in construction works.
- (56) For the assessment of the sustainable use of resources and of the impact of construction works on the environment Environmental Product Declarations should be used when available.
- (57) Wherever possible, uniform European methods should be laid down for establishing compliance with the basic requirements set out in Annex I.
- (58) Since the objective of this Regulation, namely to achieve the proper functioning of the internal market for construction products by means of harmonised technical specifications to express the performance of construction products, cannot be sufficiently achieved by the Member States and can therefore, by reason of its 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 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,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down conditions for the placing or making available on the market of construction products by establishing

harmonised rules on how to express the performance of construction products in relation to their essential characteristics and on the use of CE marking on those products.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. 'construction product' means any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works;
2. 'kit' means a construction product placed on the market by a single manufacturer as a set of at least two separate components that need to be put together to be incorporated in the construction works;
3. 'construction works' means buildings and civil engineering works;
4. 'essential characteristics' means those characteristics of the construction product which relate to the basic requirements for construction works;
5. 'performance of a construction product' means the performance related to the relevant essential characteristics, expressed by level or class, or in a description;
6. 'level' means the result of the assessment of the performance of a construction product in relation to its essential characteristics, expressed as a numerical value;
7. 'class' means a range of levels, delimited by a minimum and a maximum value, of performance of a construction product;
8. 'threshold level' means a minimum or maximum performance level of an essential characteristic of a construction product;
9. 'product-type' means the set of representative performance levels or classes of a construction product, in relation to its essential characteristics, produced using a given combination of raw materials or other elements in a specific production process;
10. 'harmonised technical specifications' means harmonised standards and European Assessment Documents;

11. 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC, on the basis of a request issued by the Commission, in accordance with Article 6 of that Directive;
12. 'European Assessment Document' means a document adopted by the organisation of TABs for the purposes of issuing European Technical Assessments;
13. 'European Technical Assessment' means the documented assessment of the performance of a construction product, in relation to its essential characteristics, in accordance with the respective European Assessment Document;
14. 'intended use' means the intended use of the construction product as defined in the applicable harmonised technical specification;
15. 'Specific Technical Documentation' means documentation demonstrating that methods within the applicable system for assessment and verification of constancy of performance have been replaced by other methods, provided that the results obtained by those other methods are equivalent to the results obtained by the test methods of the corresponding harmonised standard;
16. 'making available on the market' means any supply of a construction product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
17. 'placing on the market' means the first making available of a construction product on the Union market;
18. 'economic operator' means the manufacturer, importer, distributor or authorised representative;
19. 'manufacturer' means any natural or legal person who manufactures a construction product or who has such a product designed or manufactured, and markets that product under his name or trademark;
20. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a construction product available on the market;
21. 'importer' means any natural or legal person established within the Union, who places a construction product from a third country on the Union market;
22. 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
23. 'withdrawal' means any measure aimed at preventing a construction product in the supply chain from being made available on the market;
24. 'recall' means any measure aimed at achieving the return of a construction product that has already been made available to the end-user;
25. 'accreditation' has the meaning assigned to it by Regulation (EC) No 765/2008;
26. 'factory production control' means the documented, permanent and internal control of production in a factory, in accordance with the relevant harmonised technical specifications;
27. 'micro-enterprise' means a micro-enterprise as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ⁽¹⁾;
28. 'life cycle' means the consecutive and interlinked stages of a construction product's life, from raw material acquisition or generation from natural resources to final disposal.

Article 3

Basic requirements for construction works and essential characteristics of construction products

1. The basic requirements for construction works set out in Annex I shall constitute the basis for the preparation of standardisation mandates and harmonised technical specifications.
2. The essential characteristics of construction products shall be laid down in harmonised technical specifications in relation to the basic requirements for construction works.
3. For specific families of construction products covered by a harmonised standard, the Commission shall, where appropriate and in relation to their intended uses as defined in harmonised standards, determine by means of delegated acts in accordance with Article 60, those essential characteristics for which the manufacturer shall declare the performance of the product when it is placed on the market.

⁽¹⁾ OJ L 124, 20.5.2003, p. 36.

Where appropriate, the Commission shall also determine, by means of delegated acts in accordance with Article 60, the threshold levels for the performance in relation to the essential characteristics to be declared.

CHAPTER II

DECLARATION OF PERFORMANCE AND CE MARKING

Article 4

Declaration of performance

1. When a construction product is covered by a harmonised standard or conforms to a European Technical Assessment which has been issued for it, the manufacturer shall draw up a declaration of performance when such a product is placed on the market.

2. When a construction product is covered by a harmonised standard or conforms to a European Technical Assessment which has been issued for it, information in any form about its performance in relation to the essential characteristics, as defined in the applicable harmonised technical specification, may be provided only if included and specified in the declaration of performance except where, in accordance with Article 5, no declaration of performance has been drawn up.

3. By drawing up the declaration of performance, the manufacturer shall assume responsibility for the conformity of the construction product with such declared performance. In the absence of objective indications to the contrary, Member States shall presume the declaration of performance drawn up by the manufacturer to be accurate and reliable.

Article 5

Derogations from drawing up a declaration of performance

By way of derogation from Article 4(1) and in the absence of Union or national provisions requiring the declaration of essential characteristics where the construction products are intended to be used, a manufacturer may refrain from drawing up a declaration of performance when placing a construction product covered by a harmonised standard on the market where:

(a) the construction product is individually manufactured or custom-made in a non-series process in response to a specific order, and installed in a single identified construction work, by a manufacturer who is responsible for the safe incorporation of the product into the construction works, in compliance with the applicable national rules and under the responsibility of those

responsible for the safe execution of the construction works designated under the applicable national rules;

(b) the construction product is manufactured on the construction site for its incorporation in the respective construction works in compliance with the applicable national rules and under the responsibility of those responsible for the safe execution of the construction works designated under the applicable national rules; or

(c) the construction product is manufactured in a traditional manner or in a manner appropriate to heritage conservation and in a non-industrial process for adequately renovating construction works officially protected as part of a designated environment or because of their special architectural or historic merit, in compliance with the applicable national rules.

Article 6

Content of the declaration of performance

1. The declaration of performance shall express the performance of construction products in relation to the essential characteristics of those products in accordance with the relevant harmonised technical specifications.

2. The declaration of performance shall contain, in particular, the following information:

(a) the reference of the product-type for which the declaration of performance has been drawn up;

(b) the system or systems of assessment and verification of constancy of performance of the construction product, as set out in Annex V;

(c) the reference number and date of issue of the harmonised standard or the European Technical Assessment which has been used for the assessment of each essential characteristic;

(d) where applicable, the reference number of the Specific Technical Documentation used and the requirements with which the manufacturer claims the product complies.

3. The declaration of performance shall in addition contain:

(a) the intended use or uses for the construction product, in accordance with the applicable harmonised technical specification;

(b) the list of essential characteristics, as determined in the harmonised technical specification for the declared intended use or uses;

- (c) the performance of at least one of the essential characteristics of the construction product, relevant for the declared intended use or uses;
- (d) where applicable, the performance of the construction product, by levels or classes, or in a description, if necessary based on a calculation in relation to its essential characteristics determined in accordance with Article 3(3);
- (e) the performance of those essential characteristics of the construction product which are related to the intended use or uses, taking into consideration the provisions in relation to the intended use or uses where the manufacturer intends the product to be made available on the market;
- (f) for the listed essential characteristics for which no performance is declared, the letters 'NPD' (No Performance Determined);
- (g) when a European Technical Assessment has been issued for that product, the performance, by levels or classes, or in a description, of the construction product in relation to all essential characteristics contained in the corresponding European Technical Assessment.

4. The declaration of performance shall be drawn up using the model set out in Annex III.

5. The information referred to in Article 31 or, as the case may be, in Article 33 of Regulation (EC) No 1907/2006, shall be provided together with the declaration of performance.

Article 7

Supply of the declaration of performance

1. A copy of the declaration of performance of each product which is made available on the market shall be supplied either in paper form or by electronic means.

However, where a batch of the same product is supplied to a single user, it may be accompanied by a single copy of the declaration of performance either in paper form or by electronic means.

2. A paper copy of the declaration of performance shall be supplied if the recipient requests it.

3. By way of derogation from paragraphs 1 and 2, the copy of the declaration of performance may be made available on a web site in accordance with conditions to be established by the Commission by means of delegated acts in accordance with Article 60. Such conditions shall, inter alia, guarantee that the

declaration of performance remains available at least for the period referred to in Article 11(2).

4. The declaration of performance shall be supplied in the language or the languages required by the Member State where the product is made available.

Article 8

General principles and use of CE marking

1. The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply to the CE marking.

2. The CE marking shall be affixed to those construction products for which the manufacturer has drawn up a declaration of performance in accordance with Articles 4 and 6.

If a declaration of performance has not been drawn up by the manufacturer in accordance with Articles 4 and 6, the CE marking shall not be affixed.

By affixing or having affixed the CE marking, manufacturers indicate that they take responsibility for the conformity of the construction product with the declared performance as well as the compliance with all applicable requirements laid down in this Regulation and in other relevant Union harmonisation legislation providing for its affixing.

The rules for affixing the CE marking provided for in other relevant Union harmonisation legislation shall apply without prejudice to this paragraph.

3. For any construction product covered by a harmonised standard, or for which a European Technical Assessment has been issued, the CE marking shall be the only marking which attests conformity of the construction product with the declared performance in relation to the essential characteristics, covered by that harmonised standard or by the European Technical Assessment.

In this respect, Member States shall not introduce any references or shall withdraw any references in national measures to a marking attesting conformity with the declared performance in relation to the essential characteristics covered by a harmonised standard other than the CE marking.

4. A Member State shall not prohibit or impede, within its territory or under its responsibility, the making available on the market or the use of construction products bearing the CE marking, when the declared performances correspond to the requirements for such use in that Member State.

5. A Member State shall ensure that the use of construction products bearing the CE marking shall not be impeded by rules or conditions imposed by public bodies or private bodies acting as a public undertaking, or acting as a public body on the basis of a monopoly position or under a public mandate, when the declared performances correspond to the requirements for such use in that Member State.

6. The methods used by the Member States in their requirements for construction works, as well as other national rules in relation to the essential characteristics of construction products, shall be in accordance with harmonised standards.

Article 9

Rules and conditions for the affixing of CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the construction product or to a label attached to it. Where this is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging or to the accompanying documents.

2. The CE marking shall be followed by the two last digits of the year in which it was first affixed, the name and the registered address of the manufacturer, or the identifying mark allowing identification of the name and address of the manufacturer easily and without any ambiguity, the unique identification code of the product-type, the reference number of the declaration of performance, the level or class of the performance declared, the reference to the harmonised technical specification applied, the identification number of the notified body, if applicable, and the intended use as laid down in the harmonised technical specification applied.

3. The CE marking shall be affixed before the construction product is placed on the market. It may be followed by a pictogram or any other mark notably indicating a special risk or use.

Article 10

Product Contact Points for Construction

1. Member States shall designate Product Contact Points for Construction pursuant to Article 9 of Regulation (EC) No 764/2008.

2. Articles 10 and 11 of Regulation (EC) No 764/2008 shall apply to Product Contact Points for Construction.

3. With regard to the tasks defined in Article 10(1) of Regulation (EC) No 764/2008, each Member State shall ensure that the Product Contact Points for Construction provide information, using transparent and easily understandable terms, on the provisions within its territory aimed at fulfilling

basic requirements for construction works applicable for the intended use of each construction product, as provided for in Article 6(3)(e) of this Regulation.

4. Product Contact Points for Construction shall be able to carry out their functions in a manner that avoids conflicts of interest, particularly in respect of the procedures for obtaining the CE marking.

CHAPTER III

OBLIGATIONS OF ECONOMIC OPERATORS

Article 11

Obligations of manufacturers

1. Manufacturers shall draw up a declaration of performance in accordance with Articles 4 and 6, and affix the CE marking in accordance with Articles 8 and 9.

Manufacturers shall, as the basis for the declaration of performance, draw up technical documentation describing all the relevant elements related to the required system of assessment and verification of constancy of performance.

2. Manufacturers shall keep the technical documentation and the declaration of performance for a period of 10 years after the construction product has been placed on the market.

Where appropriate, the Commission may, by means of delegated acts in accordance with Article 60, amend that period for families of construction products on the basis of the expected life or part played by the construction product in the construction works.

3. Manufacturers shall ensure that procedures are in place to ensure that series production maintains the declared performance. Changes in the product-type and in the applicable harmonised technical specifications shall be adequately taken into account.

Manufacturers shall, where deemed appropriate with regard to ensuring the accuracy, reliability and stability of the declared performance of a construction product, carry out sample testing of construction products placed or made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming products and of product recalls, and keep distributors informed of any such monitoring.

4. Manufacturers shall ensure that their construction products bear a type, batch or serial number or any other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the construction product.

5. Manufacturers shall indicate on the construction product or, where that is not possible, on its packaging or in a document accompanying it, their name, registered trade name or registered trade mark and their contact address. The address shall indicate a single point at which the manufacturer can be contacted.

6. When making a construction product available on the market, manufacturers shall ensure that the product is accompanied by instructions and safety information in a language determined by the Member State concerned which can be easily understood by users.

7. Manufacturers who consider or have reason to believe that a construction product which they have placed on the market is not in conformity with the declaration of performance or not in compliance with other applicable requirements in this Regulation, shall immediately take the necessary corrective measures to bring that construction product into conformity, or, if appropriate, to withdraw or recall it. Furthermore, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the construction product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the construction product with the declaration of performance and compliance with other applicable requirements in this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by construction products which they have placed on the market.

