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I

(Legislative acts)

REGULATIONS

**REGULATION (EU) No 652/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014**

laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC

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) and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

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

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

Having consulted the Committee of the Regions

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

Whereas:

- (1) Union law provides for requirements regarding food and food safety and feed and feed safety, at all stages of production, including rules that aim to guarantee fair practices in trade and the provision of information to consumers. It also lays down requirements regarding the prevention and control of transmissible diseases in animals and zoonoses, as well as requirements regarding animal welfare, animal by-products, plant health and plant reproductive material, the protection of plant varieties, genetically modified organisms, the placing on the market and use of plant protection products and the sustainable use of pesticides. Union law also provides for official controls and other official activities aimed at ensuring the effective implementation of and the compliance with those requirements.
- (2) The general objective of Union law in those areas is to contribute to a high level of health for humans, animals and plants along the food chain, a high level of protection and information for consumers and a high level of protection of the environment, while favouring competitiveness and creation of jobs.

⁽¹⁾ OJ C 67, 6.3.2014, p. 166.

⁽²⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.

- (3) The pursuit of that general objective requires appropriate financial resources. It is therefore necessary for the Union to contribute to the funding of measures undertaken in the different areas relating to that general objective. In addition, in order to efficiently target the use of the expenditure, specific objectives should be laid down and indicators should be set to assess the achievement of those objectives.
- (4) Union financing for expenditure relating to food and feed has, in the past, taken the form of grants, procurement and payments to international organisations active in the field. It is appropriate to continue such financing in the same manner.
- (5) Union financing may also be used by Member States to support them in actions on plant or animal health for the control, prevention or eradication of pests or animal diseases to be carried out by organisations active in those fields.
- (6) For reasons of budgetary discipline, it is necessary to lay down in this Regulation the list of eligible measures which may benefit from a Union contribution as well as the eligible costs and applicable rates.
- (7) Taking into account Council Regulation (EU, Euratom) No 1311/2013 ⁽¹⁾, the maximum amount for expenditure in relation to food and feed during the whole period 2014 to 2020 is to be EUR 1 891 936 000.
- (8) Furthermore, Union-level funding should be provided in order to cope with exceptional circumstances such as emergency situations related to animal and plant health, when the appropriations under budget heading 3 are insufficient but emergency measures are necessary. Funding in order to cope with such crises should be mobilised by, for example, drawing on the flexibility instrument, in accordance with the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management ⁽²⁾.
- (9) The law currently provides that some of the eligible costs are to be reimbursed at fixed rates. In relation to other costs, the law does not provide for limits on reimbursement. In order to rationalise and simplify the system, a fixed maximum rate for reimbursement should be set. It is appropriate to set that rate at the level which is usually applied to grants. It is also necessary to provide the possibility to raise that maximum rate in certain circumstances.
- (10) Due to the importance of achieving the objectives of this Regulation, it is appropriate to finance 100 % of the eligible costs for certain actions, provided that the implementation of those actions also implies incurring costs which are not eligible.
- (11) The Union is responsible for ensuring that funds are properly spent and for taking measures that respond to the need to simplify its spending programmes in order to reduce the administrative burden and the costs for the beneficiaries of funds and for all actors involved, in line with the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 8 October 2010 entitled Smart Regulation in the European Union.
- (12) Union law requires Member States to implement certain measures when certain animal diseases or zoonoses occur or develop. Therefore, the Union should make a financial contribution to such emergency measures.
- (13) It is also necessary to reduce, by appropriate eradication, control and monitoring measures, the number of outbreaks of animal diseases and zoonoses which pose a risk to human and animal health, as well as to prevent the occurrence of such outbreaks. National programmes for the eradication, control and monitoring of those diseases and zoonoses should therefore benefit from Union funding.

⁽¹⁾ Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884).

⁽²⁾ OJ C 373, 20.12.2013, p. 1.

- (14) For organisational and efficiency reasons in respect of the handling of funding in the animal and plant health areas, it is appropriate to lay down rules on content, submission, evaluation and approval of national programmes, including those implemented in the outermost regions of the Union referred to in Article 349 of the Treaty on the Functioning of the European Union (TFEU). For the same reasons, deadlines for reporting and filing of payment requests should also be laid down.
- (15) Council Directive 2000/29/EC ⁽¹⁾ requires Member States to take certain emergency measures for the eradication of organisms harmful to plants or plant products ('pests'). The Union should make a financial contribution towards the eradication of those pests. A Union financial contribution should also be available, subject to certain conditions, for emergency measures aimed at containing the pests which have the most severe impact on the Union and which cannot be eradicated in certain zones and for prevention measures concerning those pests.
- (16) Emergency measures taken against pests should be eligible for Union co-financing provided that they lead to added value for the Union as a whole. For this reason, a Union financial contribution should be made available for pests listed in Section I of Part A of Annex I and Section I of Part A of Annex II to Directive 2000/29/EC under the heading 'Harmful organisms not known to occur in any part of the Union and relevant for the entire Union'. Where pests are known to occur in the Union, only measures relating to those of them which have the most severe impact on the Union should be eligible for a Union financial contribution. Such pests include in particular those subject to the measures under Council Directive 69/464/EEC ⁽²⁾, 93/85/EEC ⁽³⁾, 98/57/EC ⁽⁴⁾ or 2007/33/EC ⁽⁵⁾. A Union financial contribution should also be made available for those pests which are not listed in Annex I or Annex II to Directive 2000/29/EC which are subject to national measures and which provisionally qualify for listing in Section I of Part A of Annex I to Directive 2000/29/EC or Section I of Part A of Annex II thereto. Measures relating to pests subject to Union emergency measures that aim to eradicate them should also be eligible for a Union financial contribution.
- (17) It is necessary to detect in a timely manner the presence of certain pests. Surveys of such presence carried out by Member States are essential to ensure the immediate eradication of outbreaks of those pests. The surveys carried out by individual Member States are essential to protecting the territory of all other Member States. The Union may contribute to the financing of those surveys in general, on condition that their scope includes at least one of the two critical categories of pests, namely the pests which are not known to occur in the Union and the pests which are subject to Union emergency measures.
- (18) Union financing for measures in the field of animal and plant health should cover specific eligible costs. In exceptional and duly justified cases, it should also cover the costs incurred by the Member States in carrying out other necessary measures. Such measures may include the implementation of enhanced biosecurity measures in case of outbreak of disease or presence of pests, the destruction and transport of carcasses during eradication programmes, and the costs of compensation to owners resulting from emergency vaccination campaigns.
- (19) The outermost regions of Member States experience difficulties caused by their remoteness and by their dependence on a limited number of products. It is appropriate for the Union to grant a financial contribution to Member States for programmes that they carry out for the control of pests in those outermost regions in line with the objectives of Regulation (EU) No 228/2013 of the European Parliament and of the Council ⁽⁶⁾. Since certain outermost regions are subject to national rules specific for those regions instead of the Union rules laid down in Directive 2000/29/EC, that Union financial contribution should apply to the rules in force in those regions, regardless of whether they are Union rules or national rules.

⁽¹⁾ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

⁽²⁾ Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease (OJ L 323, 24.12.1969, p. 1).

⁽³⁾ Council Directive 93/85/EEC of 4 October 1993 on the control of potato ring rot (OJ L 259, 18.10.1993, p. 1).

⁽⁴⁾ Council Directive 98/57/EC of 20 July 1998 on the control of *Ralstonia solanacearum* (Smith) Yabuuchi et al. (OJ L 235, 21.8.1998, p. 1).

⁽⁵⁾ Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC (OJ L 156, 16.6.2007, p. 12).

⁽⁶⁾ Regulation (EU) No 228/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 (OJ L 78, 20.3.2013, p. 23).

- (20) Official controls carried out by the Member States are an essential tool for verifying and monitoring that relevant Union requirements are being implemented, complied with and enforced. The effectiveness and efficiency of official control systems is vital for maintaining a high level of safety for humans, animals and plants along the food chain whilst ensuring a high level of protection of the environment. Union financial support should be made available for such control measures. In particular, a financial contribution should be available to Union reference laboratories in order to help them bear the costs arising from the implementation of work programmes approved by the Commission. Moreover, since the effectiveness of official controls also depends on the availability to the control authorities of well trained staff with an appropriate knowledge of Union law, the Union should be able to contribute to their training and relevant exchange programmes organised by competent authorities.
- (21) The efficient management of official controls depends on a rapid exchange of data and information related to those controls. In addition, the proper and harmonised implementation of the relevant rules depends on the setting up of efficient systems involving Member State competent authorities. Therefore the establishment and operation of databases and computerised information management systems for those purposes should also be eligible for financial contributions.
- (22) The Union should make funding available for the technical, scientific, coordination and communication activities necessary to ensure the correct implementation of Union law and to ensure the adaptation of the law to scientific, technological and societal developments. Funding should also be made available for projects that aim to improve the effectiveness and efficiency of official controls.
- (23) Pursuant to Article 3 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ⁽¹⁾, any proposal submitted to the legislative authority containing derogations from the provisions of that Regulation is required to clearly indicate such derogations and to state the specific reasons justifying them. Therefore, given the specific nature of some of the objectives covered by this Regulation and since the respective competent authorities of the Member States are best placed to implement the activities associated with those objectives, those authorities should be considered to be identified beneficiaries for the purposes of Article 128(1) of Regulation (EU, Euratom) No 966/2012. It should therefore be possible to award grants to such authorities without prior publication of calls for proposals.
- (24) By way of derogation from Article 86 of Regulation (EU, Euratom) No 966/2012, and as an exception to the principle of non-retroactivity provided for in Article 130 thereof, the costs for the emergency measures covered by Articles 7 and 17 of this Regulation should be eligible from the date of notification of the occurrence of a disease or the presence of a pest by the Member State to the Commission due to the urgent and unforeseeable nature of those measures. The corresponding budgetary commitments and the payment of eligible expenditure should be made by the Commission, after assessment of the payment applications submitted by the Member States.
- (25) It is of the utmost importance that such emergency measures are implemented immediately. It would therefore be counterproductive to exclude, from funding, those costs incurred prior to the submission of the grant application, as this would encourage Member States to focus their immediate efforts on the preparation of a grant application, instead of on the implementation of emergency measures.
- (26) Given the extent of the Union law in force concerning the implementation of eradication and surveillance measures and the technical limitations as regards other expertise available, the implementation of the measures covered by this Regulation needs to be carried out principally by the competent authorities of the Member States. It is therefore necessary, in certain cases, to co-finance the salary costs of the personnel of national administrations.

⁽¹⁾ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

- (27) Programming allows coordination and prioritisation and thus contributes to the effective use of Union financial resources. In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with regard to the adoption of work programmes for the implementation of certain measures provided for in this Regulation.
- (28) To ensure responsible and effective use of Union financial resources, the Commission should be allowed to check that Union funding is effectively used for the implementation of eligible measures either by on-the-spot checks or by documentary checks.
- (29) The financial interests of the Union should be protected throughout the expenditure cycle, including by the prevention, detection and investigation of irregularities and by the recovery of funds lost, wrongly paid or incorrectly used.
- (30) The list of animal diseases which qualify for funding under emergency measures is annexed to this Regulation and contains the animal diseases referred to in Articles 3(1), 4(1), 6(2) and 14(1) of Council Decision 2009/470/EC ⁽¹⁾. In order to take account of the animal diseases which are required to be notified in accordance with Council Directive 82/894/EEC ⁽²⁾, and the diseases which are likely to constitute a new threat for the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of supplementing that list.
- (31) The lists of animal diseases and zoonoses which qualify for funding under the eradication, control and surveillance programmes are annexed to this Regulation and contain the animal diseases and zoonoses referred to in Annex I to Decision 2009/470/EC. In order to take account of the situations that are provoked by those animal diseases that have a significant impact on livestock production or trade, the development of zoonoses which pose a threat to humans, or new scientific or epidemiological developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of supplementing those lists.
- (32) When adopting delegated acts under this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (33) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with regard to the establishment of annual and multiannual work programmes; of the financial contribution for emergency measures or where it is necessary to respond to unforeseeable developments; of procedures for the submission by Member States of applications, and of reports and requests for payments for the grants. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽³⁾.
- (34) Union law should be implemented in such a way as to ensure that it delivers the intended benefits, in the light of experience. It is therefore appropriate for the Commission to evaluate the functioning and effectiveness of this Regulation and to communicate the results to the other institutions.

⁽¹⁾ Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field (OJ L 155, 18.6.2009, p. 30).

⁽²⁾ Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58).

⁽³⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (35) Different committees currently assist the Commission in the implementation of existing Union rules covered by this Regulation, in particular the Committees established by Council Decisions 66/399/EEC ⁽¹⁾, 76/894/EEC ⁽²⁾, Council Directives 98/56/EC ⁽³⁾, 2008/90/EC ⁽⁴⁾, and by Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁵⁾. It is appropriate to streamline the Committee procedure in this area. The Committee established by Article 58 of Regulation (EC) No 178/2002 should be charged with the task of assisting the Commission in the exercise of its implementing powers in respect of the expenditure incurred in the relevant areas and the name of that Committee should be changed in order to reflect its increased responsibilities. Consequently, Decisions 66/399/EEC and 76/894/EEC should be repealed and Directives 98/56/EC and 2008/90/EC and Regulation (EC) No 178/2002 should be amended accordingly.
- (36) This Regulation replaces the provisions of Decision 2009/470/EC. It also replaces Articles 13c(5) and Articles 22 to 26 of Directive 2000/29/EC, Article 66 of Regulation (EC) No 882/2004 of the European Parliament and of the Council ⁽⁶⁾, Chapter VII of Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁷⁾, Article 22 of Directive 2009/128/EC of the European Parliament and of the Council ⁽⁸⁾ and Article 76 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽⁹⁾. Consequently, Directive 2000/29/EC, Regulations (EC) No 882/2004 and (EC) No 396/2005, Directive 2009/128/EC and Regulation (EC) No 1107/2009 should be amended accordingly.
- (37) The introduction of Union co-financing for costs incurred by Member States for compensation to owners for the value of destroyed plants, plant products or other objects subject to the measures referred to in Article 16 of Directive 2000/29/EC requires the development of guidelines on the conditions applicable as regards the limits of the market value of the crops and trees concerned. That introduction should therefore apply only from 1 January 2017,

HAVE ADOPTED THIS REGULATION:

TITLE I

COMMON PROVISIONS

CHAPTER I

Subject matter, scope and objectives

Article 1

Subject matter and scope

This Regulation establishes provisions for the management of expenditure from the general budget of the European Union in the fields covered by Union rules:

- (a) governing food and food safety, at any stage of the production, processing, distribution and disposal of food, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;

⁽¹⁾ Council Decision 66/399/EEC of 14 June 1966 setting up a Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry (OJ L 125, 11.7.1966, p. 2289/66).

⁽²⁾ Council Decision 76/894/EEC of 23 November 1976 establishing a Standing Committee on Plant Health (OJ L 340, 9.12.1976, p. 25).

⁽³⁾ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

⁽⁴⁾ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

⁽⁵⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽⁶⁾ Regulation (EC) No 882/2004 of 29 April 2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽⁷⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽⁸⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

⁽⁹⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of the plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

- (b) governing feed and feed safety at any stage of the production, processing, distribution, disposal and use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;
- (c) laying down animal health requirements;
- (d) laying down welfare requirements for animals;
- (e) on protective measures against organisms harmful to plants or plant products as defined in point (e) of Article 2(1) of Directive 2000/29/EC ('pests');
- (f) on the production, with a view to placing on the market, and placing on the market of plant reproductive material;
- (g) laying down the requirements for placing on the market of plant protection products and the sustainable use of pesticides;
- (h) aiming to prevent and minimise risks to public and animal health arising from animal by-products and derived products;
- (i) governing the deliberate release into the environment of genetically modified organisms;
- (j) on the protection of intellectual property rights in relation to plant varieties and conservation and exchange of plant genetic resources.

Article 2

Objectives

1. The expenditure referred to in Article 1 shall aim to attain:
 - (a) the general objective of contributing to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating diseases and pests and by ensuring a high level of protection for consumers and the environment, while enhancing the competitiveness of the Union food and feed industry and favouring the creation of jobs;
 - (b) the following specific objectives:
 - (i) to contribute to a high level of safety of food and food production systems and of other products which may affect the safety of food, while improving the sustainability of food production;
 - (ii) to contribute to achieving a higher animal health status for the Union and to support the improvement of the welfare of animals;
 - (iii) to contribute to the timely detection of pests and their eradication where those pests have entered the Union;
 - (iv) to contribute to improving the effectiveness, efficiency and reliability of official controls and other activities carried out with a view to the effective implementation of and compliance with the Union rules referred to in Article 1.
2. In order to measure the attainment of the specific objectives referred to in paragraph 1(b) the following indicators shall be used:
 - (a) for the specific objective in paragraph 1(b)(i), a reduction in the number of cases of diseases in humans in the Union which are linked to food safety or zoonoses;

- (b) for the specific objective in paragraph 1(b)(ii):
- (i) an increase in the number of Member States or their regions which are free from animal diseases in respect of which a financial contribution is granted;
 - (ii) an overall reduction of disease parameters such as incidence, prevalence and number of outbreaks;
- (c) for the specific objective in paragraph 1(b)(iii):
- (i) the coverage of the Union territory by surveys for pests, in particular for pests not known to occur in the Union territory and pests considered to be most dangerous for the Union territory;
 - (ii) the time and success rate for the eradication of those pests;
- (d) for the specific objective in paragraph 1(b)(iv), a favourable trend in the results of controls in particular areas of concern carried out and reported on by Commission experts in the Member States.

CHAPTER II

Forms of financing and general financial provisions

Article 3

Forms of financing

1. Union financing for the expenditure referred to in Article 1 shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012.
2. When grants are awarded to the competent authorities of the Member States, they shall be considered to be identified beneficiaries within the meaning of Article 128(1) of Regulation (EU, Euratom) No 966/2012. Such grants may be awarded without a call for proposals.
3. The Union financial contribution for the measures referred to in this Regulation may also take the form of voluntary payments to international organisations, of which the Union is a member or in whose work it participates, that are active in the areas covered by the rules referred to in Article 1.

Article 4

Budget

1. The ceiling for the expenditure referred to in Article 1 for the period 2014 to 2020 shall be EUR 1 891 936 000 in current prices.
2. The ceiling referred to in paragraph 1 may also cover expenses relating to preparatory, monitoring, control, audit and evaluation activities which are required for the management and the achievement of the objectives, of the expenditure referred to in Article 1, in particular regarding studies and meetings of experts, the expenses linked to IT networks focusing on information processing and exchange, and all other costs of technical and administrative assistance incurred by the Commission for the management of that expenditure.
3. The ceiling may also cover the technical and administrative assistance expenses necessary to ensure the transition from actions adopted before to actions adopted after the entry into force of this Regulation. If necessary, appropriations may be entered in the budget beyond 2020 to cover similar expenses in order to enable the management of actions not yet completed by 31 December 2020.

*Article 5***Maximum rates of grants**

1. Where the Union financial contribution takes the form of a grant, it shall not exceed 50 % of the eligible costs.
2. The maximum rate referred to in paragraph 1 may be increased to 75 % of the eligible costs in respect of:
 - (a) cross-border activities implemented together by two or more Member States in order to control, prevent or eradicate pests or animal diseases;
 - (b) Member States whose gross national income per inhabitant based on the latest Eurostat data is less than 90 % of the Union average.
3. The maximum rate referred to in paragraph 1 may be increased to 100 % of the eligible costs where the activities benefitting from the Union contribution concern the prevention and control of serious human, plant and animal health risks for the Union, and:
 - (a) are designed to avoid human casualties or major economic disruptions for the Union as a whole;
 - (b) are specific tasks which are indispensable for the Union as a whole as laid down by the Commission in the work programme adopted in accordance with Article 36(1); or
 - (c) are implemented in third countries.

TITLE II

FINANCIAL PROVISIONS

CHAPTER I

Animal health

Section 1

Emergency Measures*Article 6***Eligible measures**

1. Grants may be awarded to Member States up to the maximum rates set in Article 5(1) to (3) in respect of the measures taken as a result of the confirmation that one of the animal diseases listed pursuant to Article 7 has occurred, provided that the measures have been applied immediately and the applicable provisions laid down in the relevant Union law have been complied with. Such grants may also include costs incurred as a result of a suspected occurrence of such a disease, provided that the occurrence is subsequently confirmed.
2. Grants may be awarded to Member States where, following the confirmation of the occurrence of one of the animal diseases listed pursuant to Article 7, two or more Member States collaborate closely to control the epidemic.
3. Grants may be awarded to Member States, third countries and international organisations in respect of protection measures taken in the case of a direct threat to the health status of the Union as a result of the occurrence or development, in the territory of a third country or a Member State, of one of the animal diseases and zoonoses listed pursuant to Articles 7 or 10.
4. Grants may be awarded to Member States where the Commission decides, at the request of a Member State, that they must establish stocks of biological products intended for the control of the animal diseases and zoonoses listed pursuant to Article 7 or 10.

5. A Union financial contribution may be awarded for the establishment of stocks of biological products or the acquisition of vaccine doses if the occurrence or the development in a third country or Member State of one of the animal diseases and zoonoses listed pursuant to Article 7 or 10 might constitute a threat to the Union.

Article 7

List of animal diseases

1. The list of animal diseases which qualify for funding under Article 6 is set out in Annex I.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 40, in order to supplement the list of animal diseases referred to in paragraph 1, taking into account the animal diseases which are required to be notified in accordance with Directive 82/894/EEC and the diseases which are likely to constitute a new threat for the Union due to their significant impact on:
 - (a) human health;
 - (b) animal health or animal welfare; or
 - (c) the agricultural or aquaculture production or related sectors of the economy.

Article 8

Eligible costs

1. The following costs incurred by the Member States in carrying out the measures referred to in Article 6(1) may qualify for funding under that paragraph:
 - (a) costs of compensation to owners for the value of their animals slaughtered or culled, limited to the market value of such animals if they had not been affected by the disease;
 - (b) costs of slaughtering or culling the animals and related transport costs;
 - (c) costs of compensation to owners for the value of their destroyed products of animal origin, limited to the market value of those products immediately before any suspicion of the disease arose or was confirmed;
 - (d) costs of cleaning, desinsectisation and disinfection of holdings and equipment, based on the epidemiology and characteristics of the pathogen;
 - (e) costs for the transport and the destruction of the contaminated feeding stuffs and, where it can not be disinfected, contaminated equipment;
 - (f) costs of purchase, storage, administration or distribution of vaccines and baits as well as the costs of inoculation itself, if the Commission decides or authorises such actions;
 - (g) costs of transport and disposal of carcasses;
 - (h) in exceptional and duly justified cases, any other costs essential for the eradication of the disease, as provided for in the financing decision referred to in Article 36(4) of this Regulation.
2. As referred to in Article 130(1) of Regulation (EU, Euratom) No 966/2012, costs shall be eligible from the date of notification of the occurrence of the disease by the Member States to the Commission. Such costs may also include costs incurred as a result of a suspected occurrence of such a disease, provided that that occurrence is subsequently confirmed.

3. After assessment of the payment applications submitted by the Member States, the Commission shall make the corresponding budgetary commitments and shall pay the eligible expenditure.

Section 2

Programmes for the eradication, control and surveillance of animal diseases and zoonoses

Article 9

Eligible programmes

Grants may be awarded to Member States' annual or multiannual national programmes for the eradication, control and surveillance of the animal diseases and zoonoses listed pursuant to Article 10 ('national programmes').

Article 10

List of animal diseases and zoonoses

1. The list of animal diseases and zoonoses which qualify for grants under Article 9 is set out in Annex II.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 40, in order to supplement the list of animal diseases and zoonoses referred to in paragraph 1 of this Article, taking into account:
 - (a) the situation of animal diseases that have a significant impact on livestock production or trade;
 - (b) the development of zoonoses which pose a threat to humans; or
 - (c) new scientific or epidemiological developments.

Article 11

Eligible costs

The following costs incurred by the Member States in implementing the national programmes may qualify for grants under Article 9:

- (a) costs of sampling animals;
- (b) costs of tests, provided that they are limited to:
 - (i) costs of test kits, reagents, and consumables which are identifiable and specifically used for carrying out those tests;
 - (ii) costs of personnel, regardless of their status, directly involved in carrying out the tests;
- (c) costs of compensation to owners for the value of their animals slaughtered or culled, limited to the market value of such animals if they had not been affected by the disease;
- (d) costs of slaughtering or culling of the animals;
- (e) costs of compensation to owners for the value of their destroyed products of animal origin, limited to the market value of those products immediately before any suspicion of the disease arose or was confirmed;
- (f) costs of purchase, storage, inoculation, administration or distribution of vaccine doses or vaccine and baits used for the programmes;

- (g) costs of cleaning, disinfection, desinsectisation of the holding and equipment based on the epidemiology and characteristics of the pathogen; and
- (h) in exceptional and duly justified cases, the costs incurred in carrying out necessary measures other than those referred to in points (a) to (g), provided that such measures are set out in the grant decision referred to in Article 13(3) and (4).

For the purposes of point (c) of the first paragraph, the salvage value of the animals, if any, shall be deducted from the compensation.

For the purposes of point (d) of the first paragraph, the salvage value of heat-treated non-incubated eggs shall be deducted from the compensation.

Article 12

Content and submission of the national programmes

1. By 31 May, Member States shall submit to the Commission the national programmes which are due to start in the following year in respect of which they wish to apply for a grant.

National programmes submitted after 31 May shall not be eligible for financing in respect of the following year.

2. The national programmes shall contain at least the following:

- (a) a description of the epidemiological situation of the animal disease or zoonosis before the date of the beginning of the programme;
- (b) a description and demarcation of the geographical and administrative areas in which the programme is to be applied;
- (c) the duration of the programme;
- (d) the measures to be implemented;
- (e) the estimated budget;
- (f) the targets to be attained by the completion date of the programme and the anticipated benefits thereof; and
- (g) appropriate indicators to measure the achievement of the targets of the programme.

In each multiannual national programme, the information referred to in points (b), (d), and (f) of the first subparagraph shall be provided for each year covered by the programme, in the case of significant changes compared to the previous year. The information referred to in point (e) of that subparagraph shall be provided for each year covered by the programme.

3. If the occurrence or the development of one of the animal diseases or zoonoses listed pursuant to Article 10 is likely to constitute a threat to the health status of the Union and in order to protect the Union from the introduction of one of those diseases or zoonoses, Member States may include in their national programmes measures to be implemented in territories of neighbouring third countries in cooperation with the authorities of those countries.

*Article 13***Evaluation and approval of the national programmes**

1. The Commission shall evaluate the national programmes taking into account the priorities and criteria set out in the annual or multiannual work programmes referred to in Article 36(1).
2. The Commission shall communicate to Member States by 30 November each year:
 - (a) the list of national programmes technically approved and proposed for co-financing;
 - (b) the provisional amount allocated to each programme;
 - (c) the provisional maximum level of the Union financial contribution for each programme; and
 - (d) any provisional conditions to which the Union financial contribution may be subject.
3. The Commission shall approve the annual national programmes and associated funding by 31 January each year by means of a grant decision in relation to the measures implemented and the costs incurred from 1 January to 31 December of that year. Following submission of the intermediate reports as referred to in Article 14, the Commission may, if necessary, amend such decisions in relation to the whole eligibility period.
4. The Commission shall approve the multiannual national programmes and associated funding by 31 January of the first year of implementation by means of a grant decision in relation to the measures implemented and the costs incurred from 1 January of the first year of implementation until the end of the implementation period.
5. In the case of approval of multiannual national programmes in accordance with paragraph 4, budgetary commitments may be divided into annual instalments. Where budgetary commitments are so divided, the Commission shall commit the annual instalments taking into account the progress of the programmes, the estimated needs and the budget available.

*Article 14***Reporting**

For each approved annual or multiannual national programme, Member States shall submit to the Commission, by 30 April each year, an annual detailed technical and financial report covering the previous year. That report shall include the results achieved, measured on the basis of the indicators referred to in Articles 12(2)(g) and a detailed account of eligible costs incurred.

In addition, for each approved annual national programme, Member States shall submit to the Commission, by 31 August each year, an intermediate financial report.

*Article 15***Payments**

The payment request for a given year in respect of a national programme shall be submitted by the Member State to the Commission by 30 April of the following year.

The Commission shall pay the Union financial contribution for the eligible costs following appropriate verification of the reports referred to in Article 14.

CHAPTER II

Plant health

Section 1

Emergency measures

Article 16

Eligible measures

1. Grants may be awarded to Member States up to the maximum rates set in Article 5(1) to (3) for the following measures against pests, subject to the conditions laid down in Article 17:

- (a) measures to eradicate a pest from an infested area, taken by the competent authorities pursuant to Article 16(1) and (2) of Directive 2000/29/EC or pursuant to the Union measures adopted in accordance with Article 16(3) of that Directive;
- (b) measures to contain a pest, against which Union containment measures have been adopted pursuant to Article 16(3) of Directive 2000/29/EC, in an infested area from which that pest cannot be eradicated, where those measures are essential to protect the Union against further spread of that pest. Those measures shall exclusively concern the eradication of that pest from the buffer zone in case its presence is detected in that buffer zone;
- (c) additional protective measures taken against the spread of a pest, against which Union measures have been adopted pursuant to Article 16(3) of Directive 2000/29/EC, other than the eradication measures referred to in point (a) and the containment measures referred to in point (b), where those measures are essential to protect the Union against further spread of that pest.

Grants for measures referred to in points (a) and (b) of the first subparagraph may also be awarded for measures taken as a result of a suspected presence of such a pest, provided that that presence is subsequently confirmed.

2. Grants referred to in paragraph 1 may also be awarded to a Member State in whose territory the pests referred to in paragraph 1 are not present, where measures have been taken against the entry of those pests into the territory of that Member State because of their presence in a neighbouring Member State or third country immediately adjacent to its border.

3. Grants may be awarded to Member States where, following the confirmation of the presence of one of the pests referred to in Article 17, two or more Member States collaborate closely in carrying out the measures referred to in paragraph 1.

4. Grants in respect of the measures referred to in points (a) to (c) of the first subparagraph of paragraph 1 may also be awarded to international organisations.

Article 17

Conditions

The measures referred to in Article 16 may qualify for grants provided that they have been applied immediately and the applicable provisions laid down in the relevant Union law have been complied with, and provided that one or more of the following conditions are fulfilled:

- (a) they concern pests listed in Section I of Part A of Annex I to Directive 2000/29/EC and Section I of Part A of Annex II thereto;
- (b) they concern pests covered by a measure adopted by the Commission pursuant to Article 16(3) of Directive 2000/29/EC;

- (c) they concern pests for which measures have been adopted pursuant to Directives 69/464/EEC, 93/85/EEC, 98/57/EC or 2007/33/EC; or
- (d) they concern pests, not listed in Annex I or Annex II to Directive 2000/29/EC, which are subject to a measure adopted by the competent authority of a Member State pursuant to Article 16(2) of Directive 2000/29/EC and which provisionally qualify for listing in Section I of Part A of Annex I to Directive 2000/29/EC or Section I of Part A of Annex II thereto.

For measures fulfilling the condition laid down in point (b) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 16(3) of Directive 2000/29/EC.

For measures fulfilling the condition laid down in point (d) of the first paragraph, the grant shall not cover costs incurred later than two years after the entry into force of the measure adopted by the competent authority of the Member State concerned, or incurred after the expiry of that measure.

Article 18

Eligible costs

1. The following costs incurred by Member States in carrying out the measures referred to in Article 16 may qualify for grants under that Article:

- (a) costs of personnel, regardless of their status, directly involved in the measures, as well as costs of renting equipment, of consumables and of any other necessary materials, of treatment products, of sampling and of laboratory tests;
- (b) costs of service contracts with third parties to execute part of the measures;
- (c) costs of compensating the operators or owners concerned for the treatment, the destruction and subsequent removal of plants, of plant products and of other objects, and for the cleaning and disinfection of premises, land, water, soil, growing media, facilities, machinery and equipment;
- (d) costs of compensating the owners concerned for the value of the destroyed plants, plant products or other objects subject to the measures referred to in Article 16 of Directive 2000/29/EC, limited to the market value of such plants, plant products and other objects as if they had not been affected by those measures; the salvage value, if any, shall be deducted from the compensation; and
- (e) in exceptional and duly justified cases, the costs incurred in carrying out necessary measures other than those referred to in points (a) to (d), provided that such measures are set out in the financing decision referred to in Article 36(4).

The compensation to owners referred to in point (c) shall only be eligible if the measures have been carried out under the supervision of the competent authority.

2. As referred to in Article 130(1) of Regulation (EU, Euratom) No 966/2012, costs shall be eligible from the date of notification of the presence of the pest by the Member States to the Commission. Such costs may also include costs incurred as a result of the suspected presence of that pest, provided that that presence is subsequently confirmed.

3. After assessment of the payment applications submitted by the Member States, the Commission shall make the corresponding budgetary commitments and the payment of eligible expenditure.

Section 2

Survey programmes concerning the presence of pests

Article 19

Eligible survey programmes

Grants may be awarded to Member States for annual and multiannual survey programmes that they carry out concerning the presence of pests ('survey programmes'), provided that those survey programmes comply with at least one of the following conditions:

- (a) they concern pests listed in Section I of Part A of Annex I to Directive 2000/29/EC and Section I of Part A of Annex II thereto;
- (b) they concern pests covered by a measure adopted by the Commission pursuant to Article 16(3) of Directive 2000/29/EC.

For the pests referred to in point (a) of the first paragraph of this Article, the survey programmes shall be based on an assessment of the risk of the entry, establishment and spread of those pests in the territory of the Member State concerned and shall as a minimum target the pests that pose the main risks and the main plant species that are exposed to those risks.

For measures fulfilling the condition laid down in point (b) of the first paragraph of this Article, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 16(3) of Directive 2000/29/EC.

Article 20

Eligible costs

The following costs incurred by the Member States in implementing the survey programmes referred to in Article 19 may qualify for grants under that Article:

- (a) costs for sampling;
- (b) costs of tests, provided that they are limited to:
 - (i) the costs of test kits, of reagents and of consumables which are identifiable and specifically used for carrying out the tests;
 - (ii) the costs of personnel, regardless of their status, directly involved in carrying out the tests;
- (c) in exceptional and duly justified cases, costs incurred in carrying out necessary measures other than those referred to in points (a) and (b), provided that such measures are set out in the grant decision referred to in Article 22(3) and (4).

Article 21

Content and submission of the survey programmes

1. By 31 May, Member States shall submit to the Commission the survey programmes which are due to start in the following year in respect of which they wish to apply for a grant.

Survey programmes submitted after 31 May shall not be eligible for financing in respect of the following year.

2. The survey programmes shall contain at least the following:
 - (a) the pests included in the programme;
 - (b) a description and demarcation of the geographical and administrative areas in which the programme is to be applied and a description of the status of those areas as regards the presence of the pests concerned;
 - (c) the duration of the programme;
 - (d) the number of visual examinations, samples and tests scheduled for the pests and plants, plants products and other objects concerned;
 - (e) the estimated budget;
 - (f) the targets to be attained by the completion date of the programme and the anticipated benefits thereof; and
 - (g) appropriate indicators to measure the achievement of the targets of the programme.

In each multiannual survey programme, the information referred to in points (b), (d), and (f) of the first subparagraph shall be provided for each year covered by the programme, in the case of significant changes compared to the previous year. The information referred to in point (e) of that subparagraph shall be provided for each year covered by the programme.

Article 22

Evaluation and approval of the survey programmes

1. The Commission shall evaluate the survey programmes taking into account the priorities and criteria set out in the annual or multiannual work programmes referred to in Article 36(1).
2. The Commission shall communicate to Member States by 30 November each year:
 - (a) the list of survey programmes technically approved and proposed for co-financing;
 - (b) the provisional amount allocated to each programme;
 - (c) the provisional maximum level of the Union financial contribution for each programme; and
 - (d) any provisional conditions to which the Union financial contribution may be subject.
3. The Commission shall approve the annual survey programmes and associated funding by 31 January each year by means of a grant decision in relation to the measures implemented and the costs incurred from 1 January to 31 December of that year. Following submission of the intermediate reports as referred to in Article 23, the Commission may, if necessary, amend such decisions in relation to the whole eligibility period.
4. The Commission shall approve the multiannual survey programmes and associated funding by 31 January of the first year of implementation by means of a grant decision in relation to the measures implemented and the costs incurred from 1 January of the first year of implementation until the end of the implementation period.

5. In the case of approval of multiannual survey programmes in accordance with paragraph 4, budgetary commitments may be divided into annual instalments. Where budgetary commitments are so divided, the Commission shall commit the annual instalments taking into account the progress of the programmes, the estimated needs and the budget available.

Article 23

Reporting

For each approved annual or multiannual survey programme, Member States shall submit to the Commission, by 30 April each year, an annual detailed technical and financial report covering the previous year. That report shall include the results achieved, measured on the basis of the indicators referred to in Articles 21(2)(g) and a detailed account of eligible costs incurred. In addition, for each approved annual survey programme, Member States shall submit to the Commission, by 31 August each year, an intermediate financial report.

Article 24

Payments

The payment request for a given year in respect of a survey programme shall be submitted by the Member State to the Commission by 30 April of the following year.

The Commission shall pay the Union financial contribution for the eligible costs following appropriate verification of the reports referred to in Article 23.

Section 3

Programmes concerning the control of pests in outermost regions of the Union

Article 25

Eligible measures and eligible costs

1. Grants may be awarded to Member States for programmes that they carry out for the control of pests in the outermost regions of the Union referred to in Article 349 TFEU in line with the objectives set out in Article 2 of Regulation (EU) No 228/2013 ('programmes for the outermost regions'). Those grants shall concern activities necessary to ensure the correct implementation in those regions of the rules, whether they are Union rules or national rules, in force in those regions, on the control of pests.

2. The following costs incurred by Member States for programmes for the outermost regions may qualify for a Union financial contribution:

- (a) costs of personnel, regardless of their status, directly involved in the implementation of the measures, as well as the costs of renting equipment, of consumables and of treatment products;
- (b) costs of service contracts with third parties to execute part of the measures;
- (c) costs of sampling;
- (d) costs of tests, provided that they are limited to:
 - (i) the costs of test kits, of reagents and of consumables which are identifiable and specifically used for carrying out the tests;
 - (ii) the costs of personnel, regardless of their status, directly involved in carrying out the tests.

*Article 26***Content and submission of the programmes for the outermost regions**

1. By 31 May Member States shall submit to the Commission the programmes for the outermost regions which are due to start in the following year in respect of which they wish to apply for a grant.

Programmes for the outermost regions submitted after 31 May shall not be eligible for financing in respect of the following year.

2. The programmes for the outermost regions shall contain at least the following:

- (a) the pests included in the programme;
- (b) a description and demarcation of the geographical and administrative areas in which the programme is to be applied and a description of the status of those areas as regards the presence of the pests concerned;
- (c) a technical analysis of the regional phytosanitary situation;
- (d) the duration of the programme;
- (e) the activities included in the programme and, where relevant, the number of visual examinations, samples and tests scheduled for the pests and plants, plants products and other objects concerned;
- (f) the estimated budget;
- (g) the targets to be attained by the completion date of the programme and the anticipated benefits thereof; and
- (h) appropriate indicators to measure the achievement of the targets of the programme.

In each multiannual programme for the outermost regions, the information referred to in points (b), (e) and (g) of the first subparagraph shall be provided for each year covered by the programme, in the case of significant changes compared to the previous year. The information referred to in point (f) of that subparagraph shall be provided for each year covered by the programme.

*Article 27***Evaluation and approval of the programmes for the outermost regions**

1. The programmes for the outermost regions shall be evaluated taking into account the priorities and criteria set out in the annual or multiannual work programmes referred to in Article 36(1).

2. The Commission shall communicate to Member States by 30 November each year:

- (a) the list of programmes for the outermost regions technically approved and proposed for co-financing;
- (b) the provisional amount allocated to each programme;
- (c) the provisional maximum level of the Union financial contribution for each programme; and
- (d) any provisional conditions to which the Union financial contribution may be subject.

3. Annual programmes for the outermost regions and associated funding shall be approved by 31 January each year by means of a grant decision in relation to the measures implemented and the costs incurred from 1 January to 31 December of that year. Following submission of the intermediate reports as referred to in Article 28, the Commission may, if necessary, amend such decisions in relation to the whole eligibility period.

4. Multiannual programmes for the outermost regions and associated funding shall be approved by 31 January of the first year of implementation by means of a grant decision in relation to the measures implemented and the costs incurred from 1 January of the first year of implementation until the end of the implementation period.

5. In the case of approval of multiannual programmes for the outermost regions in accordance with paragraph 4, budgetary commitments may be divided into annual instalments. Where budgetary commitments are so divided, the Commission shall commit the annual instalments taking into account the progress of the programmes, the estimated needs and the budget available.

Article 28

Reporting

For each approved annual or multiannual programme for the outermost regions, Member States shall submit to the Commission, by 30 April each year, an annual detailed technical and financial report covering the previous year. That report shall include the results achieved, measured on the basis of the indicators referred to in point (h) of the first subparagraph of Article 26(2) and a detailed account of eligible costs incurred.

In addition, for each approved annual programme for the outermost regions, Member States shall submit to the Commission, by 31 August each year, an intermediate financial report.

Article 29

Payments

The payment request for a given year in respect of a programme for the outermost regions shall be submitted by the Member State to the Commission by 30 April of the following year.

The Commission shall pay the Union financial contribution for the eligible costs following appropriate verification of the reports referred to in Article 28.

CHAPTER III

Financial support to official controls and other activities

Article 30

European Union reference laboratories

1. Grants may be awarded to the European Union reference laboratories referred to in Article 32 of Regulation (EC) No 882/2004 for the costs that they incur in implementing the work programmes approved by the Commission.

2. The following costs may be eligible for grants under paragraph 1:

(a) costs of personnel, regardless of their status, directly involved in activities of the laboratories which are carried out in their capacity of Union reference laboratory;

(b) costs of capital equipment;

(c) cost of consumables;

(d) costs of shipment of samples, missions, meetings, training activities.

*Article 31***Training**

1. The Union may finance the training of the staff of the competent authorities responsible for official controls, as referred to in Article 51 of Regulation (EC) No 882/2004, in order to develop a harmonised approach to official controls and other official activities to ensure a high level of protection of human, animal and plant health.
2. The Commission shall develop training programmes identifying the priorities for intervention, based on the identified risks for public health, animal health and welfare and plant health.
3. In order to be eligible for Union financing as referred to in paragraph 1, the competent authorities shall ensure that the knowledge acquired through the training activities referred to in that paragraph is disseminated as necessary and that it is appropriately used in the national training programmes.
4. The following costs may be eligible for the financial contribution referred to in paragraph 1:
 - (a) cost of the organisation of the training, including training that is also open to participants from third countries, or exchange activities;
 - (b) costs of travel, accommodation and daily subsistence of the personnel of the competent authorities taking part in the training.

*Article 32***Experts from the Member States**

A Union financial contribution may be granted for the travel, accommodation and daily subsistence expenses incurred by Member States' experts as a result of the Commission appointing them to assist its experts as provided for in Articles 45(1) and 46(1) of Regulation (EC) No 882/2004.

*Article 33***Coordinated control plans and data collection**

1. Grants may be awarded to Member States for the costs incurred for the implementation of the coordinated control plans referred to in Article 53 of Regulation (EC) No 882/2004 and for data collection.
2. The following costs may qualify for such grants:
 - (a) costs of sampling and laboratory tests,
 - (b) cost of equipment necessary to perform the official control and data collection tasks.

*CHAPTER IV****Other measures****Article 34***Information systems**

1. The Union shall finance the establishment and operation of the data bases and computerised information management systems, managed by the Commission, which are necessary for the effective and efficient implementation of the rules referred to in Article 1.

2. A Union financial contribution may be granted for the establishment and management of data bases and computerised information management systems of third parties, including international organisations, provided that those data bases and computerised information management systems:

- (a) have a proven added value for the Union as a whole and are available across the Union to all interested users; and
- (b) are necessary for the effective and efficient implementation of the rules referred to in Article 1.

Article 35

Implementation and adaptation of the rules

1. The Union may finance technical and scientific work, including studies and coordination activities, necessary to ensure the correct implementation of the rules in respect of the fields referred to in Article 1 and the adaptation of those rules to scientific, technological and societal developments.

A Union financial contribution may also be granted to the Member States or international organisations operating in the fields referred to in Article 1 in order for them to undertake activities in support of the development and implementation of the rules in respect of those fields.

2. Grants may be awarded to projects organised by one or more Member States with the aim of improving, through the use of innovative techniques and protocols, the efficient performance of official controls.

3. A Union financial contribution may also be granted to support information and awareness raising initiatives by the Union and Member States aimed at ensuring improved, compliant and sustainable behaviour in the implementation of the rules in respect of the fields referred to in Article 1.

TITLE III

PROGRAMMING, IMPLEMENTATION AND CONTROL

Article 36

Work programmes and financial contributions

1. The Commission shall adopt implementing acts, establishing common or separate annual or multiannual work programmes for the implementation of the measures referred to in Title II, except for Section 1 of Chapter I and Section 1 of Chapter II thereof. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(2).

2. The work programmes referred to in paragraph 1 shall set out the operational objectives pursued, which shall be in accordance with the general and specific objectives laid down in Article 2, the expected results, the method of implementation and their total amount. They shall also contain a description of the measures to be financed, an indication of the amount allocated to each measure and an indicative implementation timetable. In respect of grants, they shall include the priority actions, the evaluation criteria, the funding rate and the indicative list of eligible measures and costs, in accordance with Article 3 of this Regulation.

3. The work programmes for implementing the measures referred to in Section 2 of Chapter I of Title II, and in Section 2 and Section 3 of Chapter II of Title II shall be adopted by 30 of April of the year preceding their execution, provided that the draft budget is adopted. Those work programmes shall reflect the priorities as laid down in Annex III to this Regulation.

4. With regard to the implementation of the emergency measures referred to in Section 1 of Chapter I of Title II and Section 1 of Chapter II of Title II, or where it is necessary to respond to unforeseeable developments, the Commission shall adopt implementing acts, setting out its decision on the financial contribution. Those implementing acts shall be adopted, in accordance with the examination procedure referred to in Article 41(2).

5. The Commission shall adopt implementing acts laying down the procedures for submission by Member States of applications, reports and requests for payments for the grants referred to in Sections 1 and 2 of Chapter I, and Sections 1, 2 and 3 of Chapter II of Title II. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(2).

Article 37

On-the-spot checks by the Commission

The Commission may organise on-the-spot checks in Member States and at the premises of the beneficiaries with a view to verifying in particular:

- (a) the effective implementation of the measures benefitting from the Union financial contribution;
- (b) the compliance of administrative practices with Union rules;
- (c) the existence of the requisite supporting documents and their correlation with the measures benefitting from a Union contribution.

Article 38

Access to information

Member States and beneficiaries shall make available to the Commission all information necessary for verifying the implementation of the measures and shall take all appropriate measures to facilitate the checks which the Commission deems to be appropriate in connection with the management of Union financing, including on-the-spot checks.

Article 39

Protection of the Union's financial interests

1. The Commission shall take appropriate measures ensuring that, when measures financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, where irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive penalties.

2. The Commission, or its representatives, and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, implementing bodies, contractors and subcontractors who have received Union funds under this Regulation.

The European Anti-Fraud Office (OLAF) shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding in accordance with the procedures laid down in Council Regulation (Euratom, EC) No 2185/96 ⁽¹⁾ with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or decision or a contract concerning Union funding.

⁽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 (OJ L 292, 15.11.1996, p. 2).

Without prejudice to the first and the second subparagraphs, cooperation agreements with third countries and international organisations, grant agreements, grant decisions and contracts resulting from the implementation of this Regulation shall expressly entitle the Commission, the Court of Auditors and OLAF to conduct such audits, on-the-spot checks and inspections.

TITLE IV

GENERAL AND FINAL PROVISIONS

Article 40

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 7(2) and Article 10(2) shall be conferred on the Commission for a period of seven years from 30 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Article 7(2) and Article 10(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 7(2) and Article 10(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 41

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

Article 42

Evaluation

1. By 30 June 2017 the Commission shall establish and present to the European Parliament and to the Council a mid-term evaluation report on whether, in terms of their results and impacts, the measures referred to in Chapters I and II of Title II and in Articles 30 and 31 of Chapter III achieve the objectives set out in Article 2(1), as regards the efficiency of the use of resources and its added value, at Union level. The evaluation report shall also address the scope for simplification, the continued relevance of all objectives, and the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor measures. The report shall be accompanied, if appropriate, by a legislative proposal to amend this Regulation.

2. By 30 June 2022 the Commission shall carry out an *ex-post* evaluation of the measures referred to in paragraph 1 of this Article in close cooperation with the Member States. That *ex-post* evaluation shall examine the effectiveness and efficiency of the expenditure referred to in Article 1 and its impact.

3. The evaluations referred to in paragraphs 1 and 2 of this Article shall take account of the progress made by using the indicators referred to in Article 2(2).

4. The Commission shall communicate the conclusions of the evaluations referred to in paragraphs 1 and 2 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Article 43

Information, communication and publicity

1. Where appropriate, beneficiaries and Member States concerned shall ensure that suitable publicity is given to financial contributions granted under this Regulation in order to inform the public of the role of the Union in the funding of the measures.

2. The Commission shall implement information and communication actions on the measures funded and results. Moreover, budget allocated to communication under this Regulation shall also cover corporate communication on the political priorities of the Union.

Article 44

Repeals

1. Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC are repealed.

2. References to Decisions 66/399/EEC and 76/894/EEC shall be construed as references to Article 58(1) of Regulation (EC) No 178/2002.

3. References to Decision 2009/470/EC shall be construed as references to this Regulation.

Article 45

Transitional provisions

1. The Member States' national programmes referred to in Article 12(1) of this Regulation, submitted to the Commission in 2012 for implementation in 2013, those submitted in 2013 for implementation in 2014, and those submitted by 30 April 2014 for implementation in 2015, shall, if approved, be eligible for Union funding on the basis of Article 27 of Decision 2009/470/EC.

For national programmes implemented in 2013 and 2014, Article 27(7) and (8) of that Decision shall continue to apply.

For national programmes implemented in 2015, Article 27(2) of that Decision shall continue to apply.

2. The survey programmes of Member States referred to in Article 21(1) of this Regulation, submitted to the Commission by 30 April 2014 for implementation in the year 2015, shall be eligible for Union funding on the basis of Article 23(6) of Directive 2000/29/EC. For those survey programmes, Article 23(6) of that Directive shall continue to apply.

3. For applications of Member States for Union funding for the emergency measures referred to in Article 16 of this Regulation, submitted to the Commission by 30 April 2014, Articles 22 to 24 of Directive 2000/29/EC shall continue to apply.

Article 46

Amendment of Directive 98/56/EC

Directive 98/56/EC is amended as follows:

(1) In Article 17, paragraph 1 is replaced by the following:

'1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*). That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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

(2) In Article 18, paragraph 1 is replaced by the following:

'1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.'

Article 47

Amendment of Directive 2000/29/EC

Directive 2000/29/EC is amended as follows:

(1) In Article 13c, paragraph 5 is deleted.

(2) The following Article is inserted:

'Article 15a

Member States shall provide that anyone who becomes aware of the presence of a pest listed in Annex I or Annex II or a pest covered by a measure pursuant to Article 16(2) or 16(3), or has reason to suspect such a presence, shall notify, in writing, the competent authority within ten calendar days, and, if so requested by that competent authority, shall provide the information concerning that presence which is in its possession.'

(3) Articles 22 to 26 are deleted.

*Article 48***Amendment of Regulation (EC) No 178/2002**

In Article 58 of Regulation (EC) No 178/2002, paragraph 1 is replaced by the following:

'1. The Commission shall be assisted by a Standing Committee on Plants, Animals, Food and Feed, hereinafter referred to as the 'Committee'. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*). The Committee shall be organised in sections to deal with all relevant matters.

All references in Union law to the Standing Committee on the Food Chain and Animal Health shall be construed as references to the Committee referred to in the first subparagraph.

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

*Article 49***Amendment of Regulation (EC) No 882/2004**

Article 66 of Regulation (EC) No 882/2004 is deleted.

*Article 50***Amendment of Regulation (EC) No 396/2005**

Chapter VII of Regulation (EC) No 396/2005 is deleted.

*Article 51***Amendment of Directive 2008/90/EC**

In Article 19 of Directive 2008/90/EC, paragraph 1 is replaced by the following:

'1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*). That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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

*Article 52***Amendment of Directive 2009/128/EC**

Article 22 of Directive 2009/128/EC is deleted.

*Article 53***Amendment of Regulation (EC) No 1107/2009**

Article 76 of Regulation (EC) No 1107/2009 is deleted.