Article 12

Authorised representatives

1. A manufacturer may appoint, by written mandate, an authorised representative.

The drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate. The mandate shall allow the authorised representative to carry out at least the following tasks:

(a) keep the declaration of performance and the technical documentation at the disposal of national surveillance authorities for the period referred to in Article 11(2);

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the construction product with the declaration of performance and compliance with other applicable requirements in this Regulation;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by construction products covered by the mandate of the authorised representative.

Article 13

Obligations of importers

1. Importers shall place on the Union market only construction products which are compliant with the applicable requirements of this Regulation.

2. Before placing a construction product on the market, importers shall ensure that the assessment and the verification of constancy of performance has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation referred to in the second subparagraph of Article 11(1) and the declaration of performance in accordance with Articles 4 and 6. They shall also ensure that the product, where required, bears the CE marking, that the product is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 11(4) and (5).

Where an importer considers or has reason to believe that the construction product is not in conformity with the declaration of performance or not in compliance with other applicable requirements in this Regulation, the importer shall not place the construction product on the market until it conforms to the accompanying declaration of performance and it complies with the other applicable requirements in this Regulation or until the declaration of performance is corrected. Furthermore, where the construction product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities thereof.

3. Importers shall indicate on the construction product or, where that is not possible, on its packaging or in a document accompanying the product their name, registered trade name or registered trade mark and their contact address.

4. Importers shall ensure that, when making a construction product available on the market, the product is accompanied by instructions and safety information in a language determined by the Member State concerned which can be easily understood by users.

5. Importers shall ensure that, while a construction product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the declaration of performance and compliance with other applicable requirements in this Regulation.

6. Importers shall, when deemed appropriate with regard to ensuring the accuracy, reliability and stability of the declared performance of a construction product, carry out sample testing of construction products placed or made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming products and of product recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a construction product which they have placed on the market is not in conformity with the declaration of performance or not in compliance with other applicable requirements in this Regulation, shall immediately take the necessary corrective measures to bring that construction product into conformity, or, where appropriate, to withdraw or recall it. Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the construction product available thereof, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for the period referred to in Article 11(2), keep a copy of the declaration of performance at the disposal of the market surveillance authorities and ensure that the technical documentation is made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the construction product with the declaration of performance and compliance with other applicable requirements in this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by construction products which they have placed on the market.

Article 14

Obligations of distributors

1. When making a construction product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making a construction product available on the market distributors shall ensure that the product, where required, bears the CE marking and is accompanied by the documents required under this Regulation and by instructions and safety information in a language determined by the Member State concerned which can be easily understood by users. Distributors shall also ensure that the manufacturer and the

importer have complied with the requirements set out in Article 11(4) and (5) and Article 13(3) respectively.

Where a distributor considers or has reason to believe that a construction product is not in conformity with the declaration of performance or not in compliance with other applicable requirements in this Regulation, the distributor shall not make the product available on the market until it conforms to the accompanying declaration of performance and it complies with the other applicable requirements in this Regulation or until the declaration of performance is corrected. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer thereof, and the market surveillance authorities.

3. A distributor shall ensure that, while a construction product is under his responsibility, storage or transport conditions do not jeopardise its conformity with the declaration of performance and compliance with other applicable requirements in this Regulation.

4. Distributors who consider or have reason to believe that a construction product which they have made available on the market is not in conformity with the declaration of performance or not in compliance with other applicable requirements in this Regulation, shall make sure that the corrective measures necessary to bring that product in conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the product available thereof, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the construction product with the declaration of performance and compliance with other applicable requirements in this Regulation in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by construction products which they have made available on the market.

Article 15

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of a manufacturer pursuant to Article 11, where he places a product on the market under his name or trademark or modifies a construction product already placed on the market in such a way that conformity with the declaration of performance may be affected.

Article 16

Identification of economic operators

For the period referred to in Article 11(2), economic operators shall, on request, identify the following to market surveillance authorities:

- (a) any economic operator who has supplied them with a product;
- (b) any economic operator to whom they have supplied a product.

CHAPTER IV

HARMONISED TECHNICAL SPECIFICATIONS

Article 17

Harmonised standards

1. Harmonised standards shall be established by the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of requests (hereinafter referred to as 'mandates') issued by the Commission in accordance with Article 6 of that Directive after having consulted the Standing Committee on Construction referred to in Article 64 of this Regulation (hereinafter referred to as 'Standing Committee on Construction').

2. Where stakeholders are involved in the process of developing harmonised standards pursuant to this Article, the European standardisation bodies shall ensure that the various categories of stakeholders are in all instances represented in a fair and equitable manner.

3. Harmonised standards shall provide the methods and the criteria for assessing the performance of the construction products in relation to their essential characteristics.

When provided for in the relevant mandate, a harmonised standard shall refer to an intended use of products to be covered by it.

Harmonised standards shall, where appropriate and without endangering the accuracy, reliability or stability of the results, provide methods less onerous than testing for assessing the performance of the construction products in relation to their essential characteristics.

4. The European standardisation bodies shall determine in harmonised standards the applicable factory production control, which shall take into account the specific conditions of the manufacturing process of the construction product concerned.

The harmonised standard shall include technical details necessary for the implementation of the system of assessment and verification of constancy of performance.

5. The Commission shall assess the conformity of harmonised standards established by the European standardisation bodies with the relevant mandates.

The Commission shall publish in the *Official Journal of the European Union* the list of references of harmonised standards which are in conformity with the relevant mandates.

The following shall be indicated for each harmonised standard in the list:

- (a) references of superseded harmonised technical specifications, if any;
- (b) date of the beginning of the coexistence period;
- (c) date of the end of the coexistence period.

The Commission shall publish any updates to that list.

From the date of the beginning of the coexistence period it shall be possible to use a harmonised standard to make a declaration of performance for a construction product covered by it. National standardisation bodies are under the obligation to transpose the harmonised standards in conformity with Directive 98/34/EC.

Without prejudice to Articles 36 to 38, from the date of the end of the coexistence period, the harmonised standard shall be the only means used for drawing up a declaration of performance for a construction product covered by it.

At the end of the coexistence period, conflicting national standards shall be withdrawn and Member States shall terminate the validity of all conflicting national provisions.

Article 18

Formal objection against harmonised standards

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements set out in the relevant mandate, the Member State concerned or the Commission, after having consulted the Standing Committee on Construction, shall bring the matter before the Committee set up pursuant to Article 5 of Directive 98/34/EC, giving its arguments. That Committee shall, after having consulted the relevant European standardisation bodies deliver its opinion without delay.

2. In the light of the opinion of the Committee set up pursuant to Article 5 of Directive 98/34/EC, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the *Official Journal of the European Union*.

3. The Commission shall inform the European standardisation body concerned of its decision and, if necessary, request the revision of the harmonised standard concerned.

Article 19

European Assessment Document

1. Following a request for a European Technical Assessment by a manufacturer, a European Assessment Document shall be drawn up and adopted by the organisation of TABs for any construction product not covered or not fully covered by a harmonised standard, for which the performance in relation to its essential characteristics cannot be entirely assessed according to an existing harmonised standard, because, inter alia:

- (a) the product does not fall within the scope of any existing harmonised standard;
- (b) for at least one essential characteristic of that product, the assessment method provided for in the harmonised standard is not appropriate; or
- (c) the harmonised standard does not provide for any assessment method in relation to at least one essential characteristic of that product.

2. The procedure for adopting the European Assessment Document shall respect the principles set out in Article 20 and shall comply with Article 21 and Annex II.

3. The Commission may adopt delegated acts in accordance with Article 60 to amend Annex II and establish supplementary procedural rules for the development and adoption of a European Assessment Document.

4. Where appropriate, the Commission, after having consulted the Standing Committee on Construction, shall take existing European Assessment Documents as a basis for the mandates to be issued pursuant to Article 17(1) with a view to developing harmonised standards as regards the products referred to in paragraph 1 of this Article.

Article 20

Principles for the development and adoption of European Assessment Documents

1. The procedure for developing and adopting European Assessment Documents shall:

- (a) be transparent to the manufacturer concerned;
- (b) define appropriate mandatory time limits in order to avoid unjustified delay;
- (c) take appropriately into account the protection of commercial secrecy and confidentiality;
- (d) allow for adequate participation by the Commission;
- (e) be cost-effective for the manufacturer; and
- (f) ensure sufficient collegiality and coordination amongst TABs designated for the product in question.

2. The TABs shall, together with the organisation of TABs, bear the full costs of the development and adoption of European Assessment Documents.

Article 21

Obligations of the TAB receiving a request for a European Technical Assessment

1. The TAB receiving a request for a European Technical Assessment shall inform the manufacturer if the construction product is covered, fully or partially, by a harmonised technical specification as follows:

- (a) where the product is fully covered by a harmonised standard, the TAB shall inform the manufacturer that, in accordance with Article 19(1), a European Technical Assessment cannot be issued;
- (b) where the product is fully covered by a European Assessment Document, the TAB shall inform the manufacturer that such a document will be used as the basis for the European Technical Assessment to be issued;
- (c) where the product is not covered, or not fully covered, by any harmonised technical specification, the TAB shall apply the procedures set out in Annex II or those established in accordance with Article 19(3).

2. In the cases referred to in points (b) and (c) of paragraph 1, the TAB shall inform the organisation of TABs and the Commission of the content of the request and of the reference to a relevant Commission decision for assessment and verification of constancy of performance, which the TAB intends to apply for that product, or of the lack of such a Commission decision.

3. If the Commission considers that an appropriate decision for assessment and verification of constancy of performance does not exist for the construction product, Article 28 shall apply.

Article 22

Publication

European Assessment Documents adopted by the organisation of TABs shall be sent to the Commission, which shall publish a list of references of the final European Assessment Documents in the *Official Journal of the European Union*.

The Commission shall publish any updates to that list.

Article 23

Dispute resolution in cases of disagreement between TABs

If the TABs do not agree upon the European Assessment Document within the time limits provided for, the organisation of TABs shall submit this matter to the Commission for appropriate resolution.

Article 24

Content of the European Assessment Document

1. A European Assessment Document shall contain, at least, a general description of the construction product, the list of essential characteristics, relevant for the intended use of the product as foreseen by the manufacturer and agreed between the manufacturer and the organisation of TABs, as well as the methods and criteria for assessing the performance of the product in relation to those essential characteristics.

2. Principles for the applicable factory production control to be applied shall be set out in the European Assessment Document, taking into account the conditions of the manufacturing process of the construction product concerned.

3. Where the performance of some of the essential characteristics of the product can appropriately be assessed with methods and criteria already established in other harmonised technical specifications or the Guidelines referred to in Article 66(3), or used in accordance with Article 9 of Directive 89/106/EEC before 1 July 2013 in the context of issuing European technical approvals, those existing methods and criteria shall be incorporated as parts of the European Assessment Document.

Article 25

Formal objections against European Assessment Documents

1. Where a Member State or the Commission considers that a European Assessment Document does not entirely satisfy the

demands to be met in relation to the basic requirements for construction works set out in Annex I, the Member State concerned or the Commission shall bring the matter before the Standing Committee on Construction, giving its arguments. The Standing Committee on Construction shall, after having consulted the organisation of TABs, deliver its opinion without delay.

2. In the light of the opinion of the Standing Committee on Construction, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the European Assessment Documents concerned in the *Official Journal of the European Union*.

3. The Commission shall inform the organisation of TABs accordingly and, if necessary, request the revision of the European Assessment Document concerned.

Article 26

European Technical Assessment

1. The European Technical Assessment shall be issued by a TAB, at the request of a manufacturer on the basis of a European Assessment Document established in accordance with the procedures set out in Article 21 and Annex II.

Provided that there is a European Assessment Document, a European Technical Assessment may be issued even in the case where a mandate for a harmonised standard has been issued. Such issuing shall be possible until the beginning of the coexistence period as determined by the Commission in accordance with Article 17(5).

2. The European Technical Assessment shall include the performance to be declared, by levels or classes, or in a description, of those essential characteristics agreed by the manufacturer and the TAB receiving the request for the European Technical Assessment for the declared intended use, and technical details necessary for the implementation of the system of assessment and verification of constancy of performance.

3. In order to ensure the uniform implementation of this Article, the Commission shall adopt implementing acts to establish the format of the European Technical Assessment in accordance with the procedure referred to in Article 64(2).

Article 27

Levels or classes of performance

1. The Commission may adopt delegated acts in accordance with Article 60, to establish classes of performance in relation to the essential characteristics of construction products.

2. Where the Commission has established classes of performance in relation to the essential characteristics of construction products, the European standardisation bodies shall use those classes in harmonised standards. The organisation of TABs shall where relevant use those classes in European Assessment Documents.

Where classes of performance in relation to the essential characteristics of construction products are not established by the Commission, they may be established by the European standardisation bodies in harmonised standards, on the basis of a revised mandate.

3. When provided for in the relevant mandates, the European standardisation bodies shall establish in harmonised standards threshold levels in relation to essential characteristics and, when appropriate, for intended uses, to be fulfilled by construction products in Member States.

4. Where the European standardisation bodies have established classes of performance in a harmonised standard, the organisation of TABs shall use those classes in the European Assessment Documents where they are relevant for the construction product.

When deemed appropriate, the organisation of TABs may, with the agreement of the Commission and after consulting the Standing Committee on Construction, establish in the European Assessment Document classes of performance and threshold levels in relation to the essential characteristics of a construction product within its intended use as foreseen by the manufacturer.