*Article 54***Entry into force and application**

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

It shall apply from 30 June 2014.

However, point (d) of Article 18(1) and point (2) of Article 47 shall apply from 1 January 2017.

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

Done at Brussels, 15 May 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

ANNEX I

Animal diseases referred to in Article 7

- Rinderpest cattle plague
 - Sheep and goat plague
 - Swine vesicular disease
 - Bluetongue
 - Teschen disease
 - Sheep pox or goat pox
 - Rift Valley fever
 - Lumpy skin disease
 - African horse sickness
 - Vesicular stomatitis
 - Venezuelan equine viral encephalomyelitis
 - Haemorrhagic disease of deer
 - Classical swine fever
 - African swine fever
 - Contagious bovine pleuropneumonia
 - Avian influenza
 - Newcastle disease
 - Foot-and-mouth disease
 - Epizootic haematopoietic necrosis in fish (EHN)
 - Epizootic ulcerative syndrome in fish (EUS)
 - Infection with *Bonamia exitiosa*
 - Infection with *Perkinsus marinus*
 - Infection with *Microcytos mackini*
 - Taura syndrome in crustaceans
 - Yellowhead disease in crustaceans
-

ANNEX II

Animal diseases and zoonoses referred to in Article 10

- Bovine tuberculosis
 - Bovine brucellosis
 - Ovine and caprine brucellosis (*B. melitensis*)
 - Bluetongue in endemic or high risk areas
 - African swine fever
 - Swine vesicular disease
 - Classical swine fever
 - Anthrax
 - Contagious bovine pleuropneumonia
 - Avian influenza
 - Rabies
 - Echinococcosis
 - Transmissible spongiform encephalopathies (TSE)
 - Campylobacteriosis
 - Listeriosis
 - Salmonellosis (zoonotic salmonella)
 - Trichinellosis
 - Verotoxigenic *E. coli*
 - Viral haemorrhagic septicaemia (VHS)
 - Infectious haematopoietic necrosis (IHN)
 - Koi herpes virus disease (KHV)
 - Infectious salmon anaemia (ISA)
 - Infection with *Marteilia refringens*
 - Infection with *Bonamia ostreae*
 - White spot disease in crustaceans
-

ANNEX III

Priorities for the Commission work programmes referred to in Section 2 of Chapter I of Title II, and in Section 2 and Section 3 of Chapter II of Title II

Priorities for Union financial support, as regards the orientation of national programmes for the eradication, control and surveillance of animal diseases and zoonoses:

- diseases with impact on human health;
- diseases with impact on animal health, taking into consideration their potential spread and the morbidity and mortality rates in animal population;
- diseases and zoonoses which risk being introduced and/or re-introduced into the Union territory from third countries;
- diseases which have the potential to generate a crisis situation with serious economic consequences;
- diseases with impact on trade with third countries and intra-EU trade.

Priorities for Union financial support, as regards the orientation of national programmes for pest surveys for the protection of the Union territory:

- pests listed in Section I of Part A of Annex I and Section I of Part A of Annex II to Directive 2000/29/EC as not known to occur in the Union territory;
- pests subject to Union measures adopted pursuant to Article 16(3) of Directive 2000/29/EC;
- pests which are not listed in Directive 2000/29/EC and represent an imminent danger to the Union territory;
- pests which have the potential to generate a crisis situation with serious economic and environmental consequences;
- pests with impact on trade with third countries and intra-EU trade.

Priorities for Union financial support, as regards the orientation of national programmes for outermost regions:

- measures against pests associated with the imports into and the climate in those regions;
 - methods for combating those pests;
 - measures against pests listed pursuant to the rules on pests of plants in force in those regions.
-

STATEMENT BY THE COMMISSION**on the procedures for the approval of veterinary and phytosanitary programmes**

In order to better inform the Member States, the Commission will arrange an annual meeting of the Standing Committee on Plants, Animals, Food and Feed which shall focus on the outcome of the evaluation procedure of programmes. That meeting will take place no later than 30 November of the year preceding the implementation of the programmes.

In connection with that meeting, the Commission will present the list of the programmes technically approved and proposed for co-financing. Both financial and technical details will be discussed with the national delegations, and their comments will be considered.

In addition, before taking its final decision thereon, the Commission will, during a meeting of the Standing Committee on Plants, Animals, Food and Feed in January, communicate to the Member States the final list of programmes selected for co-financing and the final amount allocated to each programme.

Preparatory work for the design of the work programme for the implementation of the measures referred to in Articles 9, 19 and 25 will be carried out with experts of Member States in early February of each year in order to give Member States the relevant information to establish the eradication and surveillance programmes.

REGULATION (EU) No 653/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
amending Regulation (EC) No 1760/2000 as regards electronic identification of bovine animals and
labelling of beef

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) and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

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

Whereas:

- (1) In 1997, Council Regulation (EC) No 820/97 ⁽³⁾ reinforced Union rules on the identification and traceability of bovine animals in the light of the bovine spongiform encephalopathy (BSE) epidemic and the resulting increased need to trace the origin and movement of animals using conventional ear tags.
- (2) Regulation (EC) No 1760/2000 of the European Parliament and of the Council ⁽⁴⁾ provides that each Member State is to establish a system for the identification and registration of bovine animals in accordance with that Regulation.
- (3) Regulation (EC) No 1760/2000 establishes a system for the identification and registration of bovine animals comprising ear tags applied to both ears of each animal, computerised databases, animal passports and individual registers kept at each holding.
- (4) Tracing of beef back to source via identification and registration is a prerequisite for origin labelling throughout the food chain. Those measures ensure consumer protection and public health and promote consumer confidence.
- (5) Regulation (EC) No 1760/2000 and, more specifically, bovine identification and voluntary beef labelling systems were listed as information obligations with special importance in terms of the burdens they imply to businesses in the Communication from the Commission of 22 October 2009 entitled 'Action Programme for Reducing Administrative Burdens in the EU — Sectoral Reduction Plans and 2009 Actions'.

⁽¹⁾ OJ C 229, 31.7.2012, p. 144.

⁽²⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 6 May 2014.

⁽³⁾ Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products (OJ L 117, 7.5.1997, p. 1).

⁽⁴⁾ Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

- (6) The use of electronic identification ('EID') systems could potentially streamline traceability processes through automated and more accurate reading and recording into the holding register. Moreover, it would enable automated reporting of animal movements to the computerised database and thus improve the speed, reliability and accuracy of the traceability system. The use of EID systems would also improve the management of certain direct payments to farmers.
- (7) EID systems based on radio frequency identification have considerably improved over the last 10 years. That technology allows a faster and more accurate reading of individual animal identity codes directly into data processing systems. This results in a reduction of the time needed to trace potentially infected animals or food, leading to improved reliability of databases and an increase in the capacity to react promptly in the event of disease outbreaks, saving labour costs even if it involves an increase in equipment costs.
- (8) This Regulation is coherent with the fact that EID systems have already been introduced in the Union for non-bovine animal species, such as the mandatory system used in ovine and caprine animals.
- (9) Given the technological advances in EID systems, several Member States have decided to start to implement bovine EID on a voluntary basis. Those initiatives are likely to lead to the development of different systems in individual Member States and by different stakeholders. The development of differing systems would impede the subsequent harmonisation of technical standards within the Union. The interoperability of the Member State EID systems should be ensured, as should their consistency with the relevant ISO standards or other international technical standards adopted by recognised international standard-setting organisations, with the understanding that those international standards are able to guarantee, at the very least, a higher level of performance than ISO standards.
- (10) The Report from the Commission of 25 January 2005 on the possibility of introduction of EID for bovine animals concluded that it had been demonstrated that radio frequency identification had been developed to the extent that it could already be applied in practice. That report also concluded that it was highly desirable to switch to EID of bovine animals within the Union since, among other benefits, it would contribute to the reduction of the administrative burden.
- (11) According to the Communication from the Commission of 10 September 2008 entitled 'Action Plan for the implementation of the EU Animal Health Strategy' the Commission is to simplify information obligations, such as holding registers and animal passports in the course of the introduction of EID systems.
- (12) The Communication from the Commission of 19 September 2007 entitled 'A new Animal Health Strategy for the European Union (2007-2013) where 'Prevention is better than cure' proposes considering EID for bovine animals as a possible improvement to the existing Union system of identification and registration in order to simplify information obligations, such as holding registers and animal passports, and suggests implementing an electronic bovine passport exchange. That exchange would entail the introduction of EID with real time insertion of data. Such an exchange would lead to considerable savings in terms of costs and efforts for the competent authorities of the Member States and other stakeholders and would reduce the workload when transferring animal passports data into computerised databases. This Regulation is consistent with that initiative.
- (13) This Regulation is thus expected to contribute to some key objectives of major Union strategies including the Europe 2020 strategy for smart, sustainable and inclusive growth by improving economic growth, cohesion and competitiveness.
- (14) Certain third countries have already established rules allowing advanced EID technologies. The Union should establish similar rules to facilitate trade and increase the competitiveness of the sector.

- (15) In the light of the technological development of new types of electronic identifiers, it is appropriate to broaden the scope of the means of identification provided for in Regulation (EC) No 1760/2000 in order to enable the use of electronic identifiers as an official means of identification. Since the introduction of the corresponding provisions implies considerable investment, it is necessary to allow for a transitional period of five years to give the Member States the necessary time to prepare. During that transitional period conventional ear tags will continue to be the only official means of identification for bovine animals.
- (16) Making EID mandatory throughout the Union could have economically adverse effects on certain operators. It is therefore appropriate that, once EID becomes an official means of identification, its use by keepers should be voluntary. Under such a voluntary regime, EID would be chosen by keepers who are likely to benefit economically from it, while it should be possible for other keepers to continue to identify their animals with two conventional ear tags.
- (17) Member States have very different husbandry systems, farming practices and sector organisations. Member States should therefore be allowed to make EID compulsory on their territory only when they deem it appropriate, after considering all of those factors, including impacts on small farmers, and following consultation with organisations representing the cattle industry. During intra-Union animal trade movements the obligation to electronically identify a bovine animal should fall to the Member State which has made the use of EID compulsory on its territory. This should not imply that that Member State is obliged to re-identify animals which have already been electronically identified in the Member State of dispatch.
- (18) Animals and meat entering the Union from third countries should be subject to identification and traceability requirements that provide an equivalent level of protection.
- (19) When live animals are imported into the Union from third countries, they should be subject, on arrival, to the same identification requirements that apply to animals that are born in the Union.
- (20) The two official means of identification allocated to one animal should bear the same identification code. However, during the initial phase of adjustment to the use of electronic identifiers as an official means of identification, it could not be excluded that, in certain cases, technical limitations related to the configuration of an animal's original identification code could prevent the reproduction of that code on an electronic identifier. This could occur where the characters forming an animal's existing identification code prevent that code from being converted into an electronic format. Therefore, specific transitory derogations should be provided for in order to allow the application of an electronic identifier also to those animals, provided that full traceability is ensured and that the animals can be identified individually, including the holding on which they were born.
- (21) Regulation (EC) No 1760/2000 provides that the competent authority is to issue a passport for each animal which has to be identified in accordance with that Regulation. This causes a considerable administrative burden for Member States. The competent authorities of Member States have an obligation to set up a computerised database in accordance with Articles 14 and 18 of Council Directive 64/432/EEC ⁽¹⁾. Since those databases have had to be fully operational since 31 December 1999, they should sufficiently ensure traceability of domestic movements of bovine animals. Passports should therefore be issued only for animals intended for intra-Union trade. However, this Regulation should not preclude national provisions concerning the issuing of passports for animals not intended for intra-Union trade.
- (22) BOVEX, the pilot project for bovine passport exchange between Member States, was put in place by the Commission in order to facilitate data exchange between Member States, while at the same time ensuring the traceability of the animals during their intra-Union movements. Once the data exchange between national

⁽¹⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977/64).

computerised databases is fully operational, the requirement of issuing animal passports in a paper form should no longer apply to animals intended for intra-Union movements. This should contribute to the reduction of the administrative burden of Member States and economic operators.

- (23) Section II of Title II of Regulation (EC) No 1760/2000 lays down rules for a voluntary beef labelling system which provide for the approval of certain labelling specifications by the competent authority of the Member State concerned. The administrative burden borne and the costs incurred by Member States and by economic operators in applying that system are not proportionate to the benefits of the system. Since new legislation has entered into force following the adoption of that Regulation, specific rules on the voluntary labelling system have become superfluous and should therefore be deleted. However, the right of operators to inform consumers through voluntary labelling on the characteristics of the meat and the right of the consumers to receive verifiable information should not be compromised. Consequently, as for any other sort of meat, food information on beef which goes beyond mandatory labelling should respect the current horizontal legislation, including Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽¹⁾.
- (24) To prevent risks of fraud in meat labelling and to protect European consumers, applicable controls and penalties should have a sufficiently dissuasive effect.
- (25) In accordance with Regulation (EU) No 1169/2011, the Commission submitted a report to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance of the meat used as an ingredient. That report was to be accompanied by a legislative proposal, if appropriate, in order to ensure more transparency throughout the meat chain and to better inform European consumers. Taking into account the latest problems in relation to the labelling of meat products that have affected the functioning of the food chain, the European Parliament and the Council expected the report to be adopted as early as possible during the second semester of 2013 and it was finally adopted on 17 December 2013.
- (26) As a consequence of the entry into force of the Lisbon Treaty, the powers conferred under Regulation (EC) No 1760/2000 upon the Commission need to be aligned with Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).
- (27) In order to ensure that the necessary rules for the proper functioning of the identification, registration and traceability of bovine animals and of beef are applied, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the requirements for alternative means of identification of bovine animals; the special circumstances in which Member States are to be permitted to extend the maximum periods for the application of the means of identification; data to be exchanged between the computerised databases of the Member States; the maximum period for certain reporting obligations; the requirements for the means of identification; the addition of means of identification to the list set out in Annex I; the rules concerning the information from the computerised database to be included in the animal passports and in the individual registers to be kept on each holding; the identification and registration of movements of bovine animals when put out to seasonal grazing including transhumance; rules for labelling certain products which should be equivalent to the rules laid down in Regulation (EC) No 1760/2000; the labelling provisions relating to a simplified presentation of the indication of origin for cases of very short stay of an animal in the Member State or third country of birth or of slaughter; and the definitions and requirements applicable to terms or categories of terms that may be put on the labels of pre-packed fresh and frozen beef and veal. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up such delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

⁽¹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (28) In order to ensure uniform conditions for the implementation of Regulation (EC) No 1760/2000 with respect to the registration of holdings making use of alternative means of identification; technical characteristics and detailed arrangements for the exchange of data between the computerised databases of Member States; recognition of the full operability of the data exchange systems; the format and design of the means of identification; technical procedures and standards for the implementation of EID; the rules concerning the configuration of the identification code, the maximum size and composition of certain groups of animals, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (29) The implementation of this Regulation should be monitored. Consequently, no later than five years after the entry into force of this Regulation as regards the provisions concerning voluntary beef labelling, and nine years as regards the provisions concerning EID, the Commission should submit to the European Parliament and to the Council two reports dealing both with the implementation of this Regulation and with the technical and economic feasibility of introducing mandatory EID everywhere in the Union. Those reports should, if necessary, be accompanied by appropriate legislative proposals.
- (30) Regulation (EC) No 1760/2000 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1760/2000 is amended as follows:

- (1) in Article 1, the second sentence of paragraph 2 is deleted;
- (2) in Article 2, the first indent is replaced by the following:

‘— “animal” means a bovine animal within the meaning of Article 2(2), points (b) and (c) of Directive 64/432/EEC, including animals taking part in cultural and sporting events;’

- (3) in the first paragraph of Article 3, point (a) is replaced by the following:

‘(a) means of identification to identify animals individually;’

- (4) Article 4 is replaced by the following:

Article 4

Obligation to identify animals

1. All animals on a holding shall be identified by at least two means of identification listed in Annex I and in compliance with rules adopted pursuant to paragraph 3 and approved by the competent authority. At least one of the means of identification shall be visible and bear a visible identification code.

The first subparagraph shall not apply to animals that were born before 1 January 1998 and that are not intended for intra-Union trade. Those animals shall be identified by at least one means of identification.

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

In order to ensure the adaptation to technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b concerning the addition of means of identification to the list set out in Annex I, whilst ensuring their interoperability.

The means of identification shall be allocated to the holding, distributed and applied to the animals in a manner determined by the competent authority.

The two means of identification, authorised in accordance with the delegated and implementing acts adopted pursuant to paragraph 3 and this paragraph and which are applied to one animal, shall bear the same unique identification code, which, together with the registration of the animals, makes it possible to identify the animal individually and the holding on which it was born.

2. By way of derogation from paragraph 1, where the characters forming the animal's identification code do not permit the application of an electronic identifier with the same unique identification code, the Member State concerned may allow that, under the supervision of its competent authority, the second means of identification may bear a different code, provided each of the following conditions are fulfilled:

- (a) the animal is born before the date of entry into force of the implementing acts referred to in point (c) of the second subparagraph of paragraph 3;
- (b) full traceability is ensured;
- (c) the individual identification of the animal, including the holding on which it was born, is possible;
- (d) the animal is not intended for intra-Union trade.

3. To ensure adequate traceability and adaptability to technical progress and optimal functioning of the identification system, the Commission shall adopt delegated acts in accordance with Article 22b concerning the requirements for the means of identification set out in Annex I, and the transitional measures required for the introduction of a particular means of identification.

On the basis of the relevant ISO standards or other international technical standards adopted by recognised international standard-setting organisations, with the understanding that those international standards are able to guarantee, at the very least, a higher level of performance and reliability than ISO standards, the Commission shall lay down, by means of implementing acts, the necessary rules concerning:

- (a) the format and design of the means of identification;
- (b) technical procedures for the electronic identification of bovine animals; and
- (c) the configuration of the identification code.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

4. As from 18 July 2019, the Member States shall ensure that the necessary infrastructure is in place in order to provide for the identification of animals on the basis of an electronic identifier as an official means of identification in accordance with this Regulation.

As from 18 July 2019, Member States may introduce national provisions making the use of an electronic identifier compulsory as one of the two means of identification provided for in paragraph 1.

Member States that make use of the option under the second subparagraph shall provide the Commission with the text of such national provisions and make this information available on the internet. The Commission shall assist the Member States in making this information available to the public by providing, on its website, the links to the relevant websites of the Member States.

5. By way of derogation from paragraph 1, bovine animals intended for cultural and sporting events, other than fairs and exhibitions, may be identified by alternative means of identification offering equivalent identification standards to those provided for in paragraph 1.

Holdings making use of alternative means of identification referred to in the first subparagraph shall be registered in the computerised database provided for in Article 5.

The Commission shall, by means of implementing acts, lay down the necessary rules concerning such registration. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

In order to ensure traceability based on the identification standards equivalent to those provided for in paragraph 1, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b concerning the requirements for the alternative means of identification referred to in the first subparagraph, including transitional measures required for their introduction.

The Commission may lay down, by means of implementing acts, the rules concerning the format and design of the alternative means of identification, referred to in the first subparagraph, including transitional measures required for their introduction. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

6. Member States shall communicate to each other and to the Commission a model of the means of identification used in their territory. They shall make this information available on the internet. The Commission shall assist the Member States in making this information available to the public by providing, on its website, the links to the relevant websites of the Member States.;

(5) the following Articles are inserted:

'Article 4a

Time period for the application of the means of identification

1. The means of identification provided for in Article 4(1) shall be applied to the animal before the expiry of a maximum period, to be determined by the Member State in which the animal was born. The maximum period shall be calculated from the date of birth of the animal and shall not exceed 20 days.

By way of derogation from the first subparagraph, for reasons related to the physiological development of the animals, that period may, for the second means of identification, be extended up to 60 days following the birth of the animal.

No animal may leave the holding where it was born before the two means of identification have been applied to that animal.

2. To enable the application of the means of identification in special circumstances involving practical difficulties, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b to determine the special circumstances under which the Member States may extend the maximum periods for the application of the means of identification as provided for in the first and second subparagraphs of paragraph 1. Member States shall inform the Commission of each use of that option.

Article 4b

Identification of animals from third countries

1. Any animal subject to veterinary checks, pursuant to Directive 91/496/EEC, entering the Union from a third country and intended for a holding of destination within the territory of the Union, shall be identified at the holding of destination with the means of identification provided for in Article 4(1).

The original identification applied to the animal in the third country of origin shall be recorded in the computerised database provided for in Article 5 together with the unique identification code of the means of identification allocated to the animal by the Member State of destination.

The first subparagraph shall not apply to animals destined directly for a slaughterhouse situated in a Member State, provided that the animals are slaughtered within 20 days following those veterinary checks pursuant to Directive 91/496/EEC.

2. The means of identification of animals referred to in Article 4(1) shall be applied within a maximum period to be determined by the Member State in which the holding of destination is located. That period shall not exceed 20 days following the veterinary checks referred in paragraph 1.

By way of derogation from the first subparagraph, for reasons related to the physiological development of the animals, that period may, for the second means of identification, be extended up to 60 days following the birth of the animal.

In all cases, the two means of identification referred to in the first subparagraph of Article 4(1) shall be applied to the animals before they leave the holding of destination.

3. Where the holding of destination is situated in a Member State that has introduced national provisions under the second subparagraph of Article 4(4) to make the use of an electronic identifier compulsory, the animals shall be identified with that electronic identifier in the holding of destination in the Union, within a period to be determined by the Member State of destination. That period shall not exceed 20 days following the veterinary checks referred in paragraph 1.

By way of derogation from the first subparagraph, for reasons related to the physiological development of the animals, that period may, for the second means of identification, be extended up to 60 days following the birth of the animal.

In all cases, the electronic identifier shall be applied to the animals before they leave the holding of destination.

Article 4c

Identification of animals moved from one Member State to another

1. Animals moved from one Member State to another shall retain the original means of identification applied to them pursuant to Article 4(1).

However, by way of derogation from the first subparagraph, starting from 18 July 2019, the competent authority of the Member State of destination may allow:

- (a) the replacement of one of the means of identification by an electronic identifier without changing the original unique identification code of the animal;
- (b) the replacement of both means of identification by two new means of identification which shall both bear the same, new unique identification code. This derogation may be applied until five years after 18 July 2019, where the characters forming the identification code of an animal's conventional ear tag do not permit the application of an electronic identifier with the same unique identification code, and provided that the animal is born before the date of entry into force of the implementing acts referred to in point (c) of the second subparagraph of Article 4(3).

2. Where the holding of destination is situated in a Member State that has introduced national provisions to make the use of an electronic identifier compulsory, the animals shall be identified with that electronic identifier at the latest in the holding of destination within a maximum period to be determined by the Member State where that holding of destination is located. That maximum period shall not exceed 20 days from the date of arrival of the animals on the holding of destination.

By way of derogation from the first subparagraph, for reasons related to the physiological development of the animals, that period may, for the second means of identification, be extended up to 60 days following the birth of the animal.

In all cases, the electronic identifier shall be applied to the animals before they leave the holding of destination.

However, the first subparagraph shall not apply to animals destined directly for a slaughterhouse situated in the territory of the Member State that has introduced national provisions to make the use of an electronic identifier compulsory.

Article 4d

Removal, modification or replacement of means of identification

No means of identification may be removed, modified or replaced without the permission of the competent authority. Such permission may only be granted where the removal, modification or replacement do not compromise the traceability of the animal and where its individual identification, including the holding on which it was born, is possible.

Any replacement of an identification code shall be recorded in the computerised database provided for in Article 5, together with the unique identification code of the original means of identification of the animal.;

- (6) Article 5 is replaced by the following:

'Article 5

The competent authority of the Member States shall set up a computerised database in accordance with Articles 14 and 18 of Directive 64/432/EEC.

Member States may exchange electronic data between their computerised databases from the date on which the Commission recognises the full operability of the data exchange system. The exchange shall be done in such a way that data protection is guaranteed and any abuse prevented in order to protect the interests of the keeper.

In order to ensure the electronic exchange of information between Member States, the Commission shall adopt delegated acts in accordance with Article 22b to lay down the rules concerning the data to be exchanged between computerised databases of Member States.

The Commission shall by means of implementing acts lay down the technical conditions and modalities for such exchange and recognise the full operability of the data exchange system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).;

(7) Article 6 is replaced by the following:

Article 6

1. Where a Member State does not exchange electronic data with other Member States, in the framework of the electronic exchange system referred to in Article 5, the following applies:

- (a) the competent authority of that Member State shall, for each animal that is intended for intra-Union trade, issue a passport based on the information contained in the computerised database set up in that Member State;
- (b) each animal for which a passport is issued shall be accompanied by that passport whenever the animal is moved from one Member State to another;
- (c) upon arrival of the animal at the holding of destination, the passport accompanying the animal shall be surrendered to the competent authority of the Member State where the holding of destination is located.

2. In order to allow for the tracing of animal movements back to the holding of origin situated in a Member State, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b to lay down rules concerning the information from the computerised database to be included in the animal passport, including transitional measures required for their introduction.;

(8) the following Article is inserted:

Article 6a

This Regulation shall not prevent national provisions by a Member State concerning the issuing of passports for animals not intended for intra-Union trade.;

(9) Article 7 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) the second indent is replaced by the following:

- report to the competent authority all movements to and from the holding and all births and deaths of animals of the holding, together with the dates of those events, within a maximum period fixed by the Member State concerned; that maximum period shall be at least three days and not exceed seven days following the occurrence of one of those events; Member States may request the Commission to extend the maximum period of seven days.;

(ii) the following subparagraph is added:

'To take into account practical difficulties in exceptional cases, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b to determine the exceptional circumstances in which Member States may extend the maximum period of seven days provided for in the second indent of the first subparagraph, together with the maximum length of that extension, which shall not exceed 14 days following the period of seven days referred to in the second indent of the first subparagraph.;

(b) paragraph 2 is replaced by the following:

'2. To ensure the adequate and effective traceability of bovine animals when put out to seasonal grazing, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b concerning the Member States or part of Member States where special rules for seasonal grazing shall apply, including the time period, specific obligations of the keepers, and rules on the holding registration and registration of movements of such bovine animals, including transitional measures required for their introduction.;

(c) the following paragraphs are added:

'5. By way of derogation from paragraph 4, keeping a register shall be optional for any keeper who:

(a) has access to the computerised database provided for in Article 5 which already contains the information to be included in the register; and

(b) enters the up-to-date information, or has it entered, directly into the computerised database provided for in Article 5.

6. To ensure the accuracy and reliability of the information to be included in the holding register provided for in this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b to lay down the necessary rules concerning that information, including transitional measures required for their introduction.;

(10) Article 8 is deleted;

(11) the following Article is inserted:

'Article 9a

Training

Member States shall ensure that any person responsible for the identification and registration of animals has received instructions and guidance on the relevant provisions of this Regulation and of any delegated and implementing acts adopted by the Commission pursuant to this Regulation.

Whenever the relevant provisions are amended, the corresponding information shall be made available to the person referred to in the first subparagraph.

Member States shall ensure that appropriate training courses are available.

The Commission shall facilitate the exchange of best practices to improve the quality of information and training across the Union.;

(12) Article 10 is deleted;

(13) Article 12 is replaced by the following:

‘Article 12

For the purposes of this Title, the following definitions apply:

- (1) “beef” means all products falling within CN codes 0201, 0202, 0206 10 95 and 0206 29 91;
- (2) “labelling” means the attachment of a label to an individual piece or pieces of meat or to their packaging material, or, in the case of non-pre-wrapped products, the supply of appropriate information in written and visible form to the consumer at the point of sale;
- (3) “organisation” means a group of operators from the same or different parts of the beef trade;
- (4) “minced meat” means any boned meat that has been minced into fragments and contains less than 1 % salt and that falls within CN codes 0201, 0202, 0206 10 95 and 0206 29 91;
- (5) “trimmings” means small pieces of meat recognised as fit for human consumption produced exclusively during trimming operations during the boning of carcasses and/or the cutting up of meat;
- (6) “cut meat” means meat which has been cut into small cubes, slices or other individual portions that do not require further cutting by an operator before being bought by the final consumer and that can be directly used by that consumer. This definition does not cover minced meat and trimmings.’;

(14) Article 13 is amended as follows:

(a) paragraphs 3 and 4 are deleted;

(b) in paragraph 5, the introductory phrase of point (a) is replaced by the following:

‘(a) Operators and organisations shall also indicate on the labels.’;

(c) the following paragraph is added:

‘6. To avoid unnecessary repetition of the indication on the label of the beef of the Member States or third countries where rearing took place, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b pertaining to a simplified presentation for cases of very short stay of the animal in the Member State or third country of birth or of slaughter.

The Commission shall, by way of implementing acts, adopt rules concerning the maximum size and composition of the group of animals referred to in paragraphs 1 and 2(a), taking into account constraints as regards the homogeneity of the groups of animals where those cut meats and trimmings come from. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).’;

(15) in Article 14, the fourth paragraph is replaced by the following:

'To ensure conformity with the horizontal rules relating to the labelling in this Section, the Commission shall be empowered to adopt delegated acts in accordance with Article 22b to lay down, on the basis of the experience regarding minced meat, rules equivalent to those in the first three paragraphs of this Article for beef trimmings or cut beef';

(16) Article 15 is replaced by the following:

'Article 15

Compulsory labelling of beef from third countries

By way of derogation from Article 13, beef imported into the territory of the Union for which not all the information provided for in Article 13 is available, shall be labelled with the indication:

"Origin: non-EU" and "Slaughtered in (name of the third country)";

(17) from 13 December 2014:

(a) the heading of Section II of Title II shall be replaced by the words 'Voluntary labelling';

(b) Articles 16, 17 and 18 are deleted; and

(c) the following Article is inserted into Section II of Title II:

'Article 15a

General rules

Food information other than that specified in Articles 13, 14 and 15 which is added to labels voluntarily by operators or organisations marketing beef shall be objective, verifiable by the competent authorities and comprehensible for consumers.

That information shall comply with the horizontal legislation on labelling and in particular Regulation (EU) No 1169/2011 of the European Parliament and of the Council (*).

Where operators or organisations marketing beef do not respect the obligations referred to in the first and the second paragraphs, the competent authority shall apply appropriate penalties as laid down in Article 22.

The Commission shall be empowered to adopt delegated acts in accordance with Article 22b concerning definitions and requirements applicable to terms or categories of terms that may be put on the labels of pre-packed fresh and frozen beef and veal.

(*) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).;

(18) Articles 19, 20 and 21 are deleted;

(19) Article 22 is replaced by the following:

Article 22

1. Member States shall take all the necessary measures to ensure compliance with the provisions of this Regulation.

The controls provided for shall be without prejudice to any controls which the Commission may carry out pursuant to Article 9 of Regulation (EC, Euratom) No 2988/95.

Any penalties imposed by the Member State on a keeper, operator or organisation marketing beef shall be effective, dissuasive and proportionate.

The competent authority shall carry out each year a minimum number of official checks in relation to identification and registration of animals which shall cover at least 3 % of the holdings.

The competent authority shall immediately increase the minimum rate of official checks referred to in the second subparagraph where it is established that provisions on identification and registration of animals have not been complied with.

The selection of holdings to be inspected by the competent authority shall be made on the basis of a risk analysis.

Each Member State shall submit an annual report to the Commission by 31 August on the implementation of the official checks during the previous year.

2. Notwithstanding paragraph 1, the competent authority shall impose on a keeper the following administrative penalties:

- (a) if one or more animals on a holding do not comply with any of the provisions laid down in Title I: a restriction on the movement of all animals to or from the holding of the keeper concerned;
- (b) in the case of animals for which the identification and registration requirements laid down in Title I are not fully complied with: an immediate restriction on the movement of those animals only, until those requirements are fully complied with;
- (c) if, on one holding, the number of animals for which the identification and registration requirements laid down in Title I are not fully complied with is in excess of 20 %: an immediate restriction on the movement of all the animals present on that holding; in respect of holdings of not more than 10 animals, this measure shall apply if more than two animals are not fully identified in accordance with the requirements laid down in Title I;
- (d) if the keeper of an animal cannot prove that animal's identification and traceability: where appropriate, on the basis of an assessment of the animal health and food safety risks, the destruction of the animal without compensation;

- (e) if a keeper fails to report to the competent authority the movement of an animal to and from his holding in accordance with the second indent of Article 7(1), the competent authority shall restrict the movement of animals to and from that holding;
- (f) if a keeper fails to report to the competent authority the birth or death of an animal in accordance with the second indent of Article 7(1), the competent authority shall restrict the movement of animals to and from that holding;
- (g) in cases of persistent failure by a keeper to pay the charge referred to in Article 9, Member States may restrict the movement of animals to and from the holding of that keeper.

3. Notwithstanding paragraph 1, where operators and organisations marketing beef have labelled beef without complying with their obligations laid down in Title II, Member States shall, as appropriate, and in accordance with the principle of proportionality, require the removal of the beef from the market. In addition to the penalties referred to in paragraph 1, Member States may:

- (a) if the meat concerned conforms with relevant veterinary and hygiene rules authorise that such beef:
 - (i) be placed on the market after being properly labelled in accordance with Union requirements; or
 - (ii) be sent directly for processing into products other than those indicated in the first indent of Article 12;
- (b) order the suspension or withdrawal of the approval of the operators and organisations concerned.

4. Experts from the Commission, in conjunction with the competent authorities, shall:

- (a) verify that Member States comply with the requirements of this Regulation;
- (b) make on-the-spot checks to ensure that the checks are carried out in accordance with this Regulation.

5. A Member State in whose territory an on-the-spot check is made shall provide the experts from the Commission with any assistance they may require in the performance of their tasks. The outcome of the checks made shall be discussed with the competent authority of the Member State concerned before a final report is drawn up and circulated. This report shall, where appropriate, contain recommendations for Member States on the improvement of compliance with this Regulation.;

(20) the following Articles are inserted:

'Article 22a

Competent authorities

Member States shall designate the competent authority or authorities responsible for ensuring compliance with this Regulation and any acts adopted by the Commission on its basis.

They shall inform the Commission and the other Member States of the identity of those authorities.

*Article 22b***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions under this Article.

2. The power to adopt delegated acts referred to in Articles 4(1), 4(3), 4(5), 4a(2), 5, 6(2), 7(1), 7(2), 7(6), 13(6), 14(4) and 15a shall be conferred on the Commission for a period of five years from 17 July 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 4(1), 4(3), 4(5), 4a(2), 5, 6(2), 7(1), 7(2), 7(6), 13(6), 14(4) and 15a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Articles 4(1), 4(3), 4(5), 4a(2), 5, 6(2), 7(1), 7(2), 7(6), 13(6), 14(4) and 15a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.;

(21) Article 23 is replaced by the following:

*'Article 23***Committee procedure**

1. The Commission shall be assisted for the implementing acts adopted pursuant to Articles 4(3), 4(5), 5 and 13(6) by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*).

That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the Committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the Committee so decides or a simple majority of committee members so requests.

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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

(22) the following Article is inserted:

'Article 23a

Report and legislative developments

No later than:

- 18 July 2019 for the voluntary labelling provisions, and
- 18 July 2023 for the electronic identification provisions,

the Commission shall submit to the European Parliament and the Council the corresponding reports dealing with the implementation and impact of this Regulation including, in the first case, the possibility of reviewing the voluntary labelling provisions, and, in the second case, the technical and economic feasibility of introducing mandatory electronic identification throughout the Union.

Those reports shall, if necessary, be accompanied by appropriate legislative proposals.;

(23) the following Annex is inserted:

'ANNEX I

MEANS OF IDENTIFICATION

A) CONVENTIONAL EAR TAG

WITH EFFECT FROM 18 JULY 2019:

B) ELECTRONIC IDENTIFIER IN THE FORM OF AN ELECTRONIC EAR TAG

C) ELECTRONIC IDENTIFIER IN THE FORM OF A RUMINAL BOLUS

D) ELECTRONIC IDENTIFIER IN THE FORM OF AN INJECTABLE TRANSPONDER'

Article 2

This Regulation shall enter into force on the twentieth day following that of 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 Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

REGULATION (EU) No 654/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014

concerning the exercise of the Union's rights for the application and enforcement of international trade rules and amending Council Regulation (EC) No 3286/94 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization

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) The Union has concluded a number of multilateral, regional and bilateral international trade agreements creating rights and obligations for the mutual benefit of the parties.
- (2) It is essential that the Union possess appropriate instruments to ensure the effective exercise of the Union's rights under international trade agreements in order to safeguard its economic interests. This is particularly the case in situations where third countries enact trade restrictive measures that diminish the benefits accruing to the Union's economic operators under international trade agreements. The Union should be in a position to react swiftly and in a flexible manner in the context of the procedures and deadlines set out by the international trade agreements which it has concluded. There is therefore a need for rules defining the framework for exercising the Union's rights in certain specific situations.
- (3) The dispute settlement mechanisms set up by the Agreement establishing the World Trade Organization (WTO) and by other international trade agreements, including regional or bilateral agreements, aim at finding a positive solution to any disputes arising between the Union and the other party or parties to those agreements. The Union should, nevertheless, be able to suspend concessions or other obligations, in accordance with those dispute settlement mechanisms, when other avenues to find a positive solution to a dispute have proven unsuccessful. Action by the Union in such cases should serve the purpose of inducing compliance of the third country concerned with the relevant international trade rules in order to restore a situation of reciprocal benefits.
- (4) Under the WTO Agreement on Safeguards, a WTO member proposing to apply a safeguard measure or seeking an extension of a safeguard measure has to endeavour to maintain a substantially equivalent level of concessions and other obligations between it and the exporting Members, which would be affected by such a measure. Similar rules are laid down in other international trade agreements concluded by the Union, including regional or bilateral agreements. The Union should take rebalancing measures by suspending concessions or other obligations in cases where the third country concerned implements no adequate and proportionate adjustments. Action by the Union in such cases should serve the purpose of inducing the introduction of trade-enhancing measures by third countries in order to restore a situation of reciprocal benefits.

⁽¹⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.

- (5) Article XXVIII of the General Agreement on Tariffs and Trade 1994 (GATT 1994) and the related Understanding govern the modification or withdrawal of concessions established in the tariff schedules of WTO Members. WTO Members affected by any such modification are entitled, under certain conditions, to withdraw substantially equivalent concessions. The Union should adopt rebalancing measures in such cases, unless compensatory adjustments are agreed. Action by the Union should be aimed at inducing third countries to implement trade-enhancing measures.
- (6) The Union should have the possibility to enforce its rights in the area of public procurement when a trade partner fails to respect its commitments under the WTO Agreement on Government Procurement (GPA) or other international trade agreements. The GPA states that any dispute arising thereunder is not to result in the suspension of concessions or other obligations under any other covered agreement of the WTO. The Union's action should be aimed at ensuring the maintenance of a substantially equivalent level of concessions, as laid down in the relevant international trade agreements.
- (7) Member States should ensure the application within their respective territories of commercial policy measures in the field of public procurement in the manner that is best suited to their administrative structures and practices, while respecting Union law.
- (8) Commercial policy measures adopted under this Regulation should be selected and designed on the basis of objective criteria, including the effectiveness of the measures in inducing compliance of third countries with international trade rules, their potential to provide relief to economic operators within the Union affected by third country measures, and the aim of minimising negative economic impacts on the Union, including with regard to essential raw materials.
- (9) This Regulation should focus on those measures in respect of which the Union has experience in design and application. The possibility to extend its scope in order to provide for the adoption of measures in the sector of intellectual property rights and additional measures concerning services should be assessed as part of the review on the functioning of this Regulation, with due regard to the specificities of each area.
- (10) When enforcing the Union's rights, the origin of a good should be determined in accordance with Council Regulation (EEC) No 2913/92 ⁽¹⁾. When enforcing the Union's rights following dispute settlement in the area of public procurement, the origin of a service should be determined on the basis of the origin of the natural or legal person providing it. Contracting authorities or entities should apply normal precautions and exercise due diligence when assessing information and guarantees provided by tenderers as regards the origin of goods and services.
- (11) The Commission should review the scope, functioning and efficiency of this Regulation, including possible measures in the sector of intellectual property rights and additional measures concerning services, no later than three years after the first instance of its implementation or no later than five years from its date of entry into force, whichever is the earlier. The Commission should report on its assessment to the European Parliament and the Council. The review may be followed up by appropriate legislative proposals.
- (12) It is important to ensure an effective communication and exchange of views between the Commission on the one hand and the European Parliament and the Council on the other, in particular on disputes under international trade agreements that may lead to the adoption of measures under this Regulation.
- (13) Council Regulation (EC) No 3286/94 ⁽²⁾ should be amended in order to refer to this Regulation with regard to the implementation of commercial policy measures.

⁽¹⁾ Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

⁽²⁾ Council Regulation (EC) No 3286/94 of 22 December 1994 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization (OJ L 349, 31.12.1994, p. 71).

- (14) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (15) In light of the high complexity involved in the examination of the multiple impacts that commercial policy measures adopted under this Regulation may have, and with a view to allowing sufficient opportunities to achieve the widest possible support, implementing acts should not be adopted by the Commission where, exceptionally, the committee referred to in this Regulation delivers no opinion on the draft implementing act presented by the Commission.
- (16) In order to safeguard the Union's interests, the Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the need to adapt commercial policy measures to the behaviour of the third party concerned, imperative grounds of urgency so require.
- (17) This Regulation is without prejudice to the possible adoption of commercial policy measures on the basis of other relevant Union acts or of the provisions of the Treaty on the Functioning of the European Union, while respecting the applicable provisions in international trade agreements on the suspension or withdrawal of concessions or other obligations,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down rules and procedures to ensure an effective and timely exercise of the Union's rights to suspend or withdraw concessions or other obligations under international trade agreements, with the intention of:

- (a) responding to breaches by third countries of international trade rules which affect the Union's interests, with a view to seeking a satisfactory solution that restores benefits for the Union's economic operators;
- (b) rebalancing concessions or other obligations in the trade relations with third countries, when the treatment accorded to goods from the Union is altered in a way that affects the Union's interests.

Article 2

Definitions

For the purposes of this Regulation the following definitions apply:

- (a) "country" means any State or separate customs territory;
- (b) "concessions or other obligations" means tariff concessions or any other benefits that the Union has committed itself to applying in its trade with third countries by virtue of international trade agreements to which it is a party;
- (c) "level of nullification or impairment" means the degree to which the benefits accruing to the Union under an international trade agreement are affected. Except as otherwise defined in the relevant agreement, it includes any adverse economic impact resulting from a third country measure;
- (d) "mandatory price penalty" means an obligation on contracting authorities or entities conducting public procurement procedures to increase, subject to certain exceptions, the price of services and/or goods originating in certain third countries that have been offered in contract award procedures.

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

*Article 3***Scope**

This Regulation applies:

- (a) following the adjudication of trade disputes under the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (WTO Dispute Settlement Understanding), when the Union has been authorised to suspend concessions or other obligations under the multilateral and plurilateral agreements covered by the WTO Dispute Settlement Understanding;
- (b) following the adjudication of trade disputes under other international trade agreements, including regional or bilateral agreements, when the Union has the right to suspend concessions or other obligations under such agreements;
- (c) for the rebalancing of concessions or other obligations, to which the application of a safeguard measure by a third country may give right pursuant to Article 8 of the WTO Agreement on Safeguards, or to the provisions on safeguards included in other international trade agreements, including regional or bilateral agreements;
- (d) in cases of modification of concessions by a WTO member under Article XXVIII of the GATT 1994, where no compensatory adjustments have been agreed.

*Article 4***Exercise of the Union's rights**

1. Where action is necessary to safeguard the Union's interests in the cases referred to in Article 3, the Commission shall adopt implementing acts determining the appropriate commercial policy measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 8(2).
2. Implementing acts adopted pursuant to paragraph 1 shall meet the following conditions:
 - (a) where concessions or other obligations are suspended following the adjudication of a trade dispute under the WTO Dispute Settlement Understanding, their level shall not exceed the level authorised by the WTO Dispute Settlement Body;
 - (b) where concessions or other obligations are suspended following the discharge of an international dispute settlement procedure under other international trade agreements, including regional or bilateral agreements, their level shall not exceed the level of nullification or impairment as a result of the third country measure concerned, as determined by the Commission or through recourse to arbitration, as the case may be;
 - (c) in the case of rebalancing of concessions or other obligations under provisions on safeguards in international trade agreements, the Union's action shall be substantially equivalent to the level of concessions or other obligations affected by the safeguard measure, in accordance with the conditions of the WTO Agreement on Safeguards or of the provisions on safeguards in other international trade agreements, including regional or bilateral agreements, under which the safeguard measure is applied;
 - (d) where concessions are withdrawn in the trade with a third country in connection with Article XXVIII of the GATT 1994 and the related Understanding⁽¹⁾, they shall be substantially equivalent to the concessions modified or withdrawn by that third country, in accordance with the terms established in Article XXVIII of the GATT 1994 and the related Understanding.
3. Commercial policy measures referred to in paragraph 1 shall be determined on the basis of the following criteria, in light of available information and of the Union's general interest:
 - (a) effectiveness of the measures in inducing compliance of third countries with international trade rules;

⁽¹⁾ Understanding "Interpretation and Application of Article XXVIII".

- (b) potential of the measures to provide relief to economic operators within the Union affected by third country measures;
- (c) availability of alternative sources of supply for the goods or services concerned, in order to avoid or minimise any negative impact on downstream industries, contracting authorities or entities, or final consumers within the Union;
- (d) avoidance of disproportionate administrative complexity and costs in the application of the measures;
- (e) any specific criteria that may be established in international trade agreements in connection with the cases referred to in Article 3.

Article 5

Commercial policy measures

1. Without prejudice to any international agreement to which the Union is a party, the commercial policy measures that may be enacted by means of an implementing act pursuant to Article 4(1) shall consist of:

- (a) the suspension of tariff concessions and the imposition of new or increased customs duties, including the re-establishment of customs duties at the most favoured nation level or the imposition of customs duties beyond the most favoured nation level, or the introduction of any additional charge on imports or exports of goods;
- (b) the introduction or increase of quantitative restrictions on imports or exports of goods, whether made effective through quotas, import or export licences or other measures;
- (c) the suspension of concessions regarding goods, services or suppliers in the area of public procurement, through:
 - (i) the exclusion from public procurement of suppliers of goods or services established in and operating from the third country concerned and/or of tenders the total value of which is made up of more than 50 % of goods or services originating in the third country concerned; and/or
 - (ii) the imposition of a mandatory price penalty on tenders of suppliers of goods or services established in and operating from the third country concerned and/or on that part of the tender consisting of goods or services originating in the third country concerned.

2. Measures adopted pursuant to paragraph 1(c) shall:

- (a) include thresholds, according to the characteristics of the goods or services concerned, above which the exclusion and/or mandatory price penalty is to apply, taking into account the provisions of the trade agreement concerned and the level of nullification or impairment;
- (b) determine the sectors or the categories of goods or services to which they apply, as well as any applicable exceptions;
- (c) determine the contracting authorities or entities or categories of contracting authorities or entities, listed by Member State, whose procurement is covered. To provide the basis for this determination, each Member State shall submit a list of appropriate contracting authorities or entities or categories of contracting authorities or entities. The measures shall ensure that an appropriate level of suspension of concessions or other obligations and a fair distribution among Member States is achieved.

Article 6

Rules of origin

1. The origin of a good shall be determined in accordance with Regulation (EEC) No 2913/92.

2. The origin of a service shall be determined on the basis of the origin of the natural or legal person providing it. The origin of the service provider shall be deemed to be:

- (a) in the case of a natural person, the country of which the person is a national or where he has a right of permanent residence;
- (b) in the case of a legal person, either of the following:
 - (i) if the service is provided other than through a commercial presence within the Union, the country where the legal person is constituted or otherwise organised under the laws of that country and in the territory of which the legal person is engaged in substantive business operations;
 - (ii) if the service is provided through a commercial presence within the Union, the Member State where the legal person is established and in the territory of which it is engaged in substantive business operations such that it has a direct and effective link with the economy of that Member State.

For the purposes of point (ii) of point (b) of the first subparagraph, if the legal person providing the service is not engaged in substantive business operations such that it has a direct and effective link with the economy of the Member State in which it is established, the origin of that legal person shall be deemed to be the origin of the natural or legal persons which own or control it.

The legal person providing the service shall be considered to be "owned" by persons of a given country if more than 50 % of the equity interest in it is beneficially owned by persons of that country and "controlled" by persons of a given country if such persons have the power to name a majority of its directors or otherwise to legally direct its actions.

Article 7

Suspension, modification and repeal of measures

1. Where, after the adoption of an implementing act pursuant to Article 4(1), the third country concerned accords adequate and proportionate compensation to the Union in the cases referred to in Article 3(1)(a) and (b), the Commission may suspend the application of that implementing act for the duration of the compensation period. The suspension shall be decided in accordance with the examination procedure referred to in Article 8(2).
2. The Commission shall repeal an implementing act adopted under Article 4(1) in any of the following circumstances:
 - (a) when the third country whose measures were found to be in breach of international trade rules in a dispute settlement procedure brings itself into compliance, or where a mutually satisfactory solution has otherwise been reached;
 - (b) in cases of rebalancing of concessions or other obligations following the adoption by a third country of a safeguard measure, when the safeguard measure is withdrawn or expires, or when the third country concerned accords adequate and proportionate compensation to the Union after the adoption of an implementing act under Article 4(1);
 - (c) in cases of modification of concessions by a WTO member under Article XXVIII of the GATT 1994, when the third country concerned accords adequate and proportionate compensation to the Union after the adoption of an implementing act under Article 4(1).

The repeal referred to in the first subparagraph shall be decided in accordance with the examination procedure referred to in Article 8(2).

3. Where it is necessary to make adjustments to commercial policy measures adopted under this Regulation, subject to Article 4(2) and (3), the Commission may introduce any appropriate amendments in accordance with the examination procedure referred to in Article 8(2).

4. On duly justified imperative grounds of urgency relating to the termination or the modification of the third country measure concerned, the Commission shall adopt immediately applicable implementing acts suspending, amending or repealing implementing acts adopted under Article 4(1), as provided for in this Article, in accordance with the procedure referred to in Article 8(3).

Article 8

Committee procedure

1. The Commission shall be assisted by the committee established by Regulation (EC) No 3286/94. That committee shall be a committee within the meaning of Article 3 of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 in conjunction with Article 5 thereof, shall apply.

Article 9

Information gathering

1. The Commission shall seek information and views regarding the Union's economic interests in specific goods or services or in specific sectors, in the application of this Regulation, through a notice in the *Official Journal of the European Union* or through other suitable public communication means, indicating the period within which input is to be submitted. The Commission shall take the input received into account.

2. Information received pursuant to this Regulation shall be used only for the purpose for which it was requested.

3. Neither the European Parliament, nor the Council, nor the Commission, nor Member States, nor their respective officials shall reveal any information of a confidential nature received pursuant to this Regulation, without specific permission from the supplier of such information.

4. The supplier of information may request that information supplied be treated as confidential. In such cases, it shall be accompanied by a non-confidential summary which presents the information in a generalised form or a statement of the reasons why the information cannot be summarised.

5. If it appears that a request for confidentiality is not justified and if the supplier is unwilling either to make the information public or to authorise its disclosure in generalised or summary form, the information in question may be disregarded.

6. Paragraphs 2 to 5 shall not preclude the disclosure of general information by the institutions of the Union and the authorities of the Member States. Such disclosure must take into account the legitimate interest of the parties concerned in not having their business secrets divulged.

Article 10

Review

1. No later than three years after the first instance of the adoption of an implementing act or no later than 18 July 2019, whichever is the earlier, the Commission shall review the scope of this Regulation, particularly as regards the commercial policy measures that may be adopted, as well as its implementation, and shall report its findings to the European Parliament and the Council.

2. Notwithstanding paragraph 1, the Commission shall undertake a review aimed at envisaging under this Regulation additional commercial policy measures suspending concessions or other obligations in the field of trade in services. The Commission shall examine, inter alia, the following aspects:

- (a) international developments with regard to the suspension of other obligations under the General Agreement on Trade in Services (GATS);
- (b) developments within the Union with regard to the adoption of common rules on services sectors;
- (c) the effectiveness of possible additional commercial policy measures as a means to enforce the Union's rights under international trade agreements;
- (d) available mechanisms to ensure the practical implementation, in a uniform and efficient manner, of possible additional commercial policy measures concerning services; and
- (e) implications for service providers present in the Union at the time of adoption of implementing acts under this Regulation.

The Commission shall report its initial assessment to the European Parliament and the Council by 18 July 2017.

Article 11

Amendments to other acts

In Article 13 of Regulation (EC) No 3286/94, paragraph 3 is replaced by the following:

"3. Where the Union, having acted in accordance with Article 12(2), has to take a decision on the measures of commercial policy to be adopted pursuant to Article 11(2)(c) or pursuant to Article 12, it shall act, without delay, in accordance with Article 207 of the Treaty on the Functioning of the European Union and, as appropriate, Regulation (EU) No 654/2014 of the European Parliament and of the Council (*) or any other applicable procedures.