5. The Commission may adopt delegated acts in accordance with Article 60, to establish conditions under which a construction product shall be deemed to satisfy a certain level or class of performance without testing or without further testing.

Where such conditions are not established by the Commission, they may be established by the European standardisation bodies in harmonised standards, on the basis of a revised mandate.

6. When the Commission has established classification systems in accordance with paragraph 1, Member States may determine the levels or classes of performance to be respected by construction products in relation to their essential characteristics only in accordance with those classification systems.

7. The European standardisation bodies and the organisation of TABs shall respect the regulatory needs of Member States when determining threshold levels or classes of performance.

Article 28

Assessment and verification of constancy of performance

1. Assessment and verification of constancy of performance of construction products in relation to their essential characteristics shall be carried out in accordance with one of the systems set out in Annex V.

2. By means of delegated acts in accordance with Article 60, the Commission shall establish and may revise, taking into account in particular the effect on the health and safety of people, and on the environment, which system or systems are applicable to a given construction product or family of construction products or a given essential characteristic. In doing so, the Commission shall also take into account the documented experiences forwarded by national authorities with regard to market surveillance.

The Commission shall choose the least onerous system or systems consistent with the fulfilment of all basic requirements for construction works.

3. The system or systems thus determined shall be indicated in the mandates for harmonised standards and in the harmonised technical specifications.

CHAPTER V

TECHNICAL ASSESSMENT BODIES

Article 29

Designation, monitoring and evaluation of TABs

1. Member States may designate TABs within their territories, notably for one or several product areas listed in Table 1 of Annex IV.

Member States which have designated a TAB shall communicate to the other Member States and the Commission its name and address and the product areas for which that TAB is designated.

2. The Commission shall make publicly available by electronic means the list of TABs indicating the product areas for which they are designated, endeavouring to achieve the highest possible level of transparency.

The Commission shall make any updates to that list publicly available.

3. Member States shall monitor the activities and competence of the TABs they have designated, and evaluate them in relation to the respective requirements set out in Table 2 of Annex IV.

Member States shall inform the Commission of their national procedures for the designation of TABs, of the monitoring of their activity and competence, and of any changes to that information.

4. The Commission shall adopt guidelines for carrying out the evaluation of TABs, after consulting the Standing Committee on Construction.

Article 30

Requirements for TABs

1. A TAB shall carry out the assessment and issue the European Technical Assessment in a product area for which it has been designated.

The TAB shall satisfy the requirements set out in Table 2 of Annex IV within the scope of its designation.

2. A TAB shall make publicly available its organigram and the names of the members of its internal decision-making bodies.

3. Where a TAB no longer complies with the requirements referred to in paragraph 1, the Member State shall withdraw the designation of that TAB for the relevant product area and inform the Commission and the other Member States thereof.

Article 31

Coordination of TABs

1. The TABs shall establish an organisation for technical assessment.

2. The organisation of TABs shall be considered a body pursuing an aim of general European interest within the meaning of Article 162 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁾.

3. The common cooperation objectives and the administrative and financial conditions relating to the grants awarded to the organisation of TABs may be defined in a framework partnership agreement signed by the Commission and that organisation, in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽²⁾ (the Financial Regulation) and Regulation (EC, Euratom) No 2342/2002. The European Parliament and the

Council shall be informed of the conclusion of any such agreement.

4. The organisation of TABs shall at least carry out the following tasks:

- (a) organise the coordination of the TABs and, if necessary, ensure cooperation and consultation with other stakeholders;
- (b) ensure that examples of best practice are shared between TABs to promote greater efficiency and provide a better service to industry;
- (c) coordinate the application of the procedures set out in Article 21 and in Annex II, as well as provide the support needed to that end;
- (d) develop and adopt European Assessment Documents;
- (e) inform the Commission of any question related to the preparation of European Assessment Documents and of any aspects related to the interpretation of the procedures set out in Article 21 and in Annex II and suggest improvements to the Commission based on experience gained;
- (f) communicate any observations concerning a TAB not fulfilling its tasks in accordance with the procedures set out in Article 21 and in Annex II to the Commission and the Member State which designated the TAB;
- (g) ensure that adopted European Assessment Documents and references to European Technical Assessments are kept publicly available.

The organisation of TABs shall have a Secretariat in order to carry out these tasks.

5. Member States shall ensure that the TABs contribute with financial and human resources to the organisation of TABs.

Article 32

Union financing

1. Union financing may be granted to the organisation of TABs for the implementation of the tasks referred to in Article 31(4).

2. The appropriations allocated to the tasks set out in Article 31(4) shall be determined each year by the budgetary authority within the limits of the financial framework in force.

⁽¹⁾ OJ L 357, 31.12.2002, p. 1.

⁽²⁾ OJ L 248, 16.9.2002, p. 1.

*Article 33***Financing arrangements**

1. Union financing shall be provided, without a call for proposals, to the organisation of TABs to carry out the tasks referred to in Article 31(4) for which grants can be awarded in accordance with the Financial Regulation.

2. The activities of the Secretariat of the organisation of TABs, referred to in Article 31(4), may be financed on the basis of operating grants. In the event of renewal, the operating grants shall not be decreased automatically.

3. Grant agreements may authorise flat-rate cover of the beneficiary's overheads up to a maximum of 10 % of total eligible direct costs for actions, except where the beneficiary's indirect costs are covered by an operating grant financed from the general budget of the Union.

*Article 34***Management and monitoring**

1. The appropriations determined by the budgetary authority for the financing of tasks set out in Article 31(4) may also cover administrative expenses relating to preparation, monitoring, inspection, auditing and evaluation which are directly necessary for the achievement of the objectives of this Regulation, and in particular studies, meetings, information and publication activities, expenses relating to informatics networks for the exchange of information and any other expenditure on administrative and technical assistance which the Commission may use for activities related to the development and adoption of European Assessment Documents and the issuing of European Technical Assessments.

2. The Commission shall evaluate the relevance of the tasks set out in Article 31(4) that receive Union financing in the light of the requirements of Union policies and legislation, and inform the European Parliament and the Council of the outcome of that evaluation by 1 January 2017 and every 4 years thereafter.

*Article 35***Protection of the Union's financial interests**

1. The Commission shall ensure that when the activities financed under this Regulation are implemented, the Union's financial interests are protected by the application of preventive measures against fraud, corruption and other illegal activities, by effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportionate and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests⁽¹⁾, 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⁽²⁾ and 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)⁽³⁾.

2. For the activities financed under this Regulation, the notion of irregularity referred to in Article 1(2) of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Union law or any breach of a contractual obligation resulting from an act or omission by an economic operator which has, or would have, the effect of prejudicing the general budget of the Union or budgets managed by it by an unjustified item of expenditure.

3. Any agreements and contracts resulting from this Regulation shall provide for monitoring and financial control by the Commission or any representative which it authorises and for audits by the Court of Auditors, which, if necessary, may be conducted on-the-spot.

CHAPTER VI

SIMPLIFIED PROCEDURES*Article 36***Use of Appropriate Technical Documentation**

1. In determining the product-type, a manufacturer may replace type-testing or type-calculation by Appropriate Technical Documentation demonstrating that:

(a) for one or several essential characteristics of the construction product, which the manufacturer places on the market, that product is deemed to achieve a certain level or class of performance without testing or calculation, or without further testing or calculation, in accordance with the conditions set out in the relevant harmonised technical specification or a Commission decision;

(b) the construction product, covered by a harmonised standard, which the manufacturer places on the market corresponds to the product-type of another construction product, manufactured by another manufacturer and already tested in accordance with the relevant harmonised standard. When these conditions are fulfilled, the manufacturer is entitled to declare performance corresponding to all or part of the test results of this other product. The manufacturer may use the test results obtained by another manufacturer only after having obtained an authorisation of that manufacturer, who remains responsible for the accuracy, reliability and stability of those test results; or

⁽¹⁾ OJ L 312, 23.12.1995, p. 1.

⁽²⁾ OJ L 292, 15.11.1996, p. 2.

⁽³⁾ OJ L 136, 31.5.1999, p. 1.

(c) the construction product, covered by a harmonised technical specification, which the manufacturer places on the market is a system made of components, which the manufacturer assembles duly following precise instructions given by the provider of such a system or of a component thereof, who has already tested that system or that component for one or several of its essential characteristics in accordance with the relevant harmonised technical specification. When these conditions are fulfilled, the manufacturer is entitled to declare performance corresponding to all or part of the test results for the system or the component provided to him. The manufacturer may use the test results obtained by another manufacturer or system provider only after having obtained an authorisation of that manufacturer or system provider, who remains responsible for the accuracy, reliability and stability of those test results.

2. If the construction product referred to in paragraph 1 belongs to a family of construction products for which the applicable system for assessment and verification of constancy of performance is system 1 + or 1, as set out in Annex V, the Appropriate Technical Documentation referred to in paragraph 1 shall be verified by a notified product certification body as referred to in Annex V.

Article 37

Use of simplified procedures by micro-enterprises

Micro-enterprises manufacturing construction products covered by a harmonised standard may replace the determination of the product-type on the basis of type-testing for the applicable systems 3 and 4 as set out in Annex V by using methods differing from those contained in the applicable harmonised standard. Those manufacturers may also treat construction products to which system 3 applies in accordance with provisions for system 4. When a manufacturer uses these simplified procedures, the manufacturer shall demonstrate compliance of the construction product with the applicable requirements by means of a Specific Technical Documentation and shall demonstrate the equivalence of the procedures used to the procedures laid down in the harmonised standards.

Article 38

Other simplified procedures

1. In relation to construction products covered by a harmonised standard and which are individually manufactured or custom-made in a non-series process in response to a specific order, and which are installed in a single identified construction work, the performance assessment part of the applicable system, as set out in Annex V, may be replaced by the manufacturer by Specific Technical Documentation demonstrating compliance of that product with the applicable requirements and equivalence of the procedures used to the procedures laid down in the harmonised standards.

2. If the construction product referred to in paragraph 1 belongs to a family of construction products for which the applicable system for assessment and verification of constancy of performance is system 1 + or 1, as set out in Annex V, the Specific Technical Documentation shall be verified by a notified product certification body as referred to in Annex V.

CHAPTER VII

NOTIFYING AUTHORITIES AND NOTIFIED BODIES

Article 39

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party tasks in the process of assessment and verification of constancy of performance under this Regulation (hereinafter referred to as 'notified bodies').

Article 40

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of the bodies to be authorised to carry out third-party tasks in the process of assessment and verification of constancy of performance for the purposes of this Regulation, and for the monitoring of notified bodies, including their compliance with Article 43.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by their national accreditation bodies within the meaning of, and in accordance with, Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 41. In addition, it shall have arrangements to cover liabilities arising from its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 41

Requirements relating to notifying authorities

1. The notifying authority shall be established in such a way that no conflicts of interest with notified bodies occur.

2. The notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. The notifying authority shall be organised in such a way that each decision relating to notification of a body to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance is taken by competent persons different from those who carried out the assessment.

4. The notifying authority shall not offer or provide activities performed by notified bodies, or consultancy services on a commercial or competitive basis.

5. The notifying authority shall safeguard the confidentiality of the information obtained.

6. The notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 42

Information obligation for Member States

Member States shall inform the Commission of their national procedures for the assessment and notification of bodies to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 43

Requirements for notified bodies

1. For the purposes of notification, a notified body shall meet the requirements set out in paragraphs 2 to 11.

2. A notified body shall be established under national law and have legal personality.

3. A notified body shall be a third-party body independent from the organisation or the construction product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of construction products which it assesses, can on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body.

4. A notified body, its top-level management and the personnel responsible for carrying out the third party tasks in the process of assessment and verification of constancy of performance shall not be the designer, manufacturer, supplier,

installer, purchaser, owner, user or maintainer of the construction products which it assesses, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the notified body or the use of products for personal purposes.

A notified body, its top-level management and the personnel responsible for carrying out the third party tasks in the process of assessment and verification of constancy of performance shall not become directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of those construction products, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement and integrity related to the activities for which they have been notified. This shall, in particular, apply to consultancy services.

A notified body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its assessment and/or verification activities.

5. A notified body and its personnel shall carry out the third party tasks in the process of assessment and verification of constancy of performance with the highest degree of professional integrity and requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their assessment and/or verification activities, especially from persons or groups of persons with an interest in the results of those activities.

6. A notified body shall be capable of carrying out all the third party tasks in the process of assessment and verification of constancy of performance assigned to it in accordance with Annex V in relation to which it has been notified, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

At all times and for each system of assessment and verification of constancy of performance and for each kind or category of construction products, essential characteristics and tasks in relation to which it has been notified, the notified body shall have the following at its disposal:

(a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the third party tasks in the process of assessment and verification of constancy of performance;

- (b) the necessary description of procedures according to which the assessment of performance is carried out, ensuring the transparency and the ability of reproduction of these procedures; it shall have appropriate policies and procedures in place that distinguish between the tasks it carries out as a notified body and other activities;
- (c) the necessary procedures to perform its activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A notified body shall have the means necessary to perform the technical and administrative tasks connected with the activities for which it is notified in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out the activities in relation to which the body has been notified, shall have the following:

- (a) sound technical and vocational training covering all the third party tasks in the process of assessment and verification of constancy of performance within the relevant scope for which the body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments and verifications they carry out and adequate authority to carry out such operations;
- (c) appropriate knowledge and understanding of the applicable harmonised standards and of the relevant provisions of the Regulation;
- (d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments and the verifications have been carried out.

8. The impartiality of the notified body, its top-level management and assessment personnel shall be guaranteed.

The remuneration of the notified body's top-level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.

9. A notified body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the assessment and/or the verification performed.

10. The personnel of the notified body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under Annex V, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. A notified body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established under this Regulation and shall apply as general guidance the administrative decisions and documents produced as a work result of that group.

Article 44

Presumption of conformity

A notified body to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance which demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the requirements set out in Article 43 in so far as the applicable harmonised standards cover those requirements.

Article 45

Subsidiaries and subcontractors of notified bodies

1. Where a notified body subcontracts specific tasks connected with the third party tasks in the process of assessment and verification of constancy of performance or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 43, and shall inform the notifying authority accordingly.

2. The notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. The notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of any subcontractor or the subsidiary and the tasks carried out by such parties under Annex V.

*Article 46***Use of facilities outside the testing laboratory of the notified body**

1. On request of the manufacturer and where justified by technical, economic or logistic reasons, notified bodies may decide to carry out the tests referred to in Annex V, for the systems of assessment and verification of constancy of performance 1+, 1 and 3 or have such tests carried out under their supervision, either in the manufacturing plants using the test equipments of the internal laboratory of the manufacturer or, with the prior consent of the manufacturer, in an external laboratory, using the test equipments of that laboratory.

Notified bodies carrying out such tests shall be specifically designated as competent to work away from their own accredited test facilities.

2. Before carrying out those tests, the notified body shall verify whether the requirements of the test method are satisfied and shall evaluate whether:

- (a) test equipment has an appropriate calibration system and the traceability of the measurements is guaranteed;
- (b) the quality of the test results is ensured.

*Article 47***Application for notification**

1. A body to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application shall be accompanied by a description of the activities to be performed, the assessment and/or verification procedures for which the body claims to be competent, an accreditation certificate, where one exists, issued by the national accreditation body within the meaning of Regulation (EC) No 765/2008, attesting that the body meets the requirements laid down in Article 43.

3. Where the body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 43.

*Article 48***Notification procedure**

1. Notifying authorities may notify only bodies which have satisfied the requirements laid down in Article 43.

2. They shall notify the Commission and the other Member States, notably using the electronic notification tool developed and managed by the Commission.

Exceptionally, for cases set out in point 3 of Annex V, for which the appropriate electronic tool is not available, a hard copy of the notification shall be accepted.

3. The notification shall include full details of the functions to be performed, reference to the relevant harmonised technical specification and, for the purposes of the system set out in Annex V, the essential characteristics for which the body is competent.

However, reference to the relevant harmonised technical specification is not required in the cases set out in point 3 of Annex V.

4. Where a notification is not based on an accreditation certificate as referred to in Article 47(2), the notifying authority shall provide the Commission and the other Member States with all documentary evidence which attests to the notified body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 43.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within 2 weeks of notification where an accreditation certificate is used or within 2 months of notification where an accreditation certificate is not used.

Only such a body shall be considered as a notified body for the purpose of this Regulation.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

*Article 49***Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to each notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of bodies notified under this Regulation, including the identification numbers that have been allocated to them and the activities for which they have been notified, notably using the electronic notification tool developed and managed by the Commission.

The Commission shall ensure that this list is kept up-to-date.

Article 50

Changes to the notification

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 43, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or to fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly, notably using the electronic notification tool developed and managed by the Commission.

2. In the event of withdrawal, restriction or suspension of notification or where the notified body has ceased its activity, the notifying Member State concerned shall take the appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 51

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information related to the basis for notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State

accordingly and request it to take the necessary corrective measures, including withdrawal of notification, if necessary.

Article 52

Operational obligations for notified bodies

1. Notified bodies shall carry out third party tasks in accordance with the systems of assessment and verification of constancy of performance provided for in Annex V.

2. Assessments and verifications of constancy of performance shall be carried out with transparency as regards the manufacturer, and in a proportionate manner, avoiding an unnecessary burden for economic operators. The notified bodies shall perform their activities taking due account of the size of the undertaking, the sector in which the undertaking operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing, the notified bodies shall nevertheless respect the degree of rigour required for the product by this Regulation and the part played by the product for the fulfilment of all basic requirements for construction works.

3. Where, in the course of the initial inspection of the manufacturing plant and of factory production control, a notified body finds that the manufacturer has not ensured the constancy of performance of the manufactured product, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate.

4. Where, in the course of the monitoring activity aiming at the verification of the constancy of performance of the manufactured product, a notified body finds that a construction product no longer has the same performance to that of the product-type, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 53

Information obligations for notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of certificates;

- (b) any circumstances affecting the scope of, and conditions for, notification;
- (c) any request for information on assessment and/or verification of constancy of performance activities carried out which they have received from market surveillance authorities;
- (d) on request, third party tasks in accordance with the systems of assessment and verification of constancy of performance carried out within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar third party tasks in accordance with the systems of assessment and verification of constancy of performance and for construction products covered by the same harmonised technical specification with relevant information on issues relating to negative and, on request, positive results from these assessments and/or verifications.

Article 54

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for policy on notification.

Article 55

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified pursuant to Article 39 are put into place and properly operated in the form of a group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives, or shall ensure that the representatives of notified bodies are informed thereof.

CHAPTER VIII

MARKET SURVEILLANCE AND SAFEGUARD PROCEDURES

Article 56

Procedure to deal at national level with construction products presenting a risk

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008 or where they have sufficient reason to

believe that a construction product covered by a harmonised standard or for which a European Technical Assessment has been issued does not achieve the declared performance and presents a risk for the fulfilment of the basic requirements for construction works covered by this Regulation, they shall carry out an evaluation in relation to the product concerned covering the respective requirements laid down by this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the construction product does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the product into compliance with those requirements, notably with the declared performance, or to withdraw the product from the market, or recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the notified body accordingly, if a notified body is involved.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that the non-compliance is not limited to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the construction products concerned which that economic operator has made available on the market throughout the Union.

4. Where the relevant economic operator, within the period referred to in the second subparagraph of paragraph 1, does not take adequate corrective action, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the making available of the construction product on the national market or to withdraw the construction product from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant construction product, the origin of the construction product, the nature of the non-compliance alleged and the risk involved, the nature and duration of national measures taken as well as the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the product to achieve the declared performance and/or to meet the requirements related to the fulfilment of basic requirements for construction works laid down in this Regulation;
- (b) shortcomings in the harmonised technical specifications or in the Specific Technical Documentation.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the construction product concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within 15 working days of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State in relation to the construction product concerned, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the construction product concerned, such as withdrawal of the product from their market.

Article 57

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 56(3) and (4), objections are raised against a measure taken by a Member State or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator(s) and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator(s).

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant construction product is withdrawn from their markets and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

3. Where the national measure is considered to be justified and the non-compliance of the construction product is attributed to shortcomings in the harmonised standards as referred to in Article 56(5)(b), the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up pursuant to Article 5 of Directive 98/34/EC. That Committee shall consult with the relevant European standardisation body or bodies and deliver its opinion without delay.

Where the national measure is considered to be justified and the non-compliance of the construction product is attributed to shortcomings in the European Assessment Document or in the Specific Technical Documentation as referred to in Article 56(5)(b), the Commission shall bring the matter before the Standing Committee on Construction and subsequently adopt the appropriate measures.

Article 58

Complying construction products which nevertheless present a risk to health and safety

1. Where, having performed an evaluation pursuant to Article 56(1), a Member State finds that, although a construction product is in compliance with this Regulation, it presents a risk for the fulfilment of the basic requirements for construction works, to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the construction product concerned, when placed on the market, no longer presents that risk, to withdraw the construction product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, which it may prescribe.

2. The economic operator shall ensure that any corrective action is taken in respect of all the construction products concerned which that economic operator has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the construction product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator(s) and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator(s).

Article 59

Formal non-compliance

1. Without prejudice to Article 56, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in breach of Article 8 or 9;
- (b) the CE marking has not been affixed, when required, in accordance with Article 8(2);
- (c) without prejudice to Article 5, the declaration of performance has not been drawn up, when required, in accordance with Article 4;
- (d) the declaration of performance has not been drawn up in accordance with Articles 4, 6 and 7;
- (e) the technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 continues, the Member State shall take all appropriate measures to restrict or prohibit the making available on the market of the construction product or ensure that it is recalled or withdrawn from the market.

CHAPTER IX

FINAL PROVISIONS

Article 60

Delegated acts

For the purposes of achieving the objectives of this Regulation, in particular removing and avoiding restrictions on making construction products available on the market, the following matters shall be delegated to the Commission in accordance with Article 61, and subject to the conditions laid down in Articles 62 and 63:

- (a) the determination, where appropriate, of the essential characteristics or threshold levels within specific families of construction products, in relation to which, in accordance with Articles 3 to 6, the manufacturer shall declare, in relation to their intended use, by levels or classes, or in a description, the performance of the manufacturer's product when it is placed on the market;
- (b) the conditions on which a declaration of performance may be electronically processed, in order to make it available on a web site in accordance with Article 7;
- (c) the amendment of the period for which the manufacturer shall keep the technical documentation and the declaration of performance after the construction product has been placed on the market, in accordance with Article 11, based on the expected life or the part played by the construction product in the construction works;
- (d) the amendment of Annex II and where necessary the adoption of supplementary procedural rules in accordance with Article 19(3) in order to ensure compliance with the principles in Article 20, or the application in practice of the procedures set out in Article 21;
- (e) the adaptation of Annex III, table 1 of Annex IV, and Annex V in response to technical progress;
- (f) the establishment and adaptation of classes of performance in response to technical progress in accordance with Article 27(1);
- (g) the conditions on which a construction product shall be deemed to satisfy a certain level or class of performance without testing or without further testing in accordance with Article 27(5), provided that the fulfilment of the basic requirements for construction works is not thereby jeopardised;
- (h) the adaptation, establishment and revision of the systems of assessment and verification of constancy of performance in accordance with Article 28, relating to a given product, a given product family or a given essential characteristic, and in accordance with:
 - (i) the importance of the part played by the product or those essential characteristics with respect to the basic requirements for construction works;
 - (ii) the nature of the product;

(iii) the effect of the variability of the essential characteristics of the construction product during the expected life of the product; and

(iv) the susceptibility to defects in the product's manufacture.

Article 61

Exercise of the delegation

1. The power to adopt delegated acts referred to in Article 60 shall be conferred on the Commission for a period of 5 years from 24 April 2011. The Commission shall draw up a report in respect of the delegated power at the latest 6 months before the end of the 5-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 62.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 62 and 63.

Article 62

Revocation of the delegation

1. The delegation of power referred to in Article 60 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 63

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of 3 months from the date of notification.

At the initiative of the European Parliament or the Council, that period shall be extended by 3 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If either the European Parliament or the Council objects to a delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 64

Committee

1. The Commission shall be assisted by a Standing Committee on Construction.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply.

3. Member States shall ensure that the members of the Standing Committee on Construction are able to carry out their functions in a manner that avoids conflicts of interest, particularly in respect of the procedures for obtaining the CE marking.

Article 65

Repeal

1. Directive 89/106/EEC is repealed.

2. References to the repealed Directive shall be construed as references to this Regulation.

Article 66

Transitional provisions

1. Construction products which have been placed on the market in accordance with Directive 89/106/EEC before 1 July 2013 shall be deemed to comply with this Regulation.

2. Manufacturers may draw up a declaration of performance on the basis of a certificate of conformity or a declaration of conformity, which has been issued before 1 July 2013 in accordance with Directive 89/106/EEC.

3. Guidelines for European technical approval published before 1 July 2013 in accordance with Article 11 of Directive 89/106/EEC may be used as European Assessment Documents.

4. Manufacturers and importers may use European technical approvals issued in accordance with Article 9 of Directive 89/106/EEC before 1 July 2013 as European Technical Assessments throughout the period of validity of those approvals.

Article 67

Reporting by the Commission

1. By 25 April 2014, the Commission shall assess the specific need for information on the content of hazardous substances in construction products and consider the possible extension of the information obligation provided for in Article 6(5) to other substances, and shall report thereon to the European Parliament and to the Council. In its assessment, the Commission shall take into account, inter alia, the need to ensure a high level of protection of the health and safety of workers using construction products and of users of construction works, including with regard to recycling and/or reuse requirements of parts or materials.

If appropriate, the report shall, within 2 years of its submission to the European Parliament and to the Council, be followed up by appropriate legislative proposals.

2. By 25 April 2016, the Commission shall submit to the European Parliament and to the Council a report on the implementation of this Regulation, including on Articles 19, 20, 21, 23, 24 and 37 on the basis of reports provided by Member States, as well as by other relevant stakeholders, accompanied, where relevant, by appropriate proposals.

Article 68

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

However, Articles 3 to 28, Articles 36 to 38, Articles 56 to 63, Articles 65 and 66, as well as Annexes I, II, III and V shall apply from 1 July 2013.

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

Done at Strasbourg, 9 March 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
GYŐRI E.

ANNEX I

BASIC REQUIREMENTS FOR CONSTRUCTION WORKS

Construction works as a whole and in their separate parts must be fit for their intended use, taking into account in particular the health and safety of persons involved throughout the life cycle of the works. Subject to normal maintenance, construction works must satisfy these basic requirements for construction works for an economically reasonable working life.