(*) Regulation (EU) No 654/2014 of the European Parliament and of the Council of 15 May 2014 concerning the exercise of the Union's rights for the application and enforcement of international trade rules and amending Council Regulation (EC) No 3286/94 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization (OJ L 189 27.6.2014, p. 50)."

Article 12

Entry into force

This Regulation shall enter into force on the twentieth day following that of 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 Brussels, 15 May 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

Statement by the Commission

The Commission welcomes the adoption of the Regulation of the European Parliament and of the Council concerning the exercise of the Union's rights for the application and enforcement of international trade rules and amending Council Regulation (EC) No 3286/94.

Under the Regulation, the Commission is empowered to adopt implementing acts in certain specific situations, on the basis of objective criteria and subject to the control of the Member States. In exercising that empowerment, the Commission intends to act in accordance with this Declaration.

When preparing draft implementing acts, the Commission will undertake extensive consultations with a view to ensuring that all relevant interests are duly taken into account. Through those consultations, the Commission expects to receive input from private stakeholders affected by third country measures or by possible commercial policy measures to be adopted by the Union. Similarly, the Commission expects to receive input from public authorities that may be involved in the implementation of possible commercial policy measures to be adopted by the Union. In the case of measures in the field of public procurement, in particular input from Member States' public authorities will be duly taken into account in the preparation of draft implementing acts.

The Commission recognizes the importance of Member States receiving timely information when it is considering the adoption of implementing acts under this Regulation so as to enable them to contribute to fully informed decisions and will act to achieve this objective.

The Commission confirms that it will promptly transmit to the Parliament and to the Council draft implementing acts that it submits to the committee of Member States. Similarly, it will promptly transmit to the Parliament and the Council final draft implementing acts following the delivery of opinions in the committee.

The Commission will keep the Parliament and the Council regularly informed of international developments that may lead to situations requiring the adoption of measures under the Regulation. This will be done through the responsible committees in Council and in Parliament.

The Commission welcomes the Parliament's intention to promote a structured dialogue on dispute settlement and enforcement issues and will fully engage in dedicated sessions with the responsible Parliamentary committee to exchange views on trade disputes and enforcement actions, including with regard to impacts on Union industries.

Finally, the Commission confirms that it attaches great importance to ensuring that the Regulation is an effective and efficient tool for the enforcement of the Union's rights under international trade agreements, including in the field of trade in services. Therefore, the Commission will, in accordance with the provisions of the Regulation, review the scope of Article 5 with a view to covering additional commercial policy measures concerning trade in services as soon as the conditions for ensuring the workability and effectiveness of such measures are present.

REGULATION (EU) No 655/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
establishing a European Account Preservation Order procedure to facilitate cross-border debt
recovery in civil and commercial matters

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 points (a), (e) and (f) of Article 81(2) thereof,

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

- (1) The Union has set itself the objective of maintaining and developing an area of freedom, security and justice in which the free movement of persons is ensured. For the gradual establishment of such an area, the Union is to adopt measures relating to judicial cooperation in civil matters having cross-border implications, particularly when necessary for the proper functioning of the internal market.
- (2) In accordance with Article 81(2) of the Treaty on the Functioning of the European Union (TFEU), such measures may include measures aimed at ensuring, inter alia, the mutual recognition and enforcement of judgments between Member States, effective access to justice and the elimination of obstacles to the proper functioning of civil proceedings, if necessary by promoting the compatibility of the rules on civil procedure applicable in the Member States.
- (3) On 24 October 2006, by way of the 'Green Paper on improving the efficiency of the enforcement of judgments in the European Union: the attachment of bank accounts', the Commission launched a consultation on the need for a uniform European procedure for the preservation of bank accounts and the possible features of such a procedure.
- (4) In the Stockholm Programme of December 2009 ⁽³⁾, which sets freedom, security and justice priorities for 2010 to 2014, the European Council invited the Commission to assess the need for, and the feasibility of, providing for certain provisional, including protective, measures at Union level, to prevent for example the disappearance of assets before the enforcement of a claim, and to put forward appropriate proposals for improving the efficiency of enforcement of judgments in the Union regarding bank accounts and debtors' assets.
- (5) National procedures for obtaining protective measures such as account preservation orders exist in all Member States, but the conditions for the grant of such measures and the efficiency of their implementation vary considerably. Moreover, recourse to national protective measures may prove cumbersome in cases having cross-border implications, in particular when the creditor seeks to preserve several accounts located in different Member States. It therefore seems necessary and appropriate to adopt a binding and directly applicable legal instrument of the Union which establishes a new Union procedure allowing, in cross-border cases, for the preservation, in an efficient and speedy way, of funds held in bank accounts.

⁽¹⁾ OJ C 191, 29.6.2012, p. 57.

⁽²⁾ Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 13 May 2014.

⁽³⁾ OJ C 115, 4.5.2010, p. 1.

- (6) The procedure established by this Regulation should serve as an additional and optional means for the creditor, who remains free to make use of any other procedure for obtaining an equivalent measure under national law.
- (7) A creditor should be able to obtain a protective measure in the form of a European Account Preservation Order ('Preservation Order' or 'Order') preventing the transfer or withdrawal of funds held by his debtor in a bank account maintained in a Member State if there is a risk that, without such a measure, the subsequent enforcement of his claim against the debtor will be impeded or made substantially more difficult. The preservation of funds held in the debtor's account should have the effect of preventing not only the debtor himself, but also persons authorised by him to make payments through that account, for example by way of a standing order or through direct debit or the use of a credit card, from using the funds.
- (8) The scope of this Regulation should cover all civil and commercial matters apart from certain well-defined matters. In particular, this Regulation should not apply to claims against a debtor in insolvency proceedings. This should mean that no Preservation Order can be issued against the debtor once insolvency proceedings as defined in Council Regulation (EC) No 1346/2000 ⁽¹⁾ have been opened in relation to him. On the other hand, the exclusion should allow the Preservation Order to be used to secure the recovery of detrimental payments made by such a debtor to third parties.
- (9) This Regulation should apply to accounts held with credit institutions whose business is to take deposits or other repayable funds from the public and to grant credits for their own account.

It should thus not apply to financial institutions which do not take such deposits, for instance institutions providing financing for export and investment projects or projects in developing countries or institutions providing financial market services. Furthermore, this Regulation should not apply to accounts held by or with central banks when acting in their capacity as monetary authorities, nor to accounts that cannot be preserved by national orders equivalent to a Preservation Order or which are otherwise immune from seizure under the law of the Member State where the account in question is maintained.

- (10) This Regulation should apply to cross-border cases only and should define what constitutes a cross-border case in this particular context. For the purposes of this Regulation, a cross-border case should be considered to exist when the court dealing with the application for the Preservation Order is located in one Member State and the bank account concerned by the Order is maintained in another Member State. A cross-border case should also be considered to exist when the creditor is domiciled in one Member State and the court and the bank account to be preserved are located in another Member State.

This Regulation should not apply to the preservation of accounts maintained in the Member State of the court seized of the application for the Preservation Order if the creditor's domicile is also in that Member State, even if the creditor applies at the same time for a Preservation Order which concerns an account or accounts maintained in another Member State. In such a case, the creditor should make two separate applications, one for a Preservation Order and one for a national measure.

- (11) The procedure for a Preservation Order should be available to a creditor wishing to secure the enforcement of a later judgment on the substance of the matter prior to initiating proceedings on the substance of the matter and at any stage during such proceedings. It should also be available to a creditor who has already obtained a judgment, court settlement or authentic instrument requiring the debtor to pay the creditor's claim.
- (12) The Preservation Order should be available for the purpose of securing claims that have already fallen due. It should also be available for claims that are not yet due as long as such claims arise from a transaction or an event that has already occurred and their amount can be determined, including claims relating to tort, delict or quasi-delict and civil claims for damages or restitution which are based on an act giving rise to criminal proceedings.

⁽¹⁾ Council Regulation (EC) No 1346/2000 of 29 May 2000 on insolvency proceedings (OJ L 160, 30.6.2000, p. 1).

A creditor should be able to request that the Preservation Order be issued in the amount of the principal claim or in a lower amount. The latter may be in his interest, for instance, where he has already obtained some other security for part of his claim.

- (13) In order to ensure a close link between the proceedings for the Preservation Order and the proceedings on the substance of the matter, international jurisdiction to issue the Order should lie with the courts of the Member State whose courts have jurisdiction to rule on the substance of the matter. For the purposes of this Regulation, the notion of proceedings on the substance of the matter should cover any proceedings aimed at obtaining an enforceable title on the underlying claim including, for instance, summary proceedings concerning orders to pay and proceedings such as the French 'procédure de référé'. If the debtor is a consumer domiciled in a Member State, jurisdiction to issue the Order should lie only with the courts of that Member State.
- (14) The conditions for issuing the Preservation Order should strike an appropriate balance between the interest of the creditor in obtaining an Order and the interest of the debtor in preventing abuse of the Order.

Consequently, when the creditor applies for a Preservation Order prior to obtaining a judgment, the court with which the application is lodged should have to be satisfied on the basis of the evidence submitted by the creditor that the creditor is likely to succeed on the substance of his claim against the debtor.

Furthermore, the creditor should be required in all situations, including when he has already obtained a judgment, to demonstrate to the satisfaction of the court that his claim is in urgent need of judicial protection and that, without the Order, the enforcement of the existing or a future judgment may be impeded or made substantially more difficult because there is a real risk that, by the time the creditor is able to have the existing or a future judgment enforced, the debtor may have dissipated, concealed or destroyed his assets or have disposed of them under value, to an unusual extent or through unusual action.

The court should assess the evidence submitted by the creditor to support the existence of such a risk. This could relate, for instance, to the debtor's conduct in respect of the creditor's claim or in a previous dispute between the parties, to the debtor's credit history, to the nature of the debtor's assets and to any recent action taken by the debtor with regard to his assets. In assessing the evidence, the court may consider that withdrawals from accounts and instances of expenditure by the debtor to sustain the normal course of his business or recurrent family expenses are not, in themselves, unusual. The mere non-payment or contesting of the claim or the mere fact that the debtor has more than one creditor should not, in themselves, be considered sufficient evidence to justify the issuing of an Order. Nor should the mere fact that the financial circumstances of the debtor are poor or deteriorating, in itself, constitute a sufficient ground for the issuing of an Order. However, the court may take these factors into account in the overall assessment of the existence of the risk.

- (15) In order to ensure the surprise effect of the Preservation Order, and to ensure that it will be a useful tool for a creditor trying to recover debts from a debtor in cross-border cases, the debtor should not be informed about the creditor's application nor be heard prior to the issue of the Order or notified of the Order prior to its implementation. Where, on the basis of the evidence and information provided by the creditor or, if applicable, by his witness(es), the court is not satisfied that the preservation of the account or accounts in question is justified, it should not issue the Order.
- (16) In situations where the creditor applies for a Preservation Order before initiating proceedings on the substance of the matter before a court, this Regulation should oblige him to initiate such proceedings within a specified period of time and should also oblige him to provide proof of such initiation to the court with which he lodged his application for an Order. Should the creditor fail to comply with this obligation, the Order should be revoked by the court of its own motion or should terminate automatically.
- (17) In view of the absence of a prior hearing of the debtor, this Regulation should provide for specific safeguards in order to prevent abuse of the Order and to protect the debtor's rights.

- (18) One such important safeguard should be the possibility of requiring the creditor to provide security so as to ensure that the debtor can be compensated at a later stage for any damage caused to him by the Preservation Order. Depending on national law, such security could be provided in the form of a security deposit or an alternative assurance, such as a bank guarantee or a mortgage. The court should have discretion in determining the amount of security sufficient to prevent abuse of the Order and to ensure compensation to the debtor and it should be open to the court, in the absence of specific evidence as to the amount of the potential damage, to consider the amount in which the Order is to be issued as a guideline for determining the amount of the security.

In cases where the creditor has not yet obtained a judgment, court settlement or authentic instrument requiring the debtor to pay the creditor's claim, the provision of security should be the rule and the court should dispense with this requirement, or require the provision of security in a lower amount, only exceptionally if it considers that such security is inappropriate, superfluous or disproportionate in the circumstances of the case. Such circumstances could be, for instance, that the creditor has a particularly strong case but does not have sufficient means to provide security, that the claim relates to maintenance or to the payment of wages or that the size of the claim is such that the Order is unlikely to cause any damage to the debtor, for instance a small business debt.

In cases where the creditor has already obtained a judgment, court settlement or authentic instrument, the provision of security should be left to the discretion of the court. The provision of security may, for instance, be appropriate, except in the abovementioned exceptional circumstances, where the judgment the enforcement of which the Preservation Order intends to secure is not yet enforceable or only provisionally enforceable due to a pending appeal.

- (19) Another important element for striking an appropriate balance between the creditor's and the debtor's interests should be a rule on the creditor's liability for any damage caused to the debtor by the Preservation Order. This Regulation should therefore, as a minimum standard, provide for the liability of the creditor where the damage caused to the debtor by the Preservation Order is due to fault on the creditor's part. In this context, the burden of proof should lie with the debtor. As regards the grounds for liability specified in this Regulation, provision should be made for a harmonised rule establishing a rebuttable presumption of fault on the part of the creditor.

Furthermore, the Member States should be able to maintain or introduce in their national law grounds for liability other than those specified in this Regulation. For such other grounds of liability, the Member States should also be able to maintain or introduce other types of liability, such as strict liability.

This Regulation should also lay down a conflict-of-laws rule specifying that the law applicable to the creditor's liability should be the law of the Member State of enforcement. Where there are several Member States of enforcement, the law applicable should be the law of the Member State of enforcement in which the debtor is habitually resident. In a case in which the debtor is not habitually resident in any of the Member States of enforcement, the law applicable should be the law of the Member State of enforcement with which the case has the closest connection. In determining the closest connection, the size of the amount preserved in the different Member States of enforcement could be one of the factors to be taken into account by the court.

- (20) In order to overcome existing practical difficulties in obtaining information about the whereabouts of the debtor's bank account in a cross-border context, this Regulation should set out a mechanism allowing the creditor to request that the information needed to identify the debtor's account be obtained by the court, before a Preservation Order is issued, from the designated information authority of the Member State in which the creditor believes that the debtor holds an account. Given the particular nature of such an intervention by public authorities and of such access to private data, access to account information should, as a rule, be given only in cases where the creditor has already obtained an enforceable judgment, court settlement or authentic instrument. However, by way of exception, it should be possible for the creditor to make a request for account information even though his judgment, court settlement or authentic instrument is not yet enforceable. Such a request should be possible where the amount to be preserved is substantial taking into account the relevant circumstances and the court is satisfied, on the basis of the evidence submitted by the creditor, that there is an urgent need for such account information because there is a risk that, without it, the subsequent enforcement of the creditor's claim against the debtor is likely to be jeopardised and that this could consequently lead to a substantial deterioration of the creditor's financial situation.

To allow that mechanism to work, the Member States should make available in their national law one or more methods for obtaining such information which are effective and efficient and which are not disproportionately costly or time-consuming. The mechanism should apply only if all the conditions and requirements for issuing the Preservation Order are met and the creditor has duly substantiated in his request why there are reasons to believe that the debtor holds one or more accounts in a specific Member State, for instance because the debtor works or exercises a professional activity in that Member State or has property there.

- (21) In order to ensure protection of the personal data of the debtor, the information obtained regarding the identification of the debtor's bank account or accounts should not be provided to the creditor. It should be provided only to the requesting court and, exceptionally, to the debtor's bank if the bank or other entity responsible for enforcing the Order in the Member State of enforcement is not able to identify an account of the debtor on the basis of the information provided in the Order, for instance where there are accounts held with the same bank by several persons having the same name and the same address. Where, in such a case, it is indicated in the Order that the number or numbers of the account(s) to be preserved was or were obtained through a request for information, the bank should request that information from the information authority of the Member State of enforcement and should be able to make such a request in an informal and simple manner.
- (22) This Regulation should grant the creditor the right to appeal against a refusal to issue the Preservation Order. That right should be without prejudice to the possibility for the creditor to make a new application for a Preservation Order on the basis of new facts or new evidence.
- (23) Enforcement structures for preserving bank accounts vary considerably in the Member States. In order to avoid duplication of those structures in the Member States and to respect national procedures to the extent possible, this Regulation should, as regards the enforcement and actual implementation of the Preservation Order, build on the methods and structures in place for the enforcement and implementation of equivalent national orders in the Member State in which the Order is to be enforced.
- (24) In order to ensure swift enforcement, this Regulation should provide for transmission of the Order from the Member State of origin to the competent authority of the Member State of enforcement by any appropriate means which ensure that the content of the documents transmitted is true and faithful and easily legible.
- (25) Upon receiving the Preservation Order, the competent authority of the Member State of enforcement should take the necessary steps to have the Order enforced in accordance with its national law, either by transmitting the Order received to the bank or other entity responsible for enforcing such orders in that Member State or, where national law so provides, by otherwise instructing the bank to implement the Order.
- (26) Depending on the method available under the law of the Member State of enforcement for equivalent national orders, the Preservation Order should be implemented by blocking the preserved amount in the debtor's account or, where national law so provides, by transferring that amount to an account dedicated for preservation purposes, which could be an account held by either the competent enforcement authority, the court, the bank with which the debtor holds his account or a bank designated as coordinating entity for the preservation in a given case.
- (27) This Regulation should not prevent the payment of fees for the enforcement of the Preservation Order from being requested in advance. This issue should be left to the national law of the Member State in which the Order is to be enforced.
- (28) A Preservation Order should have the same rank, if any, as an equivalent national order in the Member State of enforcement. If, under national law, certain enforcement measures have priority over preservation measures, the same priority should be given to them in relation to Preservation Orders under this Regulation. For the purposes of this Regulation, the in personam orders which exist in some national legal systems should be considered to be equivalent national orders.

- (29) This Regulation should provide for the imposition on the bank or other entity responsible for enforcing the Preservation Order in the Member State of enforcement of an obligation to declare whether and, if so, to what extent the Order has led to the preservation of any funds of the debtor, and of an obligation on the creditor to ensure the release of any funds preserved that exceed the amount specified in the Order.
- (30) This Regulation should safeguard the debtor's right to a fair trial and his right to an effective remedy and should therefore, having regard to the ex parte nature of the proceedings for the issue of the Preservation Order, enable him to contest the Order or its enforcement on the grounds provided for in this Regulation immediately after the implementation of the Order.
- (31) In this context, this Regulation should require that the Preservation Order, all documents submitted by the creditor to the court in the Member State of origin and the necessary translations be served on the debtor promptly after the implementation of the Order. The court should have discretionary powers to append any further documents on which it based its decision and which the debtor might need for his remedy action, such as verbatim transcripts of any oral hearing.
- (32) The debtor should be able to request a review of the Preservation Order, in particular if the conditions or requirements set out in this Regulation were not met or if the circumstances that led to the issuing of the Order have changed in such a way that the issuing of the Order would no longer be founded. For instance, a remedy should be available to the debtor if the case did not constitute a cross-border case as defined in this Regulation, if the jurisdiction rules set out in this Regulation were not respected, if the creditor did not initiate proceedings on the substance of the matter within the period of time provided for in this Regulation and the court did not, as a consequence, revoke the Order of its own motion or the Order did not terminate automatically, if the creditor's claim was not in need of urgent protection in the form of a Preservation Order because there was no risk that the subsequent enforcement of that claim would be impeded or made substantially more difficult, or if the provision of security was not in conformity with the requirements set out in this Regulation.

A remedy should also be available to the debtor if the Order and the declaration on the preservation have not been served on him as provided for in this Regulation or if the documents served on him did not meet the language requirements provided for in this Regulation. However, such a remedy should not be granted if the lack of service or translation is cured within a given period of time. In order to cure the lack of service, the creditor should make a request to the body responsible for service in the Member State of origin to have the relevant documents served by registered post on the debtor or, where the debtor has agreed to collect the documents at the court, should provide the necessary translations of the documents to the court. Such a request should not be required if the lack of service has already been cured by other means, for instance if, in accordance with national law, the court initiated the service of its own motion.

- (33) The question as to who has to provide any translations required under this Regulation and who has to bear the costs for such translations is left to national law.
- (34) Jurisdiction to grant the remedies against the issue of the Preservation Order should lie with the courts of the Member State in which the Order was issued. Jurisdiction to grant the remedies against the enforcement of the Order should lie with the courts or, where applicable, with the competent enforcement authorities in the Member State of enforcement.
- (35) The debtor should have the right to apply for the release of the preserved funds if he provides appropriate alternative security. Such alternative security could be provided in the form of a security deposit or an alternative assurance, such as a bank guarantee or a mortgage.

- (36) This Regulation should ensure that the preservation of the debtor's account does not affect amounts which are exempt from seizure under the law of the Member State of enforcement, for example amounts necessary to ensure the livelihood of the debtor and his family. Depending on the procedural system applicable in that Member State, the relevant amount should either be exempted *ex officio* by the body responsible, which could be the court, the bank or the competent enforcement authority, before the Order is implemented, or be exempted at the request of the debtor after the implementation of the Order. Where accounts in several Member States are preserved and the exemption has been applied more than once, the creditor should be able to apply to the competent court of any of the Member States of enforcement or, where the national law of the Member State of enforcement concerned so provides, to the competent enforcement authority in that Member State, for an adjustment of the exemption applied in that Member State.
- (37) In order to ensure that the Preservation Order is issued and enforced swiftly and without delay, this Regulation should establish time-limits by which the different steps in the procedure must be completed. Courts or authorities involved in the procedure should only be allowed to derogate from those time-limits in exceptional circumstances, for instance in cases which are legally or factually complex.
- (38) For the purposes of calculating the periods and time-limits provided for in this Regulation, Regulation (EEC, Euratom) No 1182/71 of the Council ⁽¹⁾ should apply.
- (39) In order to facilitate the application of this Regulation, provision should be made for an obligation on the Member States to communicate certain information regarding their legislation and procedures relating to Preservation Orders and equivalent national orders to the Commission.
- (40) In order to facilitate the application of this Regulation in practice, standard forms should be established, in particular, for the application for an Order, for the Order itself, for the declaration concerning the preservation of funds and for the application for a remedy or appeal under this Regulation.
- (41) To increase the efficiency of proceedings, this Regulation should allow for the greatest possible use of modern communication technologies accepted under the procedural rules of the Member States concerned, particularly for the purposes of filling in the standard forms provided for in this Regulation and of communication between the authorities involved in the proceedings. Furthermore, the methods for signing the Preservation Order and other documents under this Regulation should be technologically neutral in order to allow for the application of existing methods, such as digital certification or secure authentication, and for future technical developments in this field.
- (42) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with regard to the establishment and subsequent amendment of the standard forms provided for in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽²⁾.
- (43) The advisory procedure should be used for the adoption of implementing acts establishing and subsequently amending the standard forms provided for in this Regulation in accordance with Article 4 of Regulation (EU) No 182/2011.
- (44) This Regulation respects the fundamental rights and observes the principles recognised in the Charter of Fundamental Rights of the European Union. In particular, it seeks to ensure respect for private and family life, the protection of personal data, the right to property, and the right to an effective remedy and to a fair trial as established in Articles 7, 8, 17 and 47 thereof respectively.

⁽¹⁾ Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits (OJ L 124, 8.6.1971, p. 1).

⁽²⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (45) In the context of access to personal data and the use and transmission of such data under this Regulation, the requirements of Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾, as transposed into the national law of the Member States, should be complied with.
- (46) For the purposes of the application of this Regulation, it is however necessary to lay down certain specific conditions for access to personal data and for the use and transmission of such data. In this context, the opinion of the European Data Protection Supervisor ⁽²⁾ has been taken into account. Notification of the data subject should take place in accordance with national law. However, the notification of the debtor about the disclosure of information relating to his account or accounts should be deferred for 30 days, in order to prevent an early notification from jeopardising the effect of the Preservation Order.
- (47) Since the objective of this Regulation, namely to establish a Union procedure for a protective measure which enables a creditor to obtain a Preservation Order preventing the subsequent enforcement of the creditor's claim from being jeopardised through the transfer or withdrawal of funds held by the debtor in a bank account within the Union, cannot be sufficiently achieved by the Member States but can rather, 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 (TEU). 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.
- (48) This Regulation should apply only to those Member States which are bound by it in accordance with the Treaties. The procedure for obtaining a Preservation Order provided for in this Regulation should therefore be available only to creditors who are domiciled in a Member State bound by this Regulation and Orders issued under this Regulation should relate only to the preservation of bank accounts which are maintained in such a Member State.
- (49) In accordance with Article 3 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the TEU and to the TFEU, Ireland has notified its wish to take part in the adoption and application of this Regulation.
- (50) In accordance with Articles 1 and 2 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the TEU and to the TFEU, and without prejudice to Article 4 of that Protocol, the United Kingdom is not taking part in the adoption of this Regulation and is not bound by it or subject to its application.
- (51) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the TEU and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application,

HAVE ADOPTED THIS REGULATION:

CHAPTER 1

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

1. This Regulation establishes a Union procedure enabling a creditor to obtain a European Account Preservation Order ('Preservation Order' or 'Order') which prevents the subsequent enforcement of the creditor's claim from being jeopardised through the transfer or withdrawal of funds up to the amount specified in the Order which are held by the debtor or on his behalf in a bank account maintained in a Member State.

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

⁽²⁾ OJ C 373, 21.12.2011, p. 4.

2. The Preservation Order shall be available to the creditor as an alternative to preservation measures under national law.

Article 2

Scope

1. This Regulation applies to pecuniary claims in civil and commercial matters in cross-border cases as defined in Article 3, whatever the nature of the court or tribunal concerned (the 'court'). It does not extend, in particular, to revenue, customs or administrative matters or to the liability of the State for acts and omissions in the exercise of State authority (*acta iure imperii*).

2. This Regulation does not apply to:

- (a) rights in property arising out of a matrimonial relationship or out of a relationship deemed by the law applicable to such relationship to have comparable effects to marriage;
- (b) wills and succession, including maintenance obligations arising by reason of death;
- (c) claims against a debtor in relation to whom bankruptcy proceedings, proceedings for the winding-up of insolvent companies or other legal persons, judicial arrangements, compositions, or analogous proceedings have been opened;
- (d) social security;
- (e) arbitration.