1. Mechanical resistance and stability

The construction works must be designed and built in such a way that the loadings that are liable to act on them during their constructions and use will not lead to any of the following:

- (a) collapse of the whole or part of the work;
- (b) major deformations to an inadmissible degree;
- (c) damage to other parts of the construction works or to fittings or installed equipment as a result of major deformation of the load-bearing construction;
- (d) damage by an event to an extent disproportionate to the original cause.

2. Safety in case of fire

The construction works must be designed and built in such a way that in the event of an outbreak of fire:

- (a) the load-bearing capacity of the construction can be assumed for a specific period of time;
- (b) the generation and spread of fire and smoke within the construction works are limited;
- (c) the spread of fire to neighbouring construction works is limited;
- (d) occupants can leave the construction works or be rescued by other means;
- (e) the safety of rescue teams is taken into consideration.

3. Hygiene, health and the environment

The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:

- (a) the giving-off of toxic gas;
- (b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;
- (c) the emission of dangerous radiation;
- (d) the release of dangerous substances into ground water, marine waters, surface waters or soil;
- (e) the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water;
- (f) faulty discharge of waste water, emission of flue gases or faulty disposal of solid or liquid waste;
- (g) dampness in parts of the construction works or on surfaces within the construction works.

4. Safety and accessibility in use

The construction works must be designed and built in such a way that they do not present unacceptable risks of accidents or damage in service or in operation such as slipping, falling, collision, burns, electrocution, injury from explosion and burglaries. In particular, construction works must be designed and built taking into consideration accessibility and use for disabled persons.

5. Protection against noise

The construction works must be designed and built in such a way that noise perceived by the occupants or people nearby is kept to a level that will not threaten their health and will allow them to sleep, rest and work in satisfactory conditions.

6. Energy economy and heat retention

The construction works and their heating, cooling, lighting and ventilation installations must be designed and built in such a way that the amount of energy they require in use shall be low, when account is taken of the occupants and of the climatic conditions of the location. Construction works must also be energy-efficient, using as little energy as possible during their construction and dismantling.

7. Sustainable use of natural resources

The construction works must be designed, built and demolished in such a way that the use of natural resources is sustainable and in particular ensure the following:

- (a) reuse or recyclability of the construction works, their materials and parts after demolition;
 - (b) durability of the construction works;
 - (c) use of environmentally compatible raw and secondary materials in the construction works.
-

ANNEX II

PROCEDURE FOR ADOPTING A EUROPEAN ASSESSMENT DOCUMENT**1. Request for a European Technical Assessment**

When a manufacturer makes a request for a European Technical Assessment to any TAB for a construction product, and after the manufacturer and the TAB (hereinafter referred to as the 'responsible TAB') have signed an agreement of commercial secrecy and confidentiality, unless the manufacturer decides otherwise, the manufacturer shall submit to the responsible TAB a technical file describing the product, its use as foreseen by the manufacturer and details of the factory production control the manufacturer intends to apply.

2. Contract

For construction products referred to in Article 21(1)(c), within 1 month from the reception of the technical file, a contract shall be concluded between the manufacturer and the responsible TAB for the production of the European Technical Assessment, defining the work programme for drawing up the European Assessment Document, including:

- the organisation of work within the organisation of TABs,
- the composition of the workgroup to be established within the organisation of TABs, designated for the product area in question,
- the coordination of TABs.

3. Work programme

After the conclusion of the contract with the manufacturer, the organisation of TABs shall inform the Commission of the work programme for drawing up the European Assessment Document, the schedule for its execution and indicating the assessment programme. This communication shall take place within 3 months of receipt of the request for a European Technical Assessment.

4. The draft European Assessment Document

The organisation of TABs shall finalise a draft European Assessment Document by means of the working group coordinated by the responsible TAB and shall communicate such draft to the parties concerned within 6 months of the date the Commission was informed of the work programme.

5. Commission Participation

A Commission representative may participate, as observer, to all the parts of the execution of the work programme.

6. Extension and delay

Any delay in relation to the time limits set in Sections 1 to 4 in this Annex shall be reported by the working group to the organisation of TABs and to the Commission.

If an extension of the time limits for developing the European Assessment Document can be justified, notably by the absence of a Commission decision on the applicable system of assessment and verification of constancy of performance for the construction product or by the need to develop a new test method, an extended time limit shall be set by the Commission.

7. Amendments and adoption of a European Assessment Document

The responsible TAB shall communicate the draft European Assessment Document to the manufacturer, who shall have 15 working days to react thereto. Thereafter, the organisation of TABs shall:

- (a) if applicable, inform the manufacturer as to how his reactions have been taken into account;
- (b) adopt the draft European Assessment Document; and
- (c) send a copy to the Commission.

If, within 15 working days of receipt, the Commission communicates to the organisation of TABs its observations on the draft European Assessment Document, the organisation of TABs, after having been given the opportunity to comment, shall amend the draft accordingly and shall send a copy of the adopted European Assessment Document to the manufacturer and to the Commission.

8. Final European Assessment Document to be published

As soon as the first European Technical Assessment is issued by the responsible TAB on the basis of the adopted European Assessment Document, that European Assessment Document shall be adjusted, if appropriate, based on experiences gained. The organisation of TABs shall adopt the final European Assessment Document and shall send a copy thereof to the Commission, together with a translation of its title in all the official languages of the Union, for publication of its reference. The organisation of TABs shall keep the European Assessment Document available by electronic means as soon as the product has been CE-marked.

ANNEX III

DECLARATION OF PERFORMANCE

No.

1. Unique identification code of the product-type:
2. Type, batch or serial number or any other element allowing identification of the construction product as required pursuant to Article 11(4):
.....
3. Intended use or uses of the construction product, in accordance with the applicable harmonised technical specification, as foreseen by the manufacturer:
.....
.....
4. Name, registered trade name or registered trade mark and contact address of the manufacturer as required pursuant to Article 11(5):
.....
.....
5. Where applicable, name and contact address of the authorised representative whose mandate covers the tasks specified in Article 12(2):
.....
.....
6. System or systems of assessment and verification of constancy of performance of the construction product as set out in Annex V:
.....
.....
7. In case of the declaration of performance concerning a construction product covered by a harmonised standard:
.....
(name and identification number of the notified body, if relevant)
performed under system
(description of the third party tasks as set out in Annex V)
and issued
(certificate of constancy of performance, certificate of conformity of the factory production control, test/calculation reports – as relevant)
8. In case of the declaration of performance concerning a construction product for which a European Technical Assessment has been issued:
.....
(name and identification number of the Technical Assessment Body, if relevant)
issued
(reference number of the European Technical Assessment)
on the basis of
(reference number of the European Assessment Document)

performed under system
(description of the third party tasks as set out in Annex V)

and issued
(certificate of constancy of performance, certificate of conformity of the factory production control, test/calculation reports – as relevant)

9. Declared performance

Notes to the table.

1. Column 1 shall contain the list of essential characteristics as determined in the harmonised technical specifications for the intended use or uses indicated in point 3 above.
2. For each essential characteristic listed in column 1 and in compliance with the requirements of Article 6, column 2 shall contain the declared performance, expressed by level or class, or in a description, related to the corresponding essential characteristics. The letters 'NPD' (No Performance Determined) shall be indicated where no performance is declared.
3. For each essential characteristic listed in column 1, column 3 shall contain:
 - (a) dated reference of the corresponding harmonised standard and, where relevant, the reference number of the Specific or Appropriate Technical Documentation used;

or

 - (b) dated reference of the corresponding European Assessment Document where available and reference number of the European Technical Assessment used.

Essential characteristics (see Note 1)	Performance (see Note 2)	Harmonised technical specification (see Note 3)

Where pursuant to Article 37 or 38 the Specific Technical Documentation has been used, the requirements with which the product complies:

.....
.....

10. The performance of the product identified in points 1 and 2 is in conformity with the declared performance in point 9.

This declaration of performance is issued under the sole responsibility of the manufacturer identified in point 4.

Signed for and on behalf of the manufacturer by:

.....
(name and function)

.....
(place and date of issue) (signature)

ANNEX IV

PRODUCT AREAS AND REQUIREMENTS FOR TABS

Table 1 — Product areas

AREA CODE	PRODUCT AREA
1	PRECAST NORMAL/LIGHTWEIGHT/AUTOCLAVED AERATED CONCRETE PRODUCTS.
2	DOORS, WINDOWS, SHUTTERS, GATES AND RELATED BUILDING HARDWARE.
3	MEMBRANES, INCLUDING LIQUID APPLIED AND KITS (FOR WATER AND/OR WATER VAPOUR CONTROL).
4	THERMAL INSULATION PRODUCTS. COMPOSITE INSULATING KITS/SYSTEMS.
5	STRUCTURAL BEARINGS. PINS FOR STRUCTURAL JOINTS.
6	CHIMNEYS, FLUES AND SPECIFIC PRODUCTS.
7	GYPSUM PRODUCTS.
8	GEOTEXTILES, GEOMEMBRANES, AND RELATED PRODUCTS.
9	CURTAIN WALLING/CLADDING/STRUCTURAL SEALANT GLAZING.
10	FIXED FIRE FIGHTING EQUIPMENT (FIRE ALARM/DETECTION, FIXED FIREFIGHTING, FIRE AND SMOKE CONTROL AND EXPLOSION SUPPRESSION PRODUCT).
11	SANITARY APPLIANCES.
12	CIRCULATION FIXTURES: ROAD EQUIPMENT.
13	STRUCTURAL TIMBER PRODUCTS/ELEMENTS AND ANCILLARIES.
14	WOOD BASED PANELS AND ELEMENTS.
15	CEMENT, BUILDING LIMES AND OTHER HYDRAULIC BINDERS.
16	REINFORCING AND PRESTRESSING STEEL FOR CONCRETE (AND ANCILLARIES). POST TENSIONING KITS.
17	MASONRY AND RELATED PRODUCTS. MASONRY UNITS, MORTARS, AND ANCILLARIES.
18	WASTE WATER ENGINEERING PRODUCTS.
19	FLOORINGS.
20	STRUCTURAL METALLIC PRODUCTS AND ANCILLARIES.
21	INTERNAL & EXTERNAL WALL AND CEILING FINISHES. INTERNAL PARTITION KITS.
22	ROOF COVERINGS, ROOF LIGHTS, ROOF WINDOWS, AND ANCILLARY PRODUCTS. ROOF KITS.
23	ROAD CONSTRUCTION PRODUCTS.
24	AGGREGATES.
25	CONSTRUCTION ADHESIVES.

AREA CODE	PRODUCT AREA
26	PRODUCTS RELATED TO CONCRETE, MORTAR AND GROUT.
27	SPACE HEATING APPLIANCES.
28	PIPES-TANKS AND ANCILLARIES NOT IN CONTACT WITH WATER INTENDED FOR HUMAN CONSUMPTION.
29	CONSTRUCTION PRODUCTS IN CONTACT WITH WATER INTENDED FOR HUMAN CONSUMPTION.
30	FLAT GLASS, PROFILED GLASS AND GLASS BLOCK PRODUCTS.
31	POWER, CONTROL AND COMMUNICATION CABLES.
32	SEALANTS FOR JOINTS.
33	FIXINGS.
34	BUILDING KITS, UNITS, AND PREFABRICATED ELEMENTS.
35	FIRE STOPPING, FIRE SEALING AND FIRE PROTECTIVE PRODUCTS. FIRE RETARDANT PRODUCTS.

Table 2 — Requirements for TABs

Competence	Description of competence	Requirement
1. Analysing risks	Identify the possible risks and benefits for the use of innovative construction products in the absence of established/consolidated technical information regarding their performance when installed in construction works.	A TAB shall be established under national law and have legal personality. It shall be independent from the stakeholders and from any particular interests. In addition, a TAB shall have staff with:
2. Setting technical criteria	Transform the outcome of the risk analysis into technical criteria for evaluating behaviour and performance of the construction products regarding the fulfilment of applicable national requirements; provide the technical information needed by those participating in the building process as potential users of the construction products (manufacturers, designers, contractors, installers).	(a) objectivity and sound technical judgement; (b) detailed knowledge of the regulatory provisions and other requirements in force in the Member States where it is designated, concerning product areas for which it is to be designated; (c) general understanding of construction practice and detailed technical knowledge, concerning product areas for which it is to be designated;
3. Setting assessment methods	Design and validate appropriate methods (tests or calculations) to assess performance for essential characteristics of construction products, taking into account the current state of the article.	(d) detailed knowledge of specific risks involved and the technical aspects of the construction process; (e) detailed knowledge of the existing harmonised standards and test methods within the product areas for which it is to be designated; (f) appropriate linguistic skills. The remuneration of the TAB personnel shall not depend on the number of the assessments carried out or on the results of such assessments.

Competence	Description of competence	Requirement
4. Determining the specific factory production control	Understand and evaluate the manufacturing process of the specific product in order to identify appropriate measures ensuring product constancy through the given manufacturing process.	A TAB shall have staff with appropriate knowledge of the relationship between the manufacturing processes and product characteristics related to factory production control.
5. Assessing the product	Assess the performance for essential characteristics of construction products on the basis of harmonised methods against harmonised criteria.	In addition to the requirements listed in points 1, 2 and 3, a TAB shall have access to the necessary means and equipment for the assessment of the performance for essential characteristics of construction products within the product areas for which it is to be designated.
6. General management	Ensure consistency, reliability, objectivity and traceability through the constant application of appropriate management methods.	<p>A TAB shall have:</p> <ul style="list-style-type: none"> (a) a proven record of respect of good administrative behaviour; (b) a policy and the supporting procedures to ensure confidentiality of sensitive information within the TAB and all its partners; (c) a document control system to ensure registration, traceability, maintenance and archiving of all relevant documents; (d) a mechanism for internal audit and management review to ensure the regular monitoring of the compliance with appropriate management methods; (e) a procedure to deal objectively with appeals and complaints.

ANNEX V

ASSESSMENT AND VERIFICATION OF CONSTANCY OF PERFORMANCE**1. SYSTEMS OF ASSESSMENT AND VERIFICATION OF CONSTANCY OF PERFORMANCE****1.1. System 1+ – Declaration of the performance of the essential characteristics of the construction product by the manufacturer on the basis of the following items:**

- (a) the manufacturer shall carry out:
 - (i) factory production control;
 - (ii) further testing of samples taken at the factory in accordance with the prescribed test plan;
- (b) the notified product certification body shall issue the certificate of constancy of performance of the product on the basis of:
 - (i) determination of the product-type on the basis of type testing (including sampling), type calculation, tabulated values or descriptive documentation of the product;
 - (ii) initial inspection of the manufacturing plant and of factory production control;
 - (iii) continuous surveillance, assessment and evaluation of factory production control;
 - (iv) audit-testing of samples taken before placing the product on the market.

1.2. System 1 – Declaration of the performance of the essential characteristics of the construction product by the manufacturer on the basis of the following items:

- (a) the manufacturer shall carry out:
 - (i) factory production control;
 - (ii) further testing of samples taken at the factory by the manufacturer in accordance with the prescribed test plan;
- (b) the notified product certification body shall issue the certificate of constancy of performance of the product on the basis of:
 - (i) determination of the product type on the basis of type testing (including sampling), type calculation, tabulated values or descriptive documentation of the product;
 - (ii) initial inspection of the manufacturing plant and of factory production control;
 - (iii) continuous surveillance, assessment and evaluation of factory production control.

1.3. System 2+ – Declaration of the performance of the essential characteristics of the construction product by the manufacturer on the basis of the following items:

- (a) the manufacturer shall carry out:
 - (i) determination of the product-type on the basis of type testing (including sampling), type calculation, tabulated values or descriptive documentation of the product;
 - (ii) factory production control;
 - (iii) testing of samples taken at the factory in accordance with the prescribed test plan;

- (b) the notified production control certification body shall issue the certificate of conformity of the factory production control on the basis of:
 - (i) initial inspection of the manufacturing plant and of factory production control;
 - (ii) continuous surveillance, assessment and evaluation of factory production control.
- 1.4. System 3 – Declaration of the performance of the essential characteristics of the construction product by the manufacturer on the basis of the following items:
- (a) the manufacturer shall carry out factory production control;
 - (b) the notified testing laboratory shall carry out determination of the product-type on the basis of type testing (based on sampling carried out by the manufacturer), type calculation, tabulated values or descriptive documentation of the product.
- 1.5. System 4 – Declaration of the performance of the essential characteristics of the construction product by the manufacturer on the basis of the following items:
- (a) the manufacturer shall carry out:
 - (i) determination of the product-type on the basis of type testing, type calculation, tabulated values or descriptive documentation of the product;
 - (ii) factory production control;
 - (b) no tasks for the notified body.
2. BODIES INVOLVED IN THE ASSESSMENT AND VERIFICATION OF CONSTANCY OF PERFORMANCE
- With respect to the function of notified bodies involved in the assessment and verification of constancy of performance for construction products, distinction shall be made between:
- (1) product certification body: a governmental or non-governmental notified body, possessing the necessary competence and responsibility to carry out a product certification in accordance with given rules of procedure and management;
 - (2) factory production control certification body: a notified body, governmental or non-governmental, possessing the necessary competence and responsibility to carry out factory production control certification in accordance to given rules of procedure and management;
 - (3) testing laboratory: a notified laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or construction products.
3. CASES OF ESSENTIAL CHARACTERISTICS WHERE REFERENCE TO A RELEVANT HARMONISED TECHNICAL SPECIFICATION IS NOT REQUIRED
- 1. Reaction to fire.
 - 2. Resistance to fire.
 - 3. External fire performance.
 - 4. Noise absorption.
 - 5. Emissions of dangerous substances.
-

REGULATION (EU) No 306/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 9 March 2011
repealing Council Regulation (EC) No 1964/2005 on the tariff rates for bananas

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 207(2) thereof,

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

(1) Council Regulation (EC) No 1964/2005 ⁽²⁾ provides that, from 1 January 2006, the tariff rate for bananas of CN code 0803 00 19 is to be EUR 176/metric tonne.

(2) On 31 May 2010, the Geneva Agreement on Trade in Bananas ⁽³⁾ between the European Union and Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru and Venezuela ('the Agreement') regarding the structure and operation of the Union's trading regime for bananas of CN code 0803 00 19 was signed.

(3) In accordance with the Agreement, the Union will gradually reduce its banana tariff from EUR 176/metric tonne to EUR 114/metric tonne. A first cut, which was

applied retroactively from 15 December 2009, the date of initialling of the Agreement, reduced the tariff to EUR 148/metric tonne. The subsequent cuts are to apply in seven annual instalments with a possible delay of a maximum of two years if agreement on agriculture modalities in the Doha Round of the World Trade Organisation (WTO) is delayed. The final tariff of EUR 114/metric tonne is to be reached on 1 January 2019 at the latest. The tariff reductions will be bound in the WTO at the moment of the certification of the EU banana schedule.

(4) After having been applied provisionally since its date of signature, the Agreement was approved by Council Decision 2011/194/EU ⁽⁴⁾.

(5) In light of the new banana tariffs to be applied pursuant to the Agreement, it is appropriate to repeal Regulation (EC) No 1964/2005,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1964/2005 is repealed.

Article 2

This Regulation shall enter into force on the date of entry into force of the Agreement.

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

Done at Strasbourg, 9 March 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
GYŐRI E.

⁽¹⁾ Position of the European Parliament of 3 February 2011 (not yet published in the Official Journal) and decision of the Council of 7 March 2011.

⁽²⁾ OJ L 316, 2.12.2005, p. 1.

⁽³⁾ OJ L 141, 9.6.2010, p. 3.

⁽⁴⁾ See page 66 of this Official Journal.

DIRECTIVES

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

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 Articles 114 and 168 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) According to Article 168(1) 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. This implies that a high level of human health protection is to be ensured also when the Union adopts acts under other Treaty provisions.
- (2) Article 114 TFEU is the appropriate legal basis since the majority of the provisions of this Directive aim to improve the functioning of the internal market and the free movement of goods, persons and services. Given that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, Union legislation has to rely on this legal basis even when public health protection is a decisive factor in the choices made. In this respect,

Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health is to be guaranteed taking account in particular of any new development based on scientific facts.

- (3) The health systems in the Union are a central component of the Union's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.
- (4) Notwithstanding the possibility for patients to receive cross-border healthcare under this Directive, Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. Furthermore, the transposition of this Directive into national legislation and its application should not result in patients being encouraged to receive treatment outside their Member State of affiliation.
- (5) As recognised by the Council in its Conclusions of 1-2 June 2006 on Common values and principles in European Union Health Systems ⁽⁴⁾ (hereinafter the 'Council Conclusions') there is a set of operating principles that are shared by health systems throughout the Union. Those operating principles are necessary to ensure patients' trust in cross-border healthcare, which is necessary for achieving patient mobility as well as a high level of health protection. In the same statement, the Council recognised that the practical ways in which these values and principles become a reality vary significantly between Member States. In particular, decisions about the basket of healthcare to which citizens are entitled and the mechanisms used to finance and deliver that healthcare, such as the extent to which it is appropriate to rely on market mechanisms and competitive pressures to manage health systems, must be taken in the national context.

⁽¹⁾ OJ C 175, 28.7.2009, p. 116.

⁽²⁾ OJ C 120, 28.5.2009, p. 65.

⁽³⁾ Position of the European Parliament of 23 April 2009 (OJ C 184 E, 8.7.2010, p. 368), position of the Council at first reading of 13 September 2010 (OJ C 275 E, 12.10.2010, p. 1), position of the European Parliament of 19 January 2011 (not yet published in the Official Journal) and decision of the Council of 28 February 2011.

⁽⁶⁾ As confirmed by the Court of Justice of the European Union (hereinafter the 'Court of Justice') on several occasions, while recognising their specific nature, all types of medical care fall within the scope of the TFEU.

⁽⁴⁾ OJ C 146, 22.6.2006, p. 1.

- (7) This Directive respects and is without prejudice to the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States.
- (8) Some issues relating to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have already been addressed by the Court of Justice. This Directive is intended to achieve a more general, and also effective, application of principles developed by the Court of Justice on a case-by-case basis.
- (9) In the Council Conclusions, the Council recognised the particular value of an initiative on cross-border healthcare ensuring clarity for Union citizens about their rights and entitlements when they move from one Member State to another, in order to ensure legal certainty.
- (10) This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.
- (11) This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.
- (12) The concept of 'overriding reasons of general interest' to which reference is made in certain provisions of this Directive has been developed by the Court of Justice in its case-law in relation to Articles 49 and 56 TFEU and may continue to evolve. The Court of Justice has held on a number of occasions that overriding reasons of general interest are capable of justifying an obstacle to the freedom to provide services such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. The Court of Justice has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within one of the derogations, on grounds of public health, provided for in Article 52 TFEU, in so far as it contributes to the attainment of a high level of health protection. The Court of Justice has also held that such provision of the TFEU permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health.
- (13) It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation.
- (14) This Directive should not apply to services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks. More specifically, this Directive should not apply to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined a life as possible. Thus, this Directive should not apply, for example, to long-term care services provided by home care services, in assisted living facilities and in residential homes or housing ('nursing homes').
- (15) Given their specificity, access to and the allocation of organs for the purpose of organ transplants should fall outside the scope of this Directive.
- (16) For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service. The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued.

- (17) This Directive should not affect Member States' rules concerning the sale of medicinal products and medical devices over the Internet.
- (18) This Directive should not give any person an entitlement to enter, stay or reside in a Member State in order to receive healthcare in that State. Where the stay of a person on the territory of a Member State is not in accordance with the legislation of that Member State concerning the right to enter or stay on its territory, such person should not be regarded as an insured person according to the definition in this Directive. Member States should continue to be able to specify in their national legislation who is considered as an insured person for the purposes of their public healthcare scheme and social security legislation as long as the patients' rights set out in this Directive are secured.
- (19) When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. The rules applicable to cross-border healthcare should be those set out in the legislation of the Member State of treatment, given that, in accordance with Article 168(7) TFEU, the organisation and delivery of health services and medical care is the responsibility of the Member States. This should help the patient in making an informed choice, and should avoid misapprehension and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider.
- (20) In order to help patients to make an informed choice when they seek to receive healthcare in another Member State, Member States of treatment should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which healthcare providers are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on specific aspects of the healthcare services they offer and on the treatment options. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.
- (21) In its Conclusions the Council recognised that there is a set of common values and principles that are shared across the Union about how health systems respond to the needs of the population and patients that they serve.
- The overarching values of universality, access to good quality care, equity, and solidarity have been widely acknowledged in the work of various Union institutions. Therefore, Member States should also ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare needs rather than on the basis of their Member State of affiliation. In doing so, Member States should respect the principles of free movement of persons within the internal market, non-discrimination, *inter alia*, with regard to nationality and necessity and proportionality of any restrictions on free movement. However, nothing in this Directive should oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients, for instance by increasing the waiting time for treatment of other patients. Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health, in accordance with Articles 52 and 62 TFEU. However, this limitation should be without prejudice to Member States' obligations under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems⁽¹⁾.
- (22) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technologies.
- (23) Ensuring clear common obligations in respect of the provision of mechanisms for responding to harm arising from healthcare is essential to prevent lack of confidence in those mechanisms being an obstacle to taking up cross-border healthcare. Systems for addressing harm in the Member State of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate for the patient.
- (24) Member States should ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it should be for the Member State to determine the nature and modalities of such a mechanism.

⁽¹⁾ OJ L 166, 30.4.2004, p. 1.

- (25) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patients' health. These personal data should be able to flow from one Member State to another, but at the same time the fundamental rights of the individuals should be safeguarded. 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⁽¹⁾ establishes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.
- (26) The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through eHealth services.
- (27) In accordance with the principles established by the Court of Justice, and without endangering the financial balance of Member States' healthcare and social security systems, greater legal certainty as regards the reimbursement of healthcare costs should be provided for patients and for health professionals, healthcare providers and social security institutions.
- (28) This Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004. In addition, this Directive should not affect an insured person's right to be granted an authorisation for treatment in another Member State where the conditions provided for by Union regulations on the coordination of social security systems are met, in particular by Regulation (EC) No 883/2004 or Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community⁽²⁾, which are applicable by virtue of Regulation (EU) No 1231/2010 of the European Parliament and of the Council of 24 November 2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality⁽³⁾ and Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality⁽⁴⁾.
- (29) It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free movement of patients, services and goods in accordance with the TFEU and with this Directive. Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.
- (30) For patients, therefore, the two systems should be coherent; either this Directive applies or the Union regulations on the coordination of social security systems apply.
- (31) Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive. Where the patient is entitled to cross-border healthcare under both this Directive and Regulation (EC) No 883/2004, and the application of that Regulation is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation.

⁽¹⁾ OJ L 281, 23.11.1995, p. 31.