3. This Regulation does not apply to bank accounts which are immune from seizure under the law of the Member State in which the account is maintained nor to accounts maintained in connection with the operation of any system as defined in point (a) of Article 2 of Directive 98/26/EC of the European Parliament and of the Council ⁽¹⁾.

4. This Regulation does not apply to bank accounts held by or with central banks when acting in their capacity as monetary authorities.

Article 3

Cross-border cases

1. For the purposes of this Regulation, a cross-border case is one in which the bank account or accounts to be preserved by the Preservation Order are maintained in a Member State other than:

- (a) the Member State of the court seised of the application for the Preservation Order pursuant to Article 6; or
- (b) the Member State in which the creditor is domiciled.

2. The relevant moment for determining whether a case is a cross-border case is the date on which the application for the Preservation Order is lodged with the court having jurisdiction to issue the Preservation Order.

⁽¹⁾ Directive 98/26/EC of the European Parliament and of the Council of 19 May 1998 on settlement finality in payment and securities settlement systems (OJ L 166, 11.6.1998, p. 45).

*Article 4***Definitions**

For the purposes of this Regulation:

- (1) 'bank account' or 'account' means any account containing funds which is held with a bank in the name of the debtor or in the name of a third party on behalf of the debtor;
- (2) 'bank' means a credit institution as defined in point (1) of Article 4(1) of Regulation (EU) No 575/2013 of the European Parliament and of the Council ⁽¹⁾, including branches, within the meaning of point (17) of Article 4(1) of that Regulation, of credit institutions having their head offices inside or, in accordance with Article 47 of Directive 2013/36/EU of the European Parliament and of the Council ⁽²⁾, outside the Union where such branches are located in the Union;
- (3) 'funds' means money credited to an account in any currency, or similar claims for the repayment of money, such as money market deposits;
- (4) 'Member State in which the bank account is maintained' means:
 - (a) the Member State indicated in the account's IBAN (International Bank Account Number); or
 - (b) for a bank account which does not have an IBAN, the Member State in which the bank with which the account is held has its head office or, where the account is held with a branch, the Member State in which the branch is located;
- (5) 'claim' means a claim for payment of a specific amount of money that has fallen due or a claim for payment of a determinable amount of money arising from a transaction or an event that has already occurred, provided that such a claim can be brought before a court;
- (6) 'creditor' means a natural person domiciled in a Member State or a legal person domiciled in a Member State or any other entity domiciled in a Member State having legal capacity to sue or be sued under the law of a Member State, who or which applies for, or has already obtained, a Preservation Order relating to a claim;
- (7) 'debtor' means a natural person or a legal person or any other entity having legal capacity to sue or be sued under the law of a Member State, against whom or which the creditor seeks to obtain, or has already obtained, a Preservation Order relating to a claim;
- (8) 'judgment' means any judgment given by a court of a Member State, whatever the judgment may be called, including a decision on the determination of costs or expenses by an officer of the court;
- (9) 'court settlement' means a settlement which has been approved by a court of a Member State or concluded before a court of a Member State in the course of proceedings;

⁽¹⁾ Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

⁽²⁾ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

- (10) 'authentic instrument' means a document which has been formally drawn up or registered as an authentic instrument in a Member State and the authenticity of which:
- (a) relates to the signature and the content of the instrument; and
 - (b) has been established by a public authority or other authority empowered for that purpose;
- (11) 'Member State of origin' means the Member State in which the Preservation Order was issued;
- (12) 'Member State of enforcement' means the Member State in which the bank account to be preserved is maintained;
- (13) 'information authority' means the authority which a Member State has designated as competent for the purposes of obtaining the necessary information on the debtor's account or accounts pursuant to Article 14;
- (14) 'competent authority' means the authority or authorities which a Member State has designated as competent for receipt, transmission or service pursuant to Article 10(2), Article 23(3), (5) and (6), Articles 25(3), 27(2) and 28(3) and the second subparagraph of Article 36(5);
- (15) 'domicile' means domicile as determined in accordance with Articles 62 and 63 of Regulation (EU) No 1215/2012 of the European Parliament and of the Council ⁽¹⁾.

CHAPTER 2

PROCEDURE FOR OBTAINING A PRESERVATION ORDER

Article 5

Availability

The Preservation Order shall be available to the creditor in the following situations:

- (a) before the creditor initiates proceedings in a Member State against the debtor on the substance of the matter, or at any stage during such proceedings up until the issuing of the judgment or the approval or conclusion of a court settlement;
- (b) after the creditor has obtained in a Member State a judgment, court settlement or authentic instrument which requires the debtor to pay the creditor's claim.

Article 6

Jurisdiction

1. Where the creditor has not yet obtained a judgment, court settlement or authentic instrument, jurisdiction to issue a Preservation Order shall lie with the courts of the Member State which have jurisdiction to rule on the substance of the matter in accordance with the relevant rules of jurisdiction applicable.
2. Notwithstanding paragraph 1, where the debtor is a consumer who has concluded a contract with the creditor for a purpose which can be regarded as being outside the debtor's trade or profession, jurisdiction to issue a Preservation Order intended to secure a claim relating to that contract shall lie only with the courts of the Member State in which the debtor is domiciled.

⁽¹⁾ Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 351, 20.12.2012, p. 1).

3. Where the creditor has already obtained a judgment or court settlement, jurisdiction to issue a Preservation Order for the claim specified in the judgment or court settlement shall lie with the courts of the Member State in which the judgment was issued or the court settlement was approved or concluded.

4. Where the creditor has obtained an authentic instrument, jurisdiction to issue a Preservation Order for the claim specified in that instrument shall lie with the courts designated for that purpose in the Member State in which that instrument was drawn up.

Article 7

Conditions for issuing a Preservation Order

1. The court shall issue the Preservation Order when the creditor has submitted sufficient evidence to satisfy the court that there is an urgent need for a protective measure in the form of a Preservation Order because there is a real risk that, without such a measure, the subsequent enforcement of the creditor's claim against the debtor will be impeded or made substantially more difficult.

2. Where the creditor has not yet obtained in a Member State a judgment, court settlement or authentic instrument requiring the debtor to pay the creditor's claim, the creditor shall also submit sufficient evidence to satisfy the court that he is likely to succeed on the substance of his claim against the debtor.

Article 8

Application for a Preservation Order

1. Applications for a Preservation Order shall be lodged using the form established in accordance with the advisory procedure referred to in Article 52(2).

2. The application shall include the following information:

(a) the name and address of the court with which the application is lodged;

(b) details concerning the creditor: name and contact details and, where applicable, name and contact details of the creditor's representative, and:

(i) where the creditor is a natural person, his date of birth and, if applicable and available, his identification or passport number; or

(ii) where the creditor is a legal person or any other entity having legal capacity to sue or be sued under the law of a Member State, the State of its incorporation, formation or registration and its identification or registration number or, where no such number exists, the date and place of its incorporation, formation or registration;

(c) details concerning the debtor: name and contact details and, where applicable, name and contact details of the debtor's representative and, if available:

(i) where the debtor is a natural person, his date of birth and identification or passport number; or

(ii) where the debtor is a legal person or any other entity having legal capacity to sue or be sued under the law of a Member State, the State of its incorporation, formation or registration and its identification or registration number or, where no such number exists, the date and place of its incorporation, formation or registration;

(d) a number enabling the identification of the bank, such as the IBAN or BIC and/or the name and address of the bank, with which the debtor holds one or more accounts to be preserved;

- (e) if available, the number of the account or accounts to be preserved and, in such a case, an indication as to whether any other accounts held by the debtor with the same bank should be preserved;
- (f) where none of the information required under point (d) can be provided, a statement that a request is made for the obtaining of account information pursuant to Article 14, where such a request is possible, and a substantiation as to why the creditor believes that the debtor holds one or more accounts with a bank in a specific Member State;
- (g) the amount for which the Preservation Order is sought:
 - (i) where the creditor has not yet obtained a judgment, court settlement or authentic instrument, the amount of the principal claim or part thereof and of any interest recoverable pursuant to Article 15;
 - (ii) where the creditor has already obtained a judgment, court settlement or authentic instrument, the amount of the principal claim as specified in the judgment, court settlement or authentic instrument or part thereof and of any interest and costs recoverable pursuant to Article 15;
- (h) where the creditor has not yet obtained a judgment, court settlement or authentic instrument:
 - (i) a description of all relevant elements supporting the jurisdiction of the court with which the application for the Preservation Order is lodged;
 - (ii) a description of all relevant circumstances invoked as the basis of the claim, and, where applicable, of the interest claimed;
 - (iii) a statement indicating whether the creditor has already initiated proceedings against the debtor on the substance of the matter;
- (i) where the creditor has already obtained a judgment, court settlement or authentic instrument, a declaration that the judgment, court settlement or authentic instrument has not yet been complied with or, where it has been complied with in part, an indication of the extent of non-compliance;
- (j) a description of all relevant circumstances justifying the issuing of the Preservation Order as required by Article 7(1);
- (k) where applicable, an indication of the reasons why the creditor believes he should be exempted from providing security pursuant to Article 12;
- (l) a list of the evidence provided by the creditor;
- (m) a declaration as provided for in Article 16 as to whether the creditor has lodged with other courts or authorities an application for an equivalent national order or whether such an order has already been obtained or refused and, if obtained, the extent to which it has been implemented;
- (n) an optional indication of the creditor's bank account to be used for any voluntary payment of the claim by the debtor;
- (o) a declaration that the information provided by the creditor in the application is true and complete to the best of his knowledge and that the creditor is aware that any deliberately false or incomplete statements may lead to legal consequences under the law of the Member State in which the application is lodged or to liability pursuant to Article 13.

3. The application shall be accompanied by all relevant supporting documents and, where the creditor has already obtained a judgment, court settlement or authentic instrument, by a copy of the judgment, court settlement or authentic instrument which satisfies the conditions necessary to establish its authenticity.
4. The application and supporting documents may be submitted by any means of communication, including electronic, which are accepted under the procedural rules of the Member State in which the application is lodged.

Article 9

Taking of evidence

1. The court shall take its decision by means of a written procedure on the basis of the information and evidence provided by the creditor in or with his application. If the court considers that the evidence provided is insufficient, it may, where national law so allows, request the creditor to provide additional documentary evidence.
2. Notwithstanding paragraph 1 and subject to Article 11, the court may, provided that this does not delay the proceedings unduly, also use any other appropriate method of taking evidence available under its national law, such as an oral hearing of the creditor or of his witness(es) including through videoconference or other communication technology.

Article 10

Initiation of proceedings on the substance of the matter

1. Where the creditor has applied for a Preservation Order before initiating proceedings on the substance of the matter, he shall initiate such proceedings and provide proof of such initiation to the court with which the application for the Preservation Order was lodged within 30 days of the date on which he lodged the application or within 14 days of the date of the issue of the Order, whichever date is the later. The court may also, at the request of the debtor, extend that time period, for example in order to allow the parties to settle the claim, and shall inform the two parties accordingly.
2. If the court has not received proof of the initiation of proceedings within the time period referred to in paragraph 1, the Preservation Order shall be revoked or shall terminate and the parties shall be informed accordingly.

Where the court that issued the Order is located in the Member State of enforcement, the revocation or termination of the Order in that Member State shall be done in accordance with the law of that Member State.

Where the revocation or termination needs to be implemented in a Member State other than the Member State of origin, the court shall revoke the Preservation Order by using the revocation form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2), and shall transmit the revocation form in accordance with Article 29 to the competent authority of the Member State of enforcement. That authority shall take the necessary steps by applying Article 23 as appropriate to have the revocation or termination implemented.

3. For the purposes of paragraph 1, proceedings on the substance of the matter shall be deemed to have been initiated:
 - (a) at the time when the document instituting the proceedings or an equivalent document is lodged with the court, provided that the creditor has not subsequently failed to take the steps he was required to take to have service effected on the debtor; or
 - (b) if the document has to be served before being lodged with the court, at the time when it is received by the authority responsible for service, provided that the creditor has not subsequently failed to take the steps he was required to take to have the document lodged with the court.

The authority responsible for service referred to in point (b) of the first subparagraph shall be the first authority receiving the documents to be served.

*Article 11***Ex parte procedure**

The debtor shall not be notified of the application for a Preservation Order or be heard prior to the issuing of the Order.

*Article 12***Security to be provided by the creditor**

1. Before issuing a Preservation Order in a case where the creditor has not yet obtained a judgment, court settlement or authentic instrument, the court shall require the creditor to provide security for an amount sufficient to prevent abuse of the procedure provided for by this Regulation and to ensure compensation for any damage suffered by the debtor as a result of the Order to the extent that the creditor is liable for such damage pursuant to Article 13.

By way of exception, the court may dispense with the requirement set out in the first subparagraph if it considers that the provision of security referred to in that subparagraph is inappropriate in the circumstances of the case.

2. Where the creditor has already obtained a judgment, court settlement or authentic instrument, the court may, before issuing the Order, require the creditor to provide security as referred to in the first subparagraph of paragraph 1 if it considers this necessary and appropriate in the circumstances of the case.

3. If the court requires security to be provided pursuant to this Article, it shall inform the creditor of the amount required and of the forms of security acceptable under the law of the Member State in which the court is located. It shall indicate to the creditor that it will issue the Preservation Order once security in accordance with those requirements has been provided.

*Article 13***Liability of the creditor**

1. The creditor shall be liable for any damage caused to the debtor by the Preservation Order due to fault on the creditor's part. The burden of proof shall lie with the debtor.

2. In the following cases, the fault of the creditor shall be presumed unless he proves otherwise:

(a) if the Order is revoked because the creditor has failed to initiate proceedings on the substance of the matter, unless that omission was a consequence of the debtor's payment of the claim or another form for settlement between the parties;

(b) if the creditor has failed to request the release of over-preserved amounts as provided for in Article 27;

(c) if it is subsequently found that the issue of the Order was not appropriate or appropriate only in a lower amount due to a failure on the part of the creditor to comply with his obligations under Article 16; or

(d) if the Order is revoked or its enforcement terminated because the creditor has failed to comply with his obligations under this Regulation with regard to service or translation of documents or with regard to curing the lack of service or the lack of translation.

3. Notwithstanding paragraph 1, Member States may maintain or introduce in their national law other grounds or types of liability or rules on the burden of proof. All other aspects relating to the creditor's liability towards the debtor not specifically addressed in paragraph 1 or 2 shall be governed by national law.

4. The law applicable to the liability of the creditor shall be the law of the Member State of enforcement.

If accounts are preserved in more than one Member State, the law applicable to the liability of the creditor shall be the law of the Member State of enforcement:

- (a) in which the debtor has his habitual residence as defined in Article 23 of Regulation (EC) No 864/2007 of the European Parliament and of the Council ⁽¹⁾, or, failing that,
 - (b) which has the closest connection with the case.
5. This Article does not deal with the question of possible liability of the creditor towards the bank or any third party.

Article 14

Request for the obtaining of account information

1. Where the creditor has obtained in a Member State an enforceable judgment, court settlement or authentic instrument which requires the debtor to pay the creditor's claim and the creditor has reasons to believe that the debtor holds one or more accounts with a bank in a specific Member State, but knows neither the name and/or address of the bank nor the IBAN, BIC or another bank number allowing the bank to be identified, he may request the court with which the application for the Preservation Order is lodged to request that the information authority of the Member State of enforcement obtain the information necessary to allow the bank or banks and the debtor's account or accounts to be identified.

Notwithstanding the first subparagraph, the creditor may make the request referred to in that subparagraph where the judgment, court settlement or authentic instrument obtained by the creditor is not yet enforceable and the amount to be preserved is substantial taking into account the relevant circumstances, and the creditor has submitted sufficient evidence to satisfy the court that there is an urgent need for account information because there is a risk that, without such information, the subsequent enforcement of the creditor's claim against the debtor is likely to be jeopardised and that this could consequently lead to a substantial deterioration of the creditor's financial situation.

2. The creditor shall make the request referred to in paragraph 1 in the application for the Preservation Order. The creditor shall substantiate why he believes that the debtor holds one or more accounts with a bank in the specific Member State and shall provide all relevant information available to him about the debtor and the account or accounts to be preserved. If the court with which the application for a Preservation Order is lodged considers that the creditor's request is not sufficiently substantiated, it shall reject it.

3. When the court is satisfied that the creditor's request is well substantiated and that all the conditions and requirements for issuing the Preservation Order are met, except for the information requirement set out in point (d) of Article 8(2) and, where applicable, the security requirement pursuant to Article 12, the court shall transmit the request for information to the information authority of the Member State of enforcement in accordance with Article 29.

4. To obtain the information referred to in paragraph 1, the information authority in the Member State of enforcement shall use one of the methods available in that Member State pursuant to paragraph 5.

5. Each Member State shall make available in its national law at least one of the following methods of obtaining the information referred to in paragraph 1:

- (a) an obligation on all banks in its territory to disclose, upon request by the information authority, whether the debtor holds an account with them;

⁽¹⁾ 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) (OJ L 199, 31.7.2007, p. 40).

- (b) access for the information authority to the relevant information where that information is held by public authorities or administrations in registers or otherwise;
- (c) the possibility for its courts to oblige the debtor to disclose with which bank or banks in its territory he holds one or more accounts where such an obligation is accompanied by an in personam order by the court prohibiting the withdrawal or transfer by him of funds held in his account or accounts up to the amount to be preserved by the Preservation Order; or
- (d) any other methods which are effective and efficient for the purposes of obtaining the relevant information, provided that they are not disproportionately costly or time-consuming.

Irrespective of the method or methods made available by a Member State, all authorities involved in obtaining the information shall act expeditiously.

6. As soon as the information authority of the Member State of enforcement has obtained the account information, it shall transmit it to the requesting court in accordance with Article 29.

7. If the information authority is unable to obtain the information referred to in paragraph 1, it shall inform the requesting court accordingly. Where, as a result of the unavailability of account information, the application for a Preservation Order is rejected in full, the requesting court shall without delay release any security that the creditor may have provided pursuant to Article 12.

8. Where under this Article the information authority is provided with information by a bank or is granted access to account information held by public authorities or administrations in registers, the notification of the debtor of the disclosure of his personal data shall be deferred for 30 days, in order to prevent an early notification from jeopardising the effect of the Preservation Order.

Article 15

Interest and costs

1. At the request of the creditor, the Preservation Order shall include any interest accrued under the law applicable to the claim up to the date when the Order is issued, provided that the amount or type of interest is not such that its inclusion constitutes a violation of overriding mandatory provisions in the law of the Member State of origin.

2. Where the creditor has already obtained a judgment, court settlement or authentic instrument, the Preservation Order shall, at the request of the creditor, also include the costs of obtaining such judgment, settlement or instrument, to the extent that a determination has been made that those costs must be borne by the debtor.

Article 16

Parallel applications

1. The creditor may not submit to several courts at the same time parallel applications for a Preservation Order against the same debtor aimed at securing the same claim.

2. In his application for a Preservation Order, the creditor shall declare whether he has lodged with any other court or authority an application for an equivalent national order against the same debtor and aimed at securing the same claim or has already obtained such an order. He shall also indicate any applications for such an order which have been rejected as inadmissible or unfounded.

3. If the creditor obtains an equivalent national order against the same debtor and aimed at securing the same claim during the proceedings for the issuing of a Preservation Order, he shall without delay inform the court thereof and of any subsequent implementation of the national order granted. He shall also inform the court of any applications for an equivalent national order which have been rejected as inadmissible or unfounded.

4. Where the court is informed that the creditor has already obtained an equivalent national order, it shall consider, having regard to all the circumstances of the case, whether it is still appropriate to issue the Preservation Order, in full or in part.

Article 17

Decision on the application for the Preservation Order

1. The court seized of an application for a Preservation Order shall examine whether the conditions and requirements set out in this Regulation are met.

2. The court shall decide on the application without delay, but no later than by the expiry of the time-limits set out in Article 18.

3. Where the creditor has not provided all the information required by Article 8, the court may, unless the application is clearly inadmissible or unfounded, give the creditor the opportunity to complete or rectify the application within a period of time to be specified by the court. If the creditor fails to complete or rectify the application within that period, the application shall be rejected.

4. The Preservation Order shall be issued in the amount justified by the evidence referred to in Article 9 and as determined by the law applicable to the underlying claim, and shall include, where appropriate, interest and/or costs pursuant to Article 15.

The Order may not under any circumstances be issued in an amount exceeding the amount indicated by the creditor in his application.

5. The decision on the application shall be brought to the notice of the creditor in accordance with the procedure provided for by the law of the Member State of origin for equivalent national orders.

Article 18

Time-limits for the decision on the application for a Preservation Order

1. Where the creditor has not yet obtained a judgment, court settlement or authentic instrument, the court shall issue its decision by the end of the tenth working day after the creditor lodged or, where applicable, completed his application.

2. Where the creditor has already obtained a judgment, court settlement or authentic instrument, the court shall issue its decision by the end of the fifth working day after the creditor lodged or, where applicable, completed his application.

3. Where the court determines pursuant to Article 9(2) that an oral hearing of the creditor and, as the case may be, his witness(es) is necessary, the court shall hold the hearing without delay and shall issue its decision by the end of the fifth working day after the hearing has taken place.

4. In the situations referred to in Article 12, the time-limits set out in paragraphs 1, 2 and 3 of this Article shall apply to the decision requiring the creditor to provide security. The court shall issue its decision on the application for a Preservation Order without delay once the creditor has provided the security required.

5. Notwithstanding paragraphs 1, 2 and 3 of this Article, in situations referred to in Article 14, the court shall issue its decision without delay once it has received the information referred to in Article 14(6) or (7), provided that any security required has been provided by the creditor by that time.

Article 19

Form and content of the Preservation Order

1. The Preservation Order shall be issued using the form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2) and shall bear a stamp, a signature and/or any other authentication of the court. The form shall consist of two parts:

- (a) part A, containing the information set out in paragraph 2 to be provided to the bank, the creditor and the debtor; and
- (b) part B, containing the information set out in paragraph 3 to be provided to the creditor and the debtor in addition to the information pursuant to paragraph 2.

2. Part A shall include the following information:

- (a) the name and address of the court and the file number of the case;
- (b) details of the creditor as indicated in point (b) of Article 8(2);
- (c) details of the debtor as indicated in point (c) of Article 8(2);
- (d) the name and address of the bank concerned by the Order;
- (e) if the creditor has provided the account number of the debtor in the application, the number of the account or accounts to be preserved, and, where applicable, an indication as to whether any other accounts held by the debtor with the same bank also have to be preserved;
- (f) where applicable, an indication that the number of any account to be preserved was obtained by means of a request pursuant to Article 14 and that the bank, where necessary pursuant to the second subparagraph of Article 24(4), is to obtain the number or numbers concerned from the information authority of the Member State of enforcement;
- (g) the amount to be preserved by the Order;
- (h) an instruction to the bank to implement the Order in accordance with Article 24;
- (i) the date of issue of the Order;
- (j) if the creditor has indicated an account in his application pursuant to point (n) of Article 8(2), an authorisation to the bank pursuant to Article 24(3) to release and transfer, if so requested by the debtor and if allowed by the law of the Member State of enforcement, funds up to the amount specified in the Order from the preserved account to the account that the creditor has indicated in his application;
- (k) information on where to find the electronic version of the form to be used for the declaration pursuant to Article 25.

3. Part B shall include the following information:
 - (a) a description of the subject matter of the case and the court's reasoning for issuing the Order;
 - (b) the amount of the security provided by the creditor, if any;
 - (c) where applicable, the time-limit for initiating the proceedings on the substance of the matter and for proving such initiation to the issuing court;
 - (d) where applicable, an indication as to which documents must be translated pursuant to the second sentence of Article 49(1);
 - (e) where applicable, an indication that the creditor is responsible for initiating the enforcement of the Order and consequently, where applicable, an indication that the creditor is responsible for transmitting it to the competent authority of the Member State of enforcement pursuant to Article 23(3) and for initiating service on the debtor pursuant to Article 28(2), (3) and (4); and
 - (f) information about the remedies available to the debtor.
4. Where the Preservation Order concerns accounts in different banks, a separate form (part A pursuant to paragraph 2) shall be filled in for each bank. In such a case, the form provided to the creditor and the debtor (parts A and B pursuant to paragraphs 2 and 3 respectively) shall contain a list of all banks concerned.

Article 20

Duration of the preservation

The funds preserved by the Preservation Order shall remain preserved as provided for in the Order or in any subsequent modification or limitation of that Order pursuant to Chapter 4:

- (a) until the Order is revoked;
- (b) until the enforcement of the Order is terminated; or
- (c) until a measure to enforce a judgment, court settlement or authentic instrument obtained by the creditor relating to the claim which the Preservation Order was aimed at securing has taken effect with respect to the funds preserved by the Order.

Article 21

Appeal against a refusal to issue the Preservation Order

1. The creditor shall have the right to appeal against any decision of the court rejecting, wholly or in part, his application for a Preservation Order.
2. Such an appeal shall be lodged within 30 days of the date on which the decision referred to in paragraph 1 was brought to the notice of the creditor. It shall be lodged with the court which the Member State concerned has communicated to the Commission pursuant to point (d) of Article 50(1).
3. Where the application for the Preservation Order was rejected in whole, the appeal shall be dealt with in *ex parte* proceedings as provided for in Article 11.

CHAPTER 3

RECOGNITION, ENFORCEABILITY AND ENFORCEMENT OF THE PRESERVATION ORDER*Article 22***Recognition and enforceability**

A Preservation Order issued in a Member State in accordance with this Regulation shall be recognised in the other Member States without any special procedure being required and shall be enforceable in the other Member States without the need for a declaration of enforceability.

*Article 23***Enforcement of the Preservation Order**

1. Subject to the provisions of this Chapter, the Preservation Order shall be enforced in accordance with the procedures applicable to the enforcement of equivalent national orders in the Member State of enforcement.
2. All authorities involved in the enforcement of the Order shall act without delay.
3. Where the Preservation Order was issued in a Member State other than the Member State of enforcement, part A of the Order as indicated in Article 19(2) and a blank standard form for the declaration pursuant to Article 25 shall, for the purposes of paragraph 1 of this Article, be transmitted in accordance with Article 29 to the competent authority of the Member State of enforcement.

The transmission shall be done by the issuing court or the creditor, depending on who is responsible under the law of the Member State of origin for initiating the enforcement procedure.

4. The Order shall be accompanied, where necessary, by a translation or transliteration into the official language of the Member State of enforcement or, where there are several official languages in that Member State, the official language or one of the official languages of the place where the Order is to be implemented. Such translation or transliteration shall be provided by the issuing court by making use of the appropriate language version of the standard form referred to in Article 19.
5. The competent authority of the Member State of enforcement shall take the necessary steps to have the Order enforced in accordance with its national law.
6. Where the Preservation Order concerns more than one bank in the same Member State or in different Member States, a separate form for each bank as indicated in Article 19(4) shall be transmitted to the competent authority in the relevant Member State of enforcement.

*Article 24***Implementation of the Preservation Order**

1. A bank to which a Preservation Order is addressed shall implement it without delay following receipt of the Order or, where the law of the Member State of enforcement so provides, of a corresponding instruction to implement the Order.
2. To implement the Preservation Order, the bank shall, subject to the provisions of Article 31, preserve the amount specified in the Order either:
 - (a) by ensuring that that amount is not transferred or withdrawn from the account or accounts indicated in the Order or identified pursuant to paragraph 4; or
 - (b) where national law so provides, by transferring that amount to an account dedicated for preservation purposes.

The final amount preserved may be subject to the settlement of transactions which are already pending at the moment when the Order or a corresponding instruction is received by the bank. However, such pending transactions may only be taken into account when they are settled before the bank issues the declaration pursuant to Article 25 by the time-limits set out in Article 25(1).

3. Notwithstanding point (a) of paragraph 2, the bank shall be authorised, at the request of the debtor, to release funds preserved and to transfer those funds to the account of the creditor indicated in the Order for the purposes of paying the creditor's claim, if all the following conditions are met:

- (a) such authorisation of the bank is specifically indicated in the Order in accordance with point (j) of Article 19(2);
- (b) the law of the Member State of enforcement allows for such release and transfer; and
- (c) there are no competing Orders with regard to the account concerned.

4. Where the Preservation Order does not specify the number or numbers of the account or accounts of the debtor but provides only the name and other details regarding the debtor, the bank or other entity responsible for enforcing the Order shall identify the account or accounts held by the debtor with the bank indicated in the Order.

If, on the basis of the information provided in the Order, it is not possible for the bank or other entity to identify with certainty an account of the debtor, the bank shall:

- (a) where, in accordance with point (f) of Article 19(2), it is indicated in the Order that the number or numbers of the account or accounts to be preserved was or were obtained by means of a request pursuant to Article 14, obtain that number or those numbers from the information authority of the Member State of enforcement; and
- (b) in all other cases, not implement the Order.

5. Any funds held in the account or accounts referred to in point (a) of paragraph 2 which exceed the amount specified in the Preservation Order shall remain unaffected by the implementation of the Order.

6. Where, at the time of the implementation of the Preservation Order, the funds held in the account or accounts referred to in point (a) of paragraph 2 are insufficient to preserve the full amount specified in the Order, the Order shall be implemented only in the amount available in the account or accounts.

7. Where the Preservation Order covers several accounts held by the debtor with the same bank and those accounts contain funds that exceed the amount specified in the Order, the Order shall be implemented in the following order of priority:

- (a) savings accounts in the sole name of the debtor;
- (b) current accounts in the sole name of the debtor;
- (c) savings accounts in joint names, subject to Article 30;
- (d) current accounts in joint names, subject to Article 30.

8. Where the currency of the funds held in the account or accounts referred to in point (a) of paragraph 2 is not the same as that in which the Preservation Order was issued, the bank shall convert the amount specified in the Order into the currency of the funds by reference to the foreign exchange reference rate of the European Central Bank or the exchange rate of the central bank of the Member State of enforcement for sale of that currency on the day and at the time of the implementation of the Order, and shall preserve the corresponding amount in the currency of the funds.

Article 25

Declaration concerning the preservation of funds

1. By the end of the third working day following the implementation of the Preservation Order, the bank or other entity responsible for enforcing the Order in the Member State of enforcement shall issue a declaration using the declaration form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2), indicating whether and to what extent funds in the debtor's account or accounts have been preserved and, if so, on which date the Order was implemented. If, in exceptional circumstances, it is not possible for the bank or other entity to issue the declaration within three working days, it shall issue it as soon as possible but by no later than the end of the eighth working day following the implementation of the Order.

The declaration shall be transmitted, without delay, in accordance with paragraphs 2 and 3.

2. Where the Order was issued in the Member State of enforcement, the bank or other entity responsible for enforcing the Order shall transmit the declaration in accordance with Article 29 to the issuing court and by registered post attested by an acknowledgment of receipt, or by equivalent electronic means, to the creditor.

3. Where the Order was issued in a Member State other than the Member State of enforcement, the declaration shall be transmitted in accordance with Article 29 to the competent authority of the Member State of enforcement, unless it was issued by that same authority.

By the end of the first working day following the receipt or issue of the declaration, that authority shall transmit the declaration in accordance with Article 29 to the issuing court and by registered post attested by an acknowledgment of receipt, or by equivalent electronic means, to the creditor.

4. The bank or other entity responsible for enforcing the Preservation Order shall, upon request by the debtor, disclose to the debtor the details of the Order. The bank or entity may also do so in the absence of such a request.

Article 26

Liability of the bank

Any liability of the bank for failure to comply with its obligations under this Regulation shall be governed by the law of the Member State of enforcement.

Article 27

Duty of the creditor to request the release of over-preserved amounts

1. The creditor shall be under a duty to take the necessary steps to ensure the release of any amount which, following the implementation of the Preservation Order, exceeds the amount specified in the Preservation Order:

(a) where the Order covers several accounts in the same Member State or in different Member States; or

(b) where the Order was issued after the implementation of one or more equivalent national orders against the same debtor and aimed at securing the same claim.

2. By the end of the third working day following receipt of any declaration pursuant to Article 25 showing such over-preservation, the creditor shall, by the swiftest possible means and using the form for requesting the release of over-preserved amounts, established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2), submit a request for the release to the competent authority of the Member State of enforcement in which the over-preservation has occurred.

That authority shall, upon receipt of the request, promptly instruct the bank concerned to effect the release of the over-preserved amounts. Article 24(7) shall apply, as appropriate, in the reverse order of priority.

3. This Article shall not preclude a Member State from providing in its national law that the release of over-preserved funds from any account maintained in its territory is to be initiated by the competent enforcement authority of that Member State of its own motion.

Article 28

Service on the debtor

1. The Preservation Order, the other documents referred to in paragraph 5 of this Article and the declaration pursuant to Article 25 shall be served on the debtor in accordance with this Article.

2. Where the debtor is domiciled in the Member State of origin, service shall be effected in accordance with the law of that Member State. Service shall be initiated by the issuing court or the creditor, depending on who is responsible for initiating service in the Member State of origin, by the end of the third working day following the day of receipt of the declaration pursuant to Article 25 showing that amounts have been preserved.

3. Where the debtor is domiciled in a Member State other than the Member State of origin, the issuing court or the creditor, depending on who is responsible for initiating service in the Member State of origin, shall, by the end of the third working day following the day of receipt of the declaration pursuant to Article 25 showing that amounts have been preserved, transmit the documents referred to in paragraph 1 of this Article in accordance with Article 29 to the competent authority of the Member State in which the debtor is domiciled. That authority shall, without delay, take the necessary steps to have service effected on the debtor in accordance with the law of the Member State in which the debtor is domiciled.

Where the Member State in which the debtor is domiciled is the only Member State of enforcement, the documents referred to in paragraph 5 of this Article shall be transmitted to the competent authority of that Member State at the time of transmission of the Order in accordance with Article 23(3). In such a case, that competent authority shall initiate the service of all documents referred to in paragraph 1 of this Article by the end of the third working day following the day of receipt or issue of the declaration pursuant to Article 25 showing that amounts have been preserved.

The competent authority shall inform the issuing court or the creditor, depending on who transmitted the documents to be served, of the result of the service on the debtor.

4. Where the debtor is domiciled in a third State, service shall be effected in accordance with the rules on international service applicable in the Member State of origin.

5. The following documents shall be served on the debtor and shall, where necessary, be accompanied by a translation or transliteration as provided for in Article 49(1):

(a) the Preservation Order using parts A and B of the form referred to in Article 19(2) and (3);

(b) the application for the Preservation Order submitted by the creditor to the court;

(c) copies of all documents submitted by the creditor to the court in order to obtain the Order.

6. Where the Preservation Order concerns more than one bank, only the first declaration pursuant to Article 25 showing that amounts have been preserved shall be served on the debtor in accordance with this Article. Any subsequent declarations pursuant to Article 25 shall be brought to the notice of the debtor without delay.

Article 29

Transmission of documents

1. Where this Regulation provides for transmission of documents in accordance with this Article, such transmission may be carried out by any appropriate means, provided that the content of the document received is true and faithful to that of the document transmitted and that all information contained in it is easily legible.

2. The court or authority that received documents in accordance with paragraph 1 of this Article shall, by the end of the working day following the day of receipt, send to the authority, creditor or bank that transmitted the documents an acknowledgment of receipt, employing the swiftest possible means of transmission and using the standard form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2).

Article 30

Preservation of joint and nominee accounts

Funds held in accounts which, according to the bank's records, are not exclusively held by the debtor or are held by a third party on behalf of the debtor or by the debtor on behalf of a third party, may be preserved under this Regulation only to the extent to which they may be subject to preservation under the law of the Member State of enforcement.

Article 31

Amounts exempt from preservation

1. Amounts that are exempt from seizure under the law of the Member State of enforcement shall be exempt from preservation under this Regulation.

2. Where, under the law of the Member State of enforcement, the amounts referred to in paragraph 1 are exempted from seizure without any request from the debtor, the body responsible for exempting such amounts in that Member State shall, of its own motion, exempt the relevant amounts from preservation.

3. Where, under the law of the Member State of enforcement, the amounts referred to in paragraph 1 of this Article are exempted from seizure at the request of the debtor, such amounts shall be exempted from preservation upon application by the debtor as provided for by point (a) of Article 34(1).

Article 32

Ranking of the Preservation Order

The Preservation Order shall have the same rank, if any, as an equivalent national order in the Member State of enforcement.

CHAPTER 4

REMEDIES

Article 33

Remedies of the debtor against the Preservation Order

1. Upon application by the debtor to the competent court of the Member State of origin, the Preservation Order shall be revoked or, where applicable, modified on the ground that:

- (a) the conditions or requirements set out in this Regulation were not met;
- (b) the Order, the declaration pursuant to Article 25 and/or the other documents referred to in Article 28(5) were not served on the debtor within 14 days of the preservation of his account or accounts;
- (c) the documents served on the debtor in accordance with Article 28 did not meet the language requirements set out in Article 49(1);
- (d) preserved amounts exceeding the amount of the Order were not released in accordance with Article 27;
- (e) the claim the enforcement of which the creditor was seeking to secure by means of the Order has been paid in full or in part;
- (f) a judgment on the substance of the matter has dismissed the claim the enforcement of which the creditor was seeking to secure by means of the Order; or
- (g) the judgment on the substance of the matter, or the court settlement or authentic instrument, the enforcement of which the creditor was seeking to secure by means of the Order has been set aside or, as the case may be, annulled.

2. Upon application by the debtor to the competent court of the Member State of origin, the decision concerning the security pursuant to Article 12 shall be reviewed on the ground that the conditions or requirements of that Article were not met.

Where, on the basis of such a remedy, the court requires the creditor to provide security or additional security, the first sentence of Article 12(3) shall apply as appropriate and the court shall indicate that the Preservation Order will be revoked or modified if the (additional) security required is not provided by the time-limit specified by the court.

3. The remedy applied for under point (b) of paragraph 1 shall be granted unless the lack of service is cured within 14 days of the creditor being informed of the debtor's application for a remedy pursuant to point (b) of paragraph 1.

Unless the lack of service was already cured by other means, the lack of service shall, for the purposes of assessing whether or not the remedy pursuant to point (b) of paragraph 1 is to be granted, be deemed to be cured:

- (a) if the creditor requests the body responsible for service under the law of the Member State of origin to serve the documents on the debtor; or
- (b) where the debtor has indicated in his application for a remedy that he agrees to collect the documents at the court of the Member State of origin and where the creditor was responsible for providing translations, if the creditor transmits to that court any translations required pursuant to Article 49(1).

The body responsible for service under the law of the Member State of origin shall, at the request of the creditor pursuant to point (a) of the second subparagraph of this paragraph, without delay serve the documents on the debtor by registered post attested by an acknowledgment of receipt at the address indicated by the debtor in accordance with paragraph 5 of this Article.

Where the creditor was responsible for initiating the service of the documents referred to in Article 28, a lack of service may only be cured if the creditor demonstrates that he had taken all the steps he was required to take to have the initial service of the documents effected.

4. The remedy applied for under point (c) of paragraph 1 shall be granted unless the creditor provides to the debtor the translations required pursuant to this Regulation within 14 days of the creditor being informed of the application by the debtor for a remedy pursuant to point (c) of paragraph 1.

The second and third subparagraphs of paragraph 3 shall apply as appropriate.

5. In his application for a remedy under points (b) and (c) of paragraph 1, the debtor shall indicate an address to which the documents and the translations referred to in Article 28 can be sent in accordance with paragraphs 3 and 4 of this Article or, alternatively, shall indicate that he agrees to collect those documents at the court of the Member State of origin.

Article 34

Remedies of the debtor against enforcement of the Preservation Order

1. Notwithstanding Articles 33 and 35, upon application by the debtor to the competent court or, where national law so provides, to the competent enforcement authority in the Member State of enforcement, the enforcement of the Preservation Order in that Member State shall be:

(a) limited on the ground that certain amounts held in the account should be exempt from seizure in accordance with Article 31(3), or that amounts exempt from seizure have not or not correctly been taken into account in the implementation of the Order in accordance with Article 31(2); or

(b) terminated on the ground that:

(i) the account preserved is excluded from the scope of this Regulation pursuant to Article 2(3) and (4);

(ii) enforcement of the judgment, court settlement or authentic instrument which the creditor was seeking to secure by means of the Order has been refused in the Member State of enforcement;

(iii) the enforceability of the judgment the enforcement of which the creditor was seeking to secure by means of the Order has been suspended in the Member State of origin; or

(iv) point (b), (c), (d), (e), (f) or (g) of Article 33(1) applies. Article 33(3), (4) and (5) shall apply as appropriate.

2. Upon application by the debtor to the competent court in the Member State of enforcement, the enforcement of the Preservation Order in that Member State shall be terminated if it is manifestly contrary to the public policy (ordre public) of the Member State of enforcement.

*Article 35***Other remedies available to the debtor and the creditor**

1. The debtor or the creditor may apply to the court that issued the Preservation Order for a modification or a revocation of the Order on the ground that the circumstances on the basis of which the Order was issued have changed.
2. The court that issued the Preservation Order may also, where the law of the Member State of origin so permits, of its own motion modify or revoke the Order due to changed circumstances.
3. The debtor and the creditor may, on the ground that they have agreed to settle the claim, apply jointly to the court that issued the Preservation Order for revocation or modification of the Order or to the competent court of the Member State of enforcement or, where national law so provides, to the competent enforcement authority in that Member State, for termination or limitation of the enforcement of the Order.
4. The creditor may apply to the competent court of the Member State of enforcement or, where national law so provides, to the competent enforcement authority in that Member State, for modification of the enforcement of the Preservation Order, consisting of an adjustment to the exemption applied in that Member State pursuant to Article 31, on the ground that other exemptions have already been applied in a sufficiently high amount in relation to one or several accounts maintained in one or more other Member States and that an adjustment is therefore appropriate.

*Article 36***Procedure for the remedies pursuant to Articles 33, 34 and 35**

1. The application for a remedy pursuant to Article 33, 34 or 35 shall be made using the remedy form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2). The application may be made at any time and may be submitted by any means of communication, including electronic means, which are accepted under the procedural rules of the Member State in which the application is lodged.
2. The application shall be brought to the notice of the other party.
3. Except where the application was submitted by the debtor pursuant to point (a) of Article 34(1) or pursuant to Article 35(3), the decision on the application shall be issued after both parties have been given the opportunity to present their case, including by such appropriate means of communication technology as are available and accepted under the national law of each of the Member States involved.
4. The decision shall be issued without delay, but no later than 21 days after the court or, where national law so provides, the competent enforcement authority has received all the information necessary for its decision. The decision shall be brought to the notice of the parties.
5. The decision revoking or modifying the Preservation Order and the decision limiting or terminating the enforcement of the Preservation Order shall be enforceable immediately.

Where the remedy was applied for in the Member State of origin, the court shall, in accordance with Article 29, transmit the decision on the remedy without delay to the competent authority of the Member State of enforcement, using the form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2). That authority shall, immediately upon receipt, ensure that the decision on the remedy is implemented.

Where the decision on the remedy relates to a bank account maintained in the Member State of origin, it shall be implemented with respect to that bank account in accordance with the law of the Member State of origin.

Where the remedy was applied for in the Member State of enforcement, the decision on the remedy shall be implemented in accordance with the law of the Member State of enforcement.

Article 37

Right to appeal

Either party shall have the right to appeal against a decision issued pursuant to Article 33, 34 or 35. Such an appeal shall be submitted using the appeal form established by means of implementing acts adopted in accordance with the advisory procedure referred to in Article 52(2).

Article 38

Right to provide security in lieu of preservation

1. Upon application by the debtor:

- (a) the court that issued the Preservation Order may order the release of the funds preserved if the debtor provides to that court security in the amount of the Order, or an alternative assurance in a form acceptable under the law of the Member State in which the court is located and of a value at least equivalent to that amount;
- (b) the competent court or, where national law so provides, the competent enforcement authority of the Member State of enforcement may terminate the enforcement of the Preservation Order in the Member State of enforcement if the debtor provides to that court or authority security in the amount preserved in that Member State, or an alternative assurance in a form acceptable under the law of the Member State in which the court is located and of a value at least equivalent to that amount.

2. Articles 23 and 24 shall apply as appropriate to the release of the funds preserved. The provision of the security in lieu of preservation shall be brought to the notice of the creditor in accordance with national law.

Article 39

Right of third parties

1. The right of a third party to contest a Preservation Order shall be governed by the law of the Member State of origin.

2. The right of a third party to contest the enforcement of a Preservation Order shall be governed by the law of the Member State of enforcement.

3. Without prejudice to other rules of jurisdiction laid down in Union law or national law, jurisdiction in respect of any action brought by a third party:

(a) to contest a Preservation Order shall lie with the courts of the Member State of origin, and

(b) to contest the enforcement of the Preservation Order in the Member State of enforcement shall lie with the courts of the Member State of enforcement or, where the national law of that Member State so provides, with the competent enforcement authority.

CHAPTER 5

GENERAL PROVISIONS*Article 40***Legalisation or other similar formality**

No legalisation or other similar formality shall be required in the context of this Regulation.

*Article 41***Legal representation**

Representation by a lawyer or other legal professional shall not be mandatory in proceedings to obtain a Preservation Order. In proceedings pursuant to Chapter 4, representation by a lawyer or another legal professional shall not be mandatory unless, under the law of the Member State of the court or authority with which the application for a remedy is lodged, such representation is mandatory irrespective of the nationality or domicile of the parties.

*Article 42***Court fees**

The court fees in proceedings to obtain a Preservation Order or a remedy against an Order shall not be higher than the fees for obtaining an equivalent national order or a remedy against such a national order.

*Article 43***Costs incurred by the banks**

1. A bank shall be entitled to seek payment or reimbursement from the creditor or the debtor of the costs incurred in implementing a Preservation Order only where, under the law of the Member State of enforcement, the bank is entitled to such payment or reimbursement in relation to equivalent national orders.

2. Fees charged by a bank to cover the costs referred to in paragraph 1 shall be determined taking into account the complexity of the implementation of the Preservation Order, and may not be higher than the fees charged for the implementation of equivalent national orders.

3. Fees charged by a bank to cover the costs of providing account information pursuant to Article 14 may not be higher than the costs actually incurred and, where applicable, not higher than the fees charged for the provision of account information in the context of equivalent national orders.

*Article 44***Fees charged by authorities**

Fees charged by any authority or other body in the Member State of enforcement which is involved in the processing or enforcement of a Preservation Order, or in providing account information pursuant to Article 14, shall be determined on the basis of a scale of fees or other set of rules established in advance by each Member State and transparently setting out the applicable fees. In establishing that scale or other set of rules, a Member State may take into account the amount of the Order and the complexity involved in processing it. Where applicable, the fees may not be higher than the fees charged in connection with equivalent national orders.

*Article 45***Time frames**

Where, in exceptional circumstances, it is not possible for the court or the authority involved to respect the time frames provided for in Article 14(7), Article 18, Article 23(2), the second subparagraph of Article 25(3), Article 28(2), (3) and (6), Article 33(3) and Article 36(4) and (5), the court or authority shall take the steps required by those provisions as soon as possible.

*Article 46***Relationship with national procedural law**

1. All procedural issues not specifically dealt with in this Regulation shall be governed by the law of the Member State in which the procedure takes place.
2. The effects of the opening of insolvency proceedings on individual enforcement actions, such as the enforcement of a Preservation Order, shall be governed by the law of the Member State in which the insolvency proceedings have been opened.

*Article 47***Data protection**

1. Personal data which are obtained, processed or transmitted under this Regulation shall be adequate, relevant and not excessive in relation to the purpose for which they were obtained, processed or transmitted, and shall be used only for that purpose.
2. The competent authority, the information authority and any other entity responsible for enforcing the Preservation Order may not store the data referred to in paragraph 1 beyond the period necessary for the purpose for which they were obtained, processed or transmitted, which in any event shall not be longer than six months after the proceedings have ended, and shall, during that period, ensure the appropriate protection of those data. This paragraph does not apply to data processed or stored by courts in the exercise of their judicial functions.

*Article 48***Relationship with other instruments**

This Regulation is without prejudice to:

- (a) Regulation (EC) No 1393/2007 of the European Parliament and of the Council⁽¹⁾, except as provided for in Article 10(2), Article 14(3) and (6), Article 17(5), Article 23(3) and (6), Article 25(2) and (3), Article 28(1), (3), (5) and (6), Article 29, Article 33(3), Article 36(2) and (4), and Article 49(1) of this Regulation;
- (b) Regulation (EU) No 1215/2012;
- (c) Regulation (EC) No 1346/2000;
- (d) Directive 95/46/EC, except as provided for in Articles 14(8) and 47 of this Regulation;
- (e) Regulation (EC) No 1206/2001 of the European Parliament and of the Council⁽²⁾;
- (f) Regulation (EC) No 864/2007, except as provided for in Article 13(4) of this Regulation.

*Article 49***Languages**

1. Any documents listed in points (a) and (b) of Article 28(5) to be served on the debtor which are not in the official language of the Member State in which the debtor is domiciled or, where there are several official languages in that Member State, the official language or one of the official languages of the place where the debtor is domiciled or another language which he understands, shall be accompanied by a translation or transliteration into one of those languages. Documents listed in point (c) of Article 28(5) shall not be translated unless the court decides, exceptionally, that specific documents need to be translated or transliterated in order to enable the debtor to assert his rights.

⁽¹⁾ Regulation (EC) No 1393/2007 of the European Parliament and of the Council of 13 November 2007 on the service in the Member States of judicial and extrajudicial documents in civil or commercial matters (service of documents), and repealing Council Regulation (EC) No 1348/2000 (OJ L 324, 10.12.2007, p. 79).

⁽²⁾ Council Regulation (EC) No 1206/2001 of 28 May 2001 on cooperation between the courts of the Member States in the taking of evidence in civil or commercial matters (OJ L 174, 27.6.2001, p. 1).

2. Any documents to be addressed under this Regulation to a court or competent authority may also be in any other official language of the institutions of the Union, if the Member State concerned has indicated that it can accept such other language.

3. Any translation made under this Regulation shall be done by a person qualified to do translations in one of the Member States.

Article 50

Information to be provided by Member States

1. By 18 July 2016, the Member States shall communicate the following information to the Commission:

- (a) the courts designated as competent to issue a Preservation Order (Article 6(4));
- (b) the authority designated as competent to obtain account information (Article 14);
- (c) the methods of obtaining account information available under their national law (Article 14(5));
- (d) the courts with which an appeal is to be lodged (Article 21);
- (e) the authority or authorities designated as competent to receive, transmit and serve the Preservation Order and other documents under this Regulation (point (14) of Article 4);
- (f) the authority competent to enforce the Preservation Order in accordance with Chapter 3;
- (g) the extent to which joint and nominee accounts can be preserved under their national law (Article 30);
- (h) the rules applicable to amounts exempt from seizure under national law (Article 31);
- (i) whether, under their national law, banks are entitled to charge fees for the implementation of equivalent national orders or for providing account information and, if so, which party is liable, provisionally and finally, to pay those fees (Article 43);
- (j) the scale of fees or other set of rules setting out the applicable fees charged by any authority or other body involved in the processing or enforcement of the Preservation Order (Article 44);
- (k) whether any ranking is conferred on equivalent national orders under national law (Article 32);
- (l) the courts or, where applicable, the enforcement authority, competent to grant a remedy (Article 33(1), Article 34(1) or (2));
- (m) the courts with which an appeal is to be lodged, the period of time, if prescribed, within which such an appeal must be lodged under national law and the event marking the start of that period (Article 37);

- (n) an indication of court fees (Article 42); and
- (o) the languages accepted for translations of the documents (Article 49(2)).

The Member States shall apprise the Commission of any subsequent changes to that information.

2. The Commission shall make the information publicly available through any appropriate means, in particular through the European Judicial Network in civil and commercial matters.

Article 51

Establishment and subsequent amendment of the forms

The Commission shall adopt implementing acts establishing and subsequently amending the forms referred to in Articles 8(1), 10(2), 19(1), 25(1), 27(2), 29(2) and 36(1), the second subparagraph of Article 36(5) and Article 37. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 52(2).

Article 52

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Article 53

Monitoring and review

1. By 18 January 2022, the Commission shall submit to the European Parliament, to the Council and to the European Economic and Social Committee a report on the application of this Regulation, including an evaluation as to whether:
 - (a) financial instruments should be included in the scope of this Regulation, and
 - (b) amounts credited to the debtor's account after the implementation of the Preservation Order could be made subject to preservation under the Order.

The report shall be accompanied, if appropriate, by a proposal to amend this Regulation and an assessment of the impact of the amendments to be introduced.

2. For the purposes of paragraph 1, the Member States shall collect and make available to the Commission upon request information on:
 - (a) the number of applications for a Preservation Order and the number of cases in which the Order was issued;
 - (b) the number of applications for a remedy pursuant to Articles 33 and 34 and, if possible, the number of cases in which the remedy was granted; and
 - (c) the number of appeals lodged pursuant to Article 37 and, if possible, the number of cases in which such an appeal was successful.