⁽²⁾ OJ L 149, 5.7.1971, p. 2.

⁽³⁾ OJ L 344, 29.12.2010, p. 1.

⁽⁴⁾ OJ L 124, 20.5.2003, p. 1.

- (32) Patients should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to the actual costs of healthcare received.
- (33) This Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person. Equally, this Directive should not prevent the Member States from extending their benefits-in-kind scheme to healthcare provided in another Member State. This Directive should recognise that Member States are free to organise their healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.
- (34) Member States of affiliation should give patients the right to receive at least the same benefits in another Member State as those provided for by the legislation of the Member State of affiliation. If the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation. The fact that the obligation to reimburse cross-border healthcare under this Directive is limited to such healthcare that is among the benefits to which the patient is entitled within its Member State of affiliation does not preclude Member States from reimbursing the cost of cross-border healthcare beyond those limits. Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory.
- (35) This Directive should not provide either for the transfer of social security entitlements between Member States or other coordination of social security systems. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State should be to enable freedom to provide healthcare for patients and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently this Directive should fully respect the differences in national healthcare systems and the Member States' responsibilities for the organisation and delivery of health services and medical care.
- (36) This Directive should provide for the right for a patient to receive any medicinal product authorised for marketing in the Member State of treatment, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State. Nothing should oblige a Member State of affiliation to reimburse an insured person for a medicinal product prescribed in the Member State of treatment, where that medicinal product is not among the benefits provided to that insured person by the statutory social security system or national health system in the Member State of affiliation.
- (37) Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State, provided that such conditions are necessary, proportionate to the aim, not discretionary or discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions should be made as quickly as possible. This should be without prejudice to the rights of the Member States to lay down criteria or conditions for prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.
- (38) In the light of the case-law of the Court of Justice, making the assumption by the statutory social security system or national health system of costs of healthcare provided in another Member State subject to prior authorisation is a restriction to the free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the assumption of the costs of healthcare provided in another Member State subject to prior authorisation, where the costs of that care, if it had been provided in its territory, would have been borne by its statutory social security system or national health system.
- (39) Patient flows between Member States are limited and expected to remain so, as the vast majority of patients in the Union receive healthcare in their own country and prefer to do so. However, in certain circumstances

patients may seek some forms of healthcare in another Member State. Examples include highly specialised care or healthcare provided in frontier areas where the nearest appropriate facility is on the other side of the border. Furthermore, some patients wish to be treated abroad in order to be close to their family members who are residing in another Member State, or in order to have access to a different method of treatment than that provided in the Member State of affiliation or because they believe that they will receive better quality healthcare in another Member State.

- (40) According to the constant case-law of the Court of Justice, Member States may make the assumption of costs by the national system of hospital care provided in another Member State subject to prior authorisation. The Court of Justice has judged that this requirement is both necessary and reasonable, since the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are equipped, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. The Court of Justice has found that such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. In addition, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. According to the Court of Justice, such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources made available for healthcare are not unlimited, whatever mode of funding is applied.
- (41) The same reasoning applies to healthcare not provided in a hospital but subjected to similar planning needs in the Member State of treatment. This may be healthcare which requires planning because it involves use of highly specialised and cost-intensive medical infrastructure or medical equipment. In light of technological progress, the development of new methods of treatment and the different policies of the Member States regarding the roles of hospitals in their healthcare systems, the question of whether this kind of healthcare is delivered within hospital or ambulatory care facilities is not the decisive factor for deciding whether it requires planning or not.
- (42) Given that the Member States are responsible for laying down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be for the Member States to decide whether

there is a need to introduce a system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system in accordance with the criteria defined by this Directive and in the light of the case-law of the Court of Justice. The information concerning this healthcare should be made publicly available in advance.

- (43) The criteria attached to the grant of prior authorisation should be justified in the light of the overriding reasons of general interest capable of justifying obstacles to the free movement of healthcare, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources. The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all and the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. It is also important to take into consideration the general principle of ensuring the safety of the patient, in a sector well known for information asymmetry, when managing a prior authorisation system. Conversely, the refusal to grant prior authorisation may not be based on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment.
- (44) According to the constant case-law of the Court of Justice, the criteria for granting or refusing prior authorisation should be limited to what is necessary and proportionate in the light of these overriding reasons in the general interest. It should be noted that the impact on national health systems caused by patient mobility might vary between Member States or between regions within a Member State, depending on factors such as geographical location, language barriers, location of hospitals in border regions or the size of the population and healthcare budget. It should therefore be for Member States to set such criteria for refusing prior authorisation that are necessary and proportionate in that specific context, also taking into account which healthcare falls within the scope of the prior authorisation system, since certain treatments of a highly specialised nature will be more easily affected even by a limited patient outflow than others. Consequently, Member States should be able to set up different criteria for different regions or other relevant administrative levels for the organisation of healthcare, or indeed for different treatments, as long as the system is transparent and easily accessible and the criteria are made public in advance.

- (45) Where the patient is entitled to healthcare and that healthcare cannot be provided within a time limit which is medically justifiable, the Member State of affiliation should in principle be obliged to grant prior authorisation. However, in certain circumstances, cross-border healthcare may expose the patient or the general public to a risk which overrides the interest of the patient to receive the cross-border healthcare sought. In such instances, the Member State of affiliation should be able to refuse the request for prior authorisation, in which case the Member State of affiliation should direct the patient towards alternative solutions.
- (46) In any event, if a Member State decides to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member State in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Regulation (EEC) No 1408/71 or Regulation (EC) No 883/2004 are fulfilled, the authorisation should be granted and the benefits provided in accordance with Regulation (EC) No 883/2004 unless otherwise requested by the patient. This should apply in particular in instances where the authorisation is granted after an administrative or judicial review of the request and the person concerned has received the treatment in another Member State. In that event, Articles 7 and 8 of this Directive should not apply. This is in line with the case-law of the Court of Justice which has specified that patients who were refused prior authorisation on grounds that were subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.
- (47) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non-discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This should also apply to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment. It is appropriate that, under normal circumstances, patients be entitled to receive decisions regarding cross-border healthcare within a reasonable period of time. However, that period should be shortened where warranted by the urgency of the treatment in question.
- (48) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for providing such information is to establish national contact points within each Member State. Information that has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may be provided in any other language.
- (49) The Member States should decide on the form and number of their national contact points. Such national contact points may also be incorporated in, or build on, activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. National contact points should be established in an efficient and transparent way and they should be able to consult with patient organisations, healthcare insurers and healthcare providers. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare. The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Union level. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.
- (50) Member States should facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient cross-border healthcare. This could be of particular importance in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local population, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology (hereinafter 'ICT') systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications⁽¹⁾ stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State is not, subject to specific provisions of Union law, to be restricted for

⁽¹⁾ OJ L 255, 30.9.2005, p. 22.

any reason relating to professional qualifications. This Directive should be without prejudice to Directive 2005/36/EC.

- (51) The Commission should encourage cooperation between Member States in the areas set out in Chapter IV of this Directive and may, in accordance with Article 168(2) TFEU, take, in close contact with the Member States, any useful initiative to facilitate and promote such cooperation. In that context, the Commission should encourage cooperation in cross-border healthcare provision at regional and local level, particularly by identifying major obstacles to collaboration between healthcare providers in border regions, and by making recommendations and disseminating information and best practices on how to overcome such obstacles.
- (52) The Member State of affiliation may need to receive confirmation that the cross-border healthcare will be, or has been, delivered by a legally practising health professional. It is therefore appropriate to ensure that information on the right to practise contained in the national or local registers of health professionals, if established in the Member State of treatment, are, upon request, made available to the authorities of the Member State of affiliation.
- (53) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. The removal of regulatory and administrative barriers to such recognition should be without prejudice to the need for appropriate agreement of the patient's treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. The recognition of prescriptions from other Member States should not affect any professional or ethical duty that would require pharmacists to refuse to dispense the prescription. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products among the benefits covered by the social security system of affiliation. It should further be noted that the reimbursement of medicinal products is not affected by the rules on mutual recognition of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in Chapter III of this Directive. The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing should prevent Member States from having further elements in their

prescriptions, as long as this does not prevent prescriptions from other Member States that contain the common list of elements from being recognised. The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

- (54) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases. This Directive should therefore give incentives to Member States to reinforce the continued development of European reference networks. European reference networks are based on the voluntary participation of their members, but the Commission should develop criteria and conditions that the networks should be required to fulfil in order to receive support from the Commission.
- (55) Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products⁽¹⁾, and they are all serious, chronic and often life threatening. Some patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy, difficulties which were also recognised by the Council Recommendation of 8 June 2009 on an action in the field of rare diseases⁽²⁾.
- (56) Technological developments in cross-border provision of healthcare through the use of ICTs may result in the exercise of supervisory responsibilities by Member States being unclear, and can thus hinder the free movement of healthcare and give rise to possible additional risks to health protection. Widely different and incompatible formats and standards are used for provision of healthcare using ICTs throughout the Union, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary for Member States to aim at interoperability of ICT systems. The deployment of health ICT systems, however, is entirely a national competence. This Directive therefore should recognise the importance of the work on interoperability and respect the division of competences by providing for the Commission and Member States to work together on developing measures which are not legally binding but provide additional tools that are available to Member States to facilitate greater interoperability of

⁽¹⁾ OJ L 18, 22.1.2000, p. 1.

⁽²⁾ OJ C 151, 3.7.2009, p. 7.

ICT systems in the healthcare field and to support patient access to eHealth applications, whenever Member States decide to introduce them.

empowered to adopt delegated acts in respect of the criteria and conditions that European reference networks have to fulfil.

(57) The interoperability of eHealth solutions should be achieved whilst respecting national regulations on the provision of healthcare services adopted in order to protect the patient, including legislation on Internet pharmacies, in particular national bans on mail order of prescription-only medicinal products to the extent that they are compatible with the case-law of the Court of Justice and Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts⁽¹⁾ and 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⁽²⁾.

(61) It is of particular importance that, when empowered to adopt delegated acts in accordance with Article 290 TFEU, the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(62) In accordance with point 34 of the Interinstitutional Agreement on better law-making⁽⁴⁾, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(58) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoid duplication of effort, and provide a better evidence base for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. Such cooperation requires sustained structures involving all the relevant authorities of the Member States, building on existing pilot projects and consultation of a wide range of stakeholders. This Directive should therefore provide a basis for continued Union support for such cooperation.

(63) The European Data Protection Supervisor has also delivered his opinion on the proposal for this Directive⁽⁵⁾.

(64) Since the objective of this Directive, namely providing rules for facilitating the access to safe and high quality cross-border healthcare in the Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of its 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 European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

(59) According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new Regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽³⁾ continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare. This Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.

(60) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of measures that would exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, as provided for in this Directive. In order to identify the reference networks which should benefit from support by the Commission, the Commission should also be

⁽¹⁾ OJ L 144, 4.6.1997, p. 19.

⁽²⁾ OJ L 178, 17.7.2000, p. 1.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁴⁾ OJ C 321, 31.12.2003, p. 1.

⁽⁵⁾ OJ C 128, 6.6.2009, p. 20.

2. This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

3. This Directive shall not apply to:

- (a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;
- (b) allocation of and access to organs for the purpose of organ transplants;
- (c) with the exception of Chapter IV, public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.

4. This Directive shall not affect laws and regulations in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. In particular, nothing in this Directive obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.

Article 2

Relationship with other Union provisions

This Directive shall apply without prejudice to:

- (a) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems ⁽¹⁾;
- (b) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ⁽²⁾, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽³⁾ and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ⁽⁴⁾;
- (c) Directive 95/46/EC and 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 ⁽⁵⁾;
- (d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services ⁽⁶⁾;
- (e) Directive 2000/31/EC;

(f) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin ⁽⁷⁾;

(g) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ⁽⁸⁾;

(h) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽⁹⁾;

(i) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ⁽¹⁰⁾;

(j) Regulation (EC) No 859/2003;

(k) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ⁽¹¹⁾;

(l) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ⁽¹²⁾;

(m) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems ⁽¹³⁾;

(n) Directive 2005/36/EC;

(o) Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC) ⁽¹⁴⁾;

⁽¹⁾ OJ L 40, 11.2.1989, p. 8.

⁽²⁾ OJ L 189, 20.7.1990, p. 17.

⁽³⁾ OJ L 169, 12.7.1993, p. 1.

⁽⁴⁾ OJ L 331, 7.12.1998, p. 1.

⁽⁵⁾ OJ L 201, 31.7.2002, p. 37.

⁽⁶⁾ OJ L 18, 21.1.1997, p. 1.

⁽⁷⁾ OJ L 180, 19.7.2000, p. 22.

⁽⁸⁾ OJ L 121, 1.5.2001, p. 34.

⁽⁹⁾ OJ L 311, 28.11.2001, p. 67.

⁽¹⁰⁾ OJ L 33, 8.2.2003, p. 30.

⁽¹¹⁾ OJ L 102, 7.4.2004, p. 48.

⁽¹²⁾ OJ L 136, 30.4.2004, p. 1.

⁽¹³⁾ OJ L 284, 30.10.2009, p. 1.

⁽¹⁴⁾ OJ L 210, 31.7.2006, p. 19.

- (p) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work ⁽¹⁾;
- (q) Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I) ⁽²⁾, Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) ⁽³⁾ and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law;
- (r) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation ⁽⁴⁾;
- (s) Regulation (EU) No 1231/2010.

Article 3

Definitions

For the purposes of this Directive, the following definitions shall apply:

- (a) 'healthcare' means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;
- (b) 'insured person' means:
 - (i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and
 - (ii) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits;
- (c) 'Member State of affiliation' means:
 - (i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;
 - (ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State;
- (d) 'Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established;
- (e) 'cross-border healthcare' means healthcare provided or prescribed in a Member State other than the Member State of affiliation;
- (f) 'health professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment;
- (g) 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State;
- (h) 'patient' means any natural person who seeks to receive or receives healthcare in a Member State;
- (i) 'medicinal product' means a medicinal product as defined by Directive 2001/83/EC;
- (j) 'medical device' means a medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;
- (k) 'prescription' means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued;

⁽¹⁾ OJ L 354, 31.12.2008, p. 70.

⁽²⁾ OJ L 177, 4.7.2008, p. 6.

⁽³⁾ OJ L 199, 31.7.2007, p. 40.

⁽⁴⁾ OJ L 207, 6.8.2010, p. 14.

- (l) 'health technology' means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare;
- (m) 'medical records' means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process.
- (c) there are transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;
- (d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;

CHAPTER II

RESPONSIBILITIES OF MEMBER STATES WITH REGARD TO CROSS-BORDER HEALTH CARE

Article 4

Responsibilities of the Member State of treatment

1. Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with:

- (a) the legislation of the Member State of treatment;
- (b) standards and guidelines on quality and safety laid down by the Member State of treatment; and
- (c) Union legislation on safety standards.

2. The Member State of treatment shall ensure that:

- (a) patients receive from the national contact point referred to in Article 6, upon request, relevant information on the standards and guidelines referred to in paragraph 1(b) of this Article, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities;
- (b) healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and that they also provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;

(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

(f) in order to ensure continuity of care, patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

3. The principle of non-discrimination with regard to nationality shall be applied to patients from other Member States.

This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources, to adopt measures regarding access to treatment aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare within its territory. Such measures shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination and shall be made publicly available in advance.

4. Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable medical situation, or that they charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients.

This paragraph shall be without prejudice to national legislation which allows healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.

5. This Directive shall not affect laws and regulations in Member States on the use of languages. Member States may choose to deliver information in other languages than those which are official languages in the Member State concerned.

Article 5

Responsibilities of the Member State of affiliation

The Member State of affiliation shall ensure that:

- (a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;
- (b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with Article 7(6) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with Article 9. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004;
- (c) where a patient has received cross-border healthcare and where medical follow-up proves necessary, the same medical follow-up is available as would have been if that healthcare had been provided on its territory;
- (d) patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Article 6

National contact points for cross-border healthcare

1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission. The Commission and the Member States shall make this information publicly available. Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers.

2. National contact points shall facilitate the exchange of information referred to in paragraph 3 and shall cooperate closely with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.

3. In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

4. National contact points in the Member State of affiliation shall provide patients and health professionals with the information referred to in Article 5(b).

5. The information referred to in this Article shall be easily accessible and shall be made available by electronic means and in formats accessible to people with disabilities, as appropriate.

CHAPTER III

REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTHCARE

Article 7

General principles for reimbursement of costs

1. Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

2. By way of derogation from paragraph 1:

- (a) if a Member State is listed in Annex IV to Regulation (EC) No 883/2004 and in compliance with that Regulation has recognised the rights to sickness benefits for pensioners and the members of their families, being resident in a different Member State, it shall provide them healthcare under this Directive at its own expense when they stay on its territory, in accordance with its legislation, as though the persons concerned were residents in the Member State listed in that Annex;

(b) if the healthcare provided in accordance with this Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation (EC) No 883/2004, and is provided in the territory of the Member State that according to that Regulation and Regulation (EC) No 987/2009 is, in the end, responsible for reimbursement of the costs, the costs shall be assumed by that Member State. That Member State may assume the costs of the healthcare in accordance with the terms, conditions, criteria for eligibility and regulatory and administrative formalities that it has established, provided that these are compatible with the TFEU.

3. It is for the Member State of affiliation to determine, whether at a local, regional or national level, the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided.

4. The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.

Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.

The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs.

5. Member States may adopt provisions in accordance with the TFEU aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

6. For the purposes of paragraph 4, Member States shall have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by

the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level.

7. The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of tele-medicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

8. The Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorisation except in the cases set out in Article 8.

9. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

10. Notwithstanding paragraph 9, Member States shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed in accordance with the authorisation.

11. The decision to limit the application of this Article pursuant to paragraph 9 shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9.

*Article 8***Healthcare that may be subject to prior authorisation**

1. The Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare, in accordance with this Article and Article 9. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

2. Healthcare that may be subject to prior authorisation shall be limited to healthcare which:

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

(i) involves overnight hospital accommodation of the patient in question for at least one night; or

(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(b) involves treatments presenting a particular risk for the patient or the population; or

(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

Member States shall notify the categories of healthcare referred to in point (a) to the Commission.

3. With regard to requests for prior authorisation made by an insured person with a view to receiving cross-border healthcare, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation unless the patient requests otherwise.

4. When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice.

5. Without prejudice to points (a) to (c) of paragraph 6, the Member State of affiliation may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with Article 7, and when this healthcare cannot be provided on its territory within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed.

6. The Member State of affiliation may refuse to grant prior authorisation for the following reasons:

(a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare;

(b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;

(c) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment;

(d) this healthcare can be provided on its territory within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned.

7. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.

*Article 9***Administrative procedures regarding cross-border healthcare**

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved.

2. Any administrative procedure of the kind referred to in paragraph 1 shall be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. Such a procedure shall be capable of ensuring that requests are dealt with objectively and impartially.

3. Member States shall set out reasonable periods of time within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member States shall take into account:

- (a) the specific medical condition;
- (b) the urgency and individual circumstances.

4. Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

5. This Directive is without prejudice to Member States' right to offer patients a voluntary system of prior notification whereby, in return for such notification, the patient receives a written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply.

Member States may choose to apply the mechanisms of financial compensation between the competent institutions as provided for by Regulation (EC) No 883/2004. Where a Member State of affiliation does not apply such mechanisms, it shall ensure that patients receive reimbursement without undue delay.

CHAPTER IV

COOPERATION IN HEALTHCARE*Article 10***Mutual assistance and cooperation**

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including

cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their national contact points in accordance with Article 6, including on provisions on supervision and mutual assistance to clarify the content of invoices.

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through ICT and other forms of cross-border cooperation.

3. The Commission shall encourage Member States, particularly neighbouring countries, to conclude agreements among themselves. The Commission shall also encourage the Member States to cooperate in cross-border healthcare provision in border regions.

4. Member States of treatment shall ensure that information on the right to practise of health professionals listed in national or local registers established on their territory is, upon request, made available to the authorities of other Member States, for the purpose of cross-border healthcare, in accordance with Chapters II and III and with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, and the principle of presumption of innocence. The exchange of information shall take place via the Internal Market Information system established pursuant to Commission Decision 2008/49/EC of 12 December 2007 concerning the implementation of the Internal Market Information System (IMI) as regards the protection of personal data ⁽¹⁾.

*Article 11***Recognition of prescriptions issued in another Member State**

1. If a medicinal product is authorised to be marketed on their territory, in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:

- (a) limited to what is necessary and proportionate to safeguard human health, and non-discriminatory; or
- (b) based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

⁽¹⁾ OJ L 13, 16.1.2008, p. 18.

The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of medicinal products is covered by Chapter III of this Directive.

In particular, the recognition of prescriptions shall not affect a pharmacist's right, by virtue of national rules, to refuse, for ethical reasons, to dispense a product that was prescribed in another Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

The Member State of affiliation shall take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation.

This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.

2. In order to facilitate implementation of paragraph 1, the Commission shall adopt:

- (a) measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;
- (b) guidelines supporting the Member States in developing the interoperability of ePrescriptions;
- (c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;

- (d) measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.

Measures referred in point (a) shall be adopted by the Commission no later than 25 December 2012 and measures in points (c) and (d) shall be adopted by the Commission no later than 25 October 2012.

3. The measures and guidelines referred to in points (a) to (d) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

4. In adopting measures or guidelines under paragraph 2, the Commission shall have regard to the proportionality of any costs of compliance with, as well as the likely benefits of, the measures or guidelines.

5. For the purpose of paragraph 1, the Commission shall also adopt, by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19 and no later than 25 October 2012 measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions provided for under this Article, where necessary in order to safeguard public health.

6. Paragraph 1 shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

Article 12

European reference networks

1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.

2. European reference networks shall have at least three of the following objectives:

- (a) to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies;

- (b) to contribute to the pooling of knowledge regarding sickness prevention;
 - (c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;
 - (d) to maximise the cost-effective use of resources by concentrating them where appropriate;
 - (e) to reinforce research, epidemiological surveillance like registries and provide training for health professionals;
 - (f) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;
 - (g) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;
 - (h) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.
3. Member States are encouraged to facilitate the development of the European reference networks:
- (a) by connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory;
 - (b) by fostering the participation of healthcare providers and centres of expertise in the European reference networks.
4. For the purposes of paragraph 1, the Commission shall:
- (a) adopt a list of specific criteria and conditions that the European reference networks must fulfil and the conditions and criteria required from healthcare providers wishing to join the European reference network. These criteria and conditions shall ensure, inter alia, that European reference networks:
 - (i) have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;
 - (ii) follow a multi-disciplinary approach;
 - (iii) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;
 - (iv) make a contribution to research;
 - (v) organise teaching and training activities; and
 - (vi) collaborate closely with other centres of expertise and networks at national and international level;
 - (b) develop and publish criteria for establishing and evaluating European reference networks;
 - (c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and their evaluation.
5. The Commission shall adopt the measures referred to in paragraph 4(a) by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19. The measures referred to in points (b) and (c) of paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).
6. Measures adopted pursuant to this Article shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.
- Article 13*
- Rare diseases**
- The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:
- (a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;
 - (b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

*Article 14***eHealth**

1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2. The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

*Article 15***Cooperation on health technology assessment**

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the

principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

2. The objectives of the health technology assessment network shall be to:

(a) support cooperation between national authorities or bodies;

(b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;

(c) support the analysis of the nature and type of information that can be exchanged;

(d) avoid duplication of assessments.

3. In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:

(a) contribute to the financing of administrative and technical support;

(b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;

(c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;

(d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;

(e) facilitate the consultation of stakeholders on the work of the network.

4. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

5. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.

6. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.

7. Measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

CHAPTER V

IMPLEMENTING AND FINAL PROVISIONS

Article 16

Committee

1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Article 17

Exercise of the delegation

1. The powers to adopt delegated acts referred to in Articles 11(5) and 12(5) shall be conferred on the Commission for a period of 5 years from 24 April 2011. The Commission shall make a report in respect of the delegated powers not later than 6 months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 18.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 18 and 19.

Article 18

Revocation of the delegation

1. The delegation of power referred to in Articles 11(5) and 12(5) may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of

power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 19

Objections to delegated acts

1. The European Parliament or the Council may object to the delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by 2 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 20

Reports

1. The Commission shall by 25 October 2015 and subsequently every 3 years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.

2. The report shall in particular include information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and Article 8, and on the functioning of the European reference networks and national contact points. To this end, the Commission shall conduct an assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Union legislation relating to patient mobility.

The Member States shall provide the Commission with assistance and all available information for carrying out the assessment and preparing the reports.

3. Member States and the Commission shall have recourse to the Administrative Commission established pursuant to Article 71 of Regulation (EC) No 883/2004, in order to address the financial consequences of the application of this Directive on the Member States which have opted for reimbursement on the basis of fixed amounts, in cases covered by Articles 20(4) and 27(5) of that Regulation.

The Commission shall monitor and regularly report on the effect of Article 3(c)(i) and Article 8 of this Directive. A first report shall be presented by 25 October 2013. On the basis of these reports, the Commission shall, where appropriate, make proposals to alleviate any disproportionalities.

Article 21

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 25 October 2013. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a

reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

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 22

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 23

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 9 March 2011.

For the European Parliament

The President

J. BUZEK

For the Council

The President

GYŐRI E.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 7 March 2011

on the conclusion of a Geneva Agreement on Trade in Bananas between the European Union and Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru and Venezuela and of an Agreement on Trade in Bananas between the European Union and the United States of America

(2011/194/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(6)(a) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) In accordance with Council Decision 2010/314/EU ⁽¹⁾, the Geneva Agreement on Trade in Bananas between the European Union and Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru and Venezuela and the Agreement on Trade in Bananas between the European Union and the United States of America were signed on behalf of the Union on 31 May 2010 and 8 June 2010, respectively, subject to their conclusion at a later date.

(2) Those two Agreements should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The following Agreements are hereby approved:

(a) the Geneva Agreement on Trade in Bananas between the European Union and Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru and Venezuela ⁽²⁾ (the 'Geneva Agreement');

(b) the Agreement on Trade in Bananas between the European Union and the United States of America ⁽³⁾ (the 'EU/US Agreement').

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to proceed, on behalf of the Union, to the notification provided for in paragraph 8(a) of the Geneva Agreement and in paragraph 6 of the EU/US Agreement, in order to express the consent of the Union to be bound by those Agreements.

Article 3

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 7 March 2011.

For the Council
The President
CZOMBA S.

⁽¹⁾ OJ L 141, 9.6.2010, p. 1.

⁽²⁾ OJ L 141, 9.6.2010, p. 3.

⁽³⁾ OJ L 141, 9.6.2010, p. 6.

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