CHAPTER 6

FINAL PROVISIONS

Article 54

Entry into force

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

It shall apply from 18 January 2017, with the exception of Article 50, which shall apply from 18 July 2016.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

REGULATION (EU) No 656/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014

establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union

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 point (d) of Article 77(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) The objective of Union policy in the field of the Union external borders is to ensure the efficient monitoring of the crossing of external borders including through border surveillance, while contributing to ensuring the protection and saving of lives. The purpose of border surveillance is to prevent unauthorised border crossings, to counter cross-border criminality and to apprehend or take other measures against those persons who have crossed the border in an irregular manner. Border surveillance should be effective in preventing and discouraging persons from circumventing the checks at border crossing points. To this end, border surveillance is not limited to the detection of attempts at unauthorised border crossings but equally extends to steps such as intercepting vessels suspected of trying to gain entry to the Union without submitting to border checks, as well as arrangements intended to address situations such as search and rescue that may arise during a border surveillance operation at sea and arrangements intended to bring such an operation to a successful conclusion.
- (2) The policies of the Union in border management, asylum and immigration and their implementation should be governed by the principle of solidarity and fair sharing of responsibility between the Member States pursuant to Article 80 of the Treaty on the Functioning of the European Union (TFEU). Wherever necessary, Union acts adopted in the framework of those policies are to contain appropriate measures to give effect to that principle and promote burden-sharing including through the transfer, on a voluntary basis, of beneficiaries of international protection.
- (3) The scope of application of this Regulation should be limited to border surveillance operations carried out by Member States at their external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union ('the Agency') established by Council Regulation (EC) No 2007/2004 ⁽²⁾. Investigative and punitive measures are governed by national criminal law and the existing instruments of mutual legal assistance in the field of judicial cooperation in criminal matters in the Union.
- (4) The Agency is responsible for the coordination of operational cooperation between Member States in the field of management of the external borders, including as regards border surveillance. The Agency is also responsible for assisting Member States in circumstances requiring increased technical assistance at the external borders, taking into account the fact that some situations may involve humanitarian emergencies and rescue at sea. Specific rules with regard to border surveillance activities carried out by maritime, land and aerial units of one Member State at the sea border of other Member States or on the high seas in the context of operational cooperation coordinated by the Agency are necessary to further strengthen such cooperation.

⁽¹⁾ Position of the European Parliament of 16 April 2014 (not yet published in the Official Journal) and decision of the Council of 13 May 2014.

⁽²⁾ Council Regulation (EC) No 2007/2004 of 26 October 2004 establishing a European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (OJ L 349, 25.11.2004, p. 1).

- (5) Cooperation with neighbouring third countries is crucial to prevent unauthorised border crossings, to counter cross-border criminality and to avoid loss of life at sea. In accordance with Regulation (EC) No 2007/2004 and insofar as full respect for the fundamental rights of migrants is ensured, the Agency may cooperate with the competent authorities of third countries, in particular as regards risk analysis and training, and should facilitate operational cooperation between Member States and third countries. When cooperation with third countries takes place on the territory or the territorial sea of those countries, the Member States and the Agency should comply with norms and standards at least equivalent to those set by Union law.
- (6) The European Border Surveillance System (Eurosur) established by Regulation (EU) No 1052/2013 of the European Parliament and of the Council⁽¹⁾ aims to strengthen the information exchange and operational cooperation between Member States and with the Agency. That is to ensure that the situational awareness and reaction capability of Member States improves considerably, also with the support of the Agency, for the purposes of detecting, preventing and combating illegal immigration and cross-border crime and contributing to ensuring the protection and saving the lives of migrants at their external borders. When coordinating border surveillance operations, the Agency should provide Member States with information and analysis concerning those operations in accordance with that Regulation.
- (7) This Regulation replaces Council Decision 2010/252/EU⁽²⁾ which was annulled by the Court of Justice of the European Union ('the Court') by its judgment of 5 September 2012 in Case C-355/10. In that judgment, the Court maintained the effects of Decision 2010/252/EU until the entry into force of new rules. Therefore, as of the day of entry into force of this Regulation, that Decision ceases to produce effects.
- (8) During border surveillance operations at sea, Member States should respect their respective obligations under international law, in particular the United Nations Convention on the Law of the Sea, the International Convention for the Safety of Life at Sea, the International Convention on Maritime Search and Rescue, the United Nations Convention against Transnational Organized Crime and its Protocol against the Smuggling of Migrants by Land, Sea and Air, the United Nations Convention relating to the Status of Refugees, the European Convention for the Protection of Human Rights and Fundamental Freedoms, the International Covenant on Civil and Political Rights, the United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, the United Nations Convention on the Rights of the Child and other relevant international instruments.
- (9) When coordinating border surveillance operations at sea, the Agency should fulfil its tasks in full compliance with relevant Union law, including the Charter of Fundamental Rights of the European Union ('the Charter'), and relevant international law, in particular that referred to in recital 8.
- (10) In accordance with Regulation (EC) No 562/2006 of the European Parliament and of the Council⁽³⁾ and general principles of Union law, any measure taken in the course of a surveillance operation should be proportionate to the objectives pursued, non-discriminatory and should fully respect human dignity, fundamental rights and the rights of refugees and asylum seekers, including the principle of *non-refoulement*. Member States and the Agency are bound by the provisions of the asylum *acquis*, and in particular of Directive 2013/32/EU of the European Parliament and of the Council⁽⁴⁾ with regard to applications for international protection made in the territory, including at the border, in the territorial waters or in the transit zones of Member States.
- (11) The application of this Regulation should be without prejudice to Directive 2011/36/EU of the European Parliament and the Council⁽⁵⁾, in particular as regards assistance to be given to victims of trafficking in human beings.

⁽¹⁾ Regulation (EU) No 1052/2013 of the European Parliament and of the Council of 22 October 2013 establishing the European Border Surveillance System (Eurosur) (OJ L 295, 6.11.2013, p. 11).

⁽²⁾ Council Decision 2010/252/EU of 26 April 2010 supplementing the Schengen Borders Code as regards the surveillance of the sea external borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (OJ L 111, 4.5.2010, p. 20).

⁽³⁾ Regulation (EC) No 562/2006 of the European Parliament and of the Council of 15 March 2006 establishing a Community Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 105, 13.4.2006, p. 1).

⁽⁴⁾ Directive 2013/32/EU of the European Parliament and of the Council of 26 June 2013 on common procedures for granting and withdrawing international protection (OJ L 180, 29.6.2013, p. 60).

⁽⁵⁾ Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA (OJ L 101, 15.4.2011, p. 1).

- (12) This Regulation should be applied in full compliance with the principle of *non-refoulement* as defined in the Charter and as interpreted by the case-law of the Court and of the European Court of Human Rights. In accordance with that principle, no person should be disembarked in, forced to enter, conducted to or otherwise handed over to the authorities of a country where, inter alia, there is a serious risk that he or she would be subjected to the death penalty, torture, persecution or other inhuman or degrading treatment or punishment, or where his or her life or freedom would be threatened on account of his or her race, religion, nationality, sexual orientation, membership of a particular social group or political opinion, or from which there is a serious risk of an expulsion, removal or extradition to another country in contravention of the principle of *non-refoulement*.
- (13) The possible existence of an arrangement between a Member State and a third country does not absolve Member States from their obligations under Union and international law, in particular as regards compliance with the principle of *non-refoulement*, whenever they are aware or ought to be aware that systemic deficiencies in the asylum procedure and in the reception conditions of asylum seekers in that third country amount to substantial grounds for believing that the asylum seeker would face a serious risk of being subjected to inhuman or degrading treatment or where they are aware or ought to be aware that that third country engages in practices in contravention of the principle of *non-refoulement*.
- (14) During a border surveillance operation at sea, a situation may occur where it will be necessary to render assistance to persons found in distress. In accordance with international law, every State must require the master of a vessel flying its flag, in so far as he can do so without serious danger to the vessel, the crew or the passengers, to render assistance without delay to any person found at sea in danger of being lost and to proceed with all possible speed to the rescue of persons in distress. Such assistance should be provided regardless of the nationality or status of the persons to be assisted or of the circumstances in which they are found. The shipmaster and crew should not face criminal penalties for the sole reason of having rescued persons in distress at sea and brought them to a place of safety.
- (15) The obligation to render assistance to persons found in distress should be fulfilled by Member States in accordance with the applicable provisions of international instruments governing search and rescue situations and in accordance with requirements concerning the protection of fundamental rights. This Regulation should not affect the responsibilities of search and rescue authorities, including for ensuring that coordination and cooperation is conducted in such a way that the persons rescued can be delivered to a place of safety.
- (16) When the operational area of a sea operation includes the search and rescue region of a third country, the establishment of communication channels with the search and rescue authorities of that third country should be sought when planning a sea operation, thereby ensuring that those authorities will be able to respond to search and rescue cases developing within their search and rescue region.
- (17) Pursuant to Regulation (EC) No 2007/2004, border surveillance operations coordinated by the Agency are conducted in accordance with an operational plan. Accordingly, as regards sea operations, the operational plan should include specific information on the application of the relevant jurisdiction and legislation in the geographical area where the joint operation, pilot project or rapid intervention takes place, including references to Union and international law regarding interception, rescue at sea and disembarkation. The operational plan should be established in accordance with the provisions of this Regulation governing interception, rescue at sea and disembarkation in the context of border surveillance operations at sea coordinated by the Agency and having regard to the particular circumstances of the operation concerned. The operational plan should include procedures ensuring that persons with international protection needs, victims of trafficking in human beings, unaccompanied minors and other vulnerable persons are identified and provided with appropriate assistance, including access to international protection.
- (18) The practice under Regulation (EC) No 2007/2004 is that for each sea operation, a coordination structure is established within the host Member State, composed of officers from the host Member State, guest officers and representatives of the Agency, including the Coordinating Officer of the Agency. This coordination structure, usually called International Coordination Centre, should be used as a channel for communication between the officers involved in the sea operation and the authorities concerned.

- (19) This Regulation respects the fundamental rights and observes the principles recognised by Articles 2 and 6 of the Treaty on European Union (TEU) and by the Charter, in particular respect for human dignity, the right to life, the prohibition of torture and of inhuman or degrading treatment or punishment, the prohibition of trafficking in human beings, the right to liberty and security, the right to the protection of personal data, the right to asylum and to protection against removal and expulsion, the principles of *non-refoulement* and non-discrimination, the right to an effective remedy and the rights of the child. This Regulation should be applied by Member States and the Agency in accordance with those rights and principles.
- (20) Since the objective of this Regulation, namely to adopt specific rules for the surveillance of the sea borders by border guards operating under the coordination of the Agency, cannot be sufficiently achieved by the Member States due to the differences in their laws and practices, but can rather, by reason of the multinational character of the operations, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. 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.
- (21) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the TEU and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen *acquis*, Denmark shall, in accordance with Article 4 of that Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law.
- (22) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen *acquis* ⁽¹⁾ which fall within the area referred to in Article 1, point A, of Council Decision 1999/437/EC ⁽²⁾.
- (23) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽³⁾ which fall within the area referred to in Article 1, point A, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC ⁽⁴⁾.
- (24) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁵⁾, which fall within the area referred to in Article 1, point A, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ⁽⁶⁾.

⁽¹⁾ OJ L 176, 10.7.1999, p. 36.

⁽²⁾ Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

⁽³⁾ OJ L 53, 27.2.2008, p. 52.

⁽⁴⁾ Council Decision 2008/146/EC of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

⁽⁵⁾ OJ L 160, 18.6.2011, p. 21.

⁽⁶⁾ Council Decision 2011/350/EU of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

- (25) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which the United Kingdom does not take part, in accordance with Council Decision 2000/365/EC ⁽¹⁾; the United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.
- (26) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ⁽²⁾; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Regulation shall apply to border surveillance operations carried out by Member States at their external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union.

Article 2

Definitions

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

- (1) 'Agency' means the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union established by Regulation (EC) No 2007/2004;
- (2) 'sea operation' means a joint operation, pilot project or rapid intervention carried out by Member States for the surveillance of their external sea borders under the coordination of the Agency;
- (3) 'host Member State' means a Member State in which a sea operation takes place or from which it is launched;
- (4) 'participating Member State' means a Member State which participates in a sea operation by providing technical equipment, border guards deployed as part of the European Border Guard Teams or other relevant staff but which is not a host Member State;
- (5) 'participating unit' means a maritime, land or aerial unit under the responsibility of the host Member State or of a participating Member State that takes part in a sea operation;
- (6) 'International Coordination Centre' means the coordination structure established within the host Member State for the coordination of a sea operation;
- (7) 'National Coordination Centre' means the national coordination centre established for the purposes of the European Border Surveillance System (Eurosur) in accordance with Regulation (EU) No 1052/2013;

⁽¹⁾ Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* (OJ L 131, 1.6.2000, p. 43).

⁽²⁾ Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

- (8) 'operational plan' means the operational plan referred to in Article 3a and Article 8e of Regulation (EC) No 2007/2004;
- (9) 'vessel' means any type of water craft, including boats, dinghies, floating platforms, non-displacement craft and seaplanes, used or capable of being used at sea;
- (10) 'stateless vessel' means a vessel without nationality or assimilated to a vessel without nationality when the vessel has not been granted by any State the right to fly its flag or when it sails under the flags of two or more States, using them according to convenience;
- (11) 'Protocol against the Smuggling of Migrants' means the Protocol against the Smuggling of Migrants by Land, Sea and Air, supplementing the United Nations Convention against Transnational Organised Crime signed in Palermo, Italy in December 2000;
- (12) 'place of safety' means a location where rescue operations are considered to terminate and where the survivors' safety of life is not threatened, where their basic human needs can be met and from which transportation arrangements can be made for the survivors' next destination or final destination, taking into account the protection of their fundamental rights in compliance with the principle of *non-refoulement*;
- (13) 'Rescue Coordination Centre' means a unit responsible for promoting efficient organisation of search and rescue services and for coordinating the conduct of search and rescue operations within a search and rescue region as defined in the International Convention on Maritime Search and Rescue;
- (14) 'contiguous zone' means a zone contiguous to the territorial sea as defined in Article 33 of the United Nations Convention on the Law of the Sea, where formally proclaimed;
- (15) 'coastal Member State' means a Member State in whose territorial sea or contiguous zone an interception takes place.

CHAPTER II

GENERAL RULES

Article 3

Safety at sea

Measures taken for the purpose of a sea operation shall be conducted in a way that, in all instances, ensures the safety of the persons intercepted or rescued, the safety of the participating units or that of third parties.

Article 4

Protection of fundamental rights and the principle of non-refoulement

1. No person shall, in contravention of the principle of *non-refoulement*, be disembarked in, forced to enter, conducted to or otherwise handed over to the authorities of a country where, inter alia, there is a serious risk that he or she would be subjected to the death penalty, torture, persecution or other inhuman or degrading treatment or punishment, or where his or her life or freedom would be threatened on account of his or her race, religion, nationality, sexual orientation, membership of a particular social group or political opinion, or from which there is a serious risk of an expulsion, removal or extradition to another country in contravention of the principle of *non-refoulement*.

2. When considering the possibility of disembarkation in a third country, in the context of planning a sea operation, the host Member State, in coordination with participating Member States and the Agency, shall take into account the general situation in that third country.

The assessment of the general situation in a third country shall be based on information derived from a broad range of sources, which may include other Member States, Union bodies, offices and agencies, and relevant international organisations and it may take into account the existence of agreements and projects on migration and asylum carried out in accordance with Union law and through Union funds. That assessment shall be part of the operational plan, shall be provided to the participating units and shall be updated as necessary.

Intercepted or rescued persons shall not be disembarked, forced to enter, conducted to or otherwise handed over to the authorities of a third country when the host Member State or the participating Member States are aware or ought to be aware that that third country engages in practices as described in paragraph 1.

3. During a sea operation, before the intercepted or rescued persons are disembarked in, forced to enter, conducted to or otherwise handed over to the authorities of a third country and taking into account the assessment of the general situation in that third country in accordance with paragraph 2, the participating units shall, without prejudice to Article 3, use all means to identify the intercepted or rescued persons, assess their personal circumstances, inform them of their destination in a way that those persons understand or may reasonably be presumed to understand and give them an opportunity to express any reasons for believing that disembarkation in the proposed place would be in violation of the principle of *non-refoulement*.

For those purposes, further details shall be provided in the operational plan including, when necessary, the availability of shore-based medical staff, interpreters, legal advisers and other relevant experts of the host and participating Member States. Each participating unit shall include at least one person with basic first aid training.

The report referred to in Article 13 shall, based on information that shall be provided by the host and participating Member States, include further details on cases of disembarkation in third countries and how each element of the procedures laid down in the first subparagraph of this paragraph was applied by the participating units to ensure compliance with the principle of *non-refoulement*.

4. Throughout a sea operation, the participating units shall address the special needs of children, including unaccompanied minors, victims of trafficking in human beings, persons in need of urgent medical assistance, disabled persons, persons in need of international protection and other persons in a particularly vulnerable situation.

5. Any exchange with third countries of personal data obtained during a sea operation for the purposes of this Regulation shall be strictly limited to what is absolutely necessary and shall be carried out in accordance with Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾, Council Framework Decision 2008/977/JHA ⁽²⁾ and relevant national provisions on data protection.

The exchange with third countries of personal data regarding intercepted or rescued persons obtained during a sea operation shall be prohibited where there is a serious risk of contravention of the principle of *non-refoulement*.

6. Participating units shall, in the performance of their duties, fully respect human dignity.

7. This Article shall apply to all measures taken by Member States or the Agency in accordance with this Regulation.

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

⁽²⁾ Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters (OJ L 350, 30.12.2008, p. 60).

8. Border guards and other staff participating in a sea operation shall be trained with regard to relevant provisions of fundamental rights, refugee law and the international legal regime of search and rescue in accordance with the second paragraph of Article 5 of Regulation (EC) No 2007/2004.

CHAPTER III

SPECIFIC RULES

Article 5

Detection

1. Upon detection, the participating units shall approach a vessel suspected of carrying persons circumventing or intending to circumvent checks at border crossing points or of being engaged in the smuggling of migrants by sea in order to observe its identity and nationality and, pending further measures, shall survey that vessel at a prudent distance taking all due precautions. The participating units shall collect and immediately report information about that vessel to the International Coordination Centre, including, where possible, information about the situation of persons on board, in particular whether there is an imminent risk to their lives or whether there are persons in urgent need of medical assistance. The International Coordination Centre shall transmit that information to the National Coordination Centre of the host Member State.

2. Where a vessel is about to enter or it has entered the territorial sea or the contiguous zone of a Member State that is not participating in the sea operation, the participating units shall collect and report information about that vessel to the International Coordination Centre, which shall transmit that information to the National Coordination Centre of the Member State concerned.

3. The participating units shall collect and report information about any vessel suspected of being engaged in illegal activities at sea, which are outside the scope of the sea operation, to the International Coordination Centre, which shall transmit that information to the National Coordination Centre of the Member State concerned.

Article 6

Interception in the territorial sea

1. In the territorial sea of the host Member State or a neighbouring participating Member State, that State shall authorise the participating units to take one or more of the following measures where there are reasonable grounds to suspect that a vessel may be carrying persons intending to circumvent checks at border crossing points or is engaged in the smuggling of migrants by sea:

- (a) requesting information and documentation on ownership, registration and elements relating to the voyage of the vessel, and on the identity, nationality and other relevant data on persons on board, including whether there are persons in urgent need of medical assistance, and making persons on board aware that they may not be authorised to cross the border;
- (b) stopping, boarding and searching the vessel, its cargo and persons on board, and questioning persons on board and informing them that persons directing the vessel may face penalties for facilitating the voyage.

2. If evidence confirming that suspicion is found, that host Member State or neighbouring participating Member State may authorise the participating units to take one or more of the following measures:

- (a) seizing the vessel and apprehending persons on board;
- (b) ordering the vessel to alter its course outside of or towards a destination other than the territorial sea or the contiguous zone, including escorting the vessel or steaming nearby until it is confirmed that the vessel is keeping to that given course;

(c) conducting the vessel or persons on board to the coastal Member State in accordance with the operational plan.

3. Any measure taken in accordance with paragraph 1 or 2 shall be proportionate and shall not exceed what is necessary to achieve the objectives of this Article.

4. For the purposes of paragraphs 1 and 2, the host Member State shall instruct the participating unit appropriately through the International Coordination Centre.

The participating unit shall inform the host Member State, through the International Coordination Centre, whenever the master of the vessel requests that a diplomatic agent or a consular officer of the flag State be notified.

5. Where there are reasonable grounds to suspect that a stateless vessel is carrying persons intending to circumvent the checks at border crossing points or is engaged in the smuggling of migrants by sea, the host Member State or the neighbouring participating Member State in whose territorial sea that stateless vessel is intercepted shall authorise one or more of the measures laid down in paragraph 1 and may authorise one or more of the measures laid down in paragraph 2. The host Member State shall instruct the participating unit appropriately through the International Coordination Centre.

6. Any operational activities in the territorial sea of a Member State that is not participating in the sea operation shall be conducted in accordance with the authorisation of that Member State. The host Member State shall instruct the participating unit through the International Coordination Centre based on the course of action authorised by that Member State.

Article 7

Interception on the high seas

1. On the high seas, where there are reasonable grounds to suspect that a vessel is engaged in the smuggling of migrants by sea, the participating units shall take one or more of the following measures, subject to the authorisation of the flag State, in accordance with the Protocol against the Smuggling of Migrants, and where relevant, national and international law:

- (a) requesting information and documentation on ownership, registration and elements relating to the voyage of the vessel, and on the identity, nationality and other relevant data on persons on board, including whether there are persons in urgent need of medical assistance;
- (b) stopping, boarding and searching the vessel, its cargo and persons on board, and questioning persons on board and informing them that persons directing the vessel may face penalties for facilitating the voyage.

2. If evidence confirming that suspicion is found, the participating units may take one or more of the following measures, subject to the authorisation of the flag State, in accordance with the Protocol against the Smuggling of Migrants, and where relevant, national and international law:

- (a) seizing the vessel and apprehending persons on board;
- (b) warning and ordering the vessel not to enter the territorial sea or the contiguous zone, and, where necessary, requesting the vessel to alter its course towards a destination other than the territorial sea or the contiguous zone;
- (c) conducting the vessel or persons on board to a third country or otherwise handing over the vessel or persons on board to the authorities of a third country;
- (d) conducting the vessel or persons on board to the host Member State or to a neighbouring participating Member State.

3. Any measure taken in accordance with paragraph 1 or 2 shall be proportionate and shall not exceed what is necessary to achieve the objectives of this Article.
4. For the purposes of paragraphs 1 and 2, the host Member State shall instruct the participating unit appropriately through the International Coordination Centre.
5. Where the vessel is flying the flag or displays the marks of registry of the host Member State or of a participating Member State, that Member State may, after confirming the nationality of the vessel, authorise one or more of the measures laid down in paragraphs 1 and 2. The host Member State shall then instruct the participating unit appropriately through the International Coordination Centre.
6. Where the vessel is flying the flag or displays the marks of registry of a Member State that is not participating in the sea operation or of a third country, the host Member State or a participating Member State, depending on whose participating unit has intercepted that vessel, shall notify the flag State, shall request confirmation of registry and, if nationality is confirmed, shall request that the flag State take action to suppress the use of its vessel for smuggling of migrants. If the flag State is unwilling or unable to do so either directly or with the assistance of the Member State to whom the participating unit belongs, that Member State shall request authorisation from the flag State to take any of the measures laid down in paragraphs 1 and 2. The host Member State or the participating Member State shall inform the International Coordination Centre of any communication with the flag State and of the intended actions or measures authorised by the flag State. The host Member State shall then instruct the participating unit appropriately through the International Coordination Centre.
7. Where, though flying a foreign flag or refusing to show its flag, there are reasonable grounds to suspect that the vessel is, in reality, of the same nationality as a participating unit, that participating unit shall verify the vessel's right to fly its flag. To that end, it may approach the suspect vessel. If suspicion remains, it shall proceed to a further examination on board the vessel, which shall be carried out with all possible consideration.
8. Where, though flying a foreign flag or refusing to show its flag, there are reasonable grounds to suspect that the vessel is, in reality, of the nationality of the host Member State or a participating Member State, the participating unit shall verify the vessel's right to fly its flag.
9. Where, in the cases referred to in paragraph 7 or 8, the suspicions regarding the nationality of the vessel prove to be founded, that host Member State or that participating Member State may authorise one or more of the measures laid down in paragraphs 1 and 2. The host Member State shall then instruct the participating unit appropriately through the International Coordination Centre.
10. Pending or in the absence of authorisation of the flag State, the vessel shall be surveyed at a prudent distance. No other measures shall be taken without the express authorisation of the flag State, except those necessary to relieve imminent danger to the lives of persons or those measures which derive from relevant bilateral or multilateral agreements.
11. Where there are reasonable grounds to suspect that a stateless vessel is engaged in the smuggling of migrants by sea, the participating unit may board and search the vessel with a view to verifying its statelessness. If evidence confirming that suspicion is found, the participating unit shall inform the host Member State which may take, directly or with the assistance of the Member State to whom the participating unit belongs, further appropriate measures as laid down in paragraphs 1 and 2 in accordance with national and international law.
12. A Member State whose participating unit has taken any measure in accordance with paragraph 1 shall promptly inform the flag State of the outcome of that measure.

13. The national official representing the host Member State or a participating Member State at the International Coordination Centre shall be responsible for facilitating communications with the relevant authorities of that Member State in seeking authorisation to verify the right of a vessel to fly its flag or to take any of the measures laid down in paragraphs 1 and 2.

14. Where the grounds to suspect that a vessel is engaged in the smuggling of migrants on the high seas prove to be unfounded or where the participating unit does not have jurisdiction to act, but there remains a reasonable suspicion that the vessel is carrying persons intending to reach the border of a Member State and to circumvent checks at border crossing points, that vessel shall continue to be monitored. The International Coordination Centre shall communicate information about that vessel to the National Coordination Centre of the Member States towards which it is directed.

Article 8

Interception in the contiguous zone

1. In the contiguous zone of the host Member State or of a neighbouring participating Member State, the measures laid down in paragraphs 1 and 2 of Article 6 shall be taken in accordance with those paragraphs and with paragraphs 3 and 4 thereof. Any authorisation referred to in Article 6(1) and (2) may only be given for measures that are necessary to prevent the infringement of relevant laws and regulations within that Member State's territory or territorial sea.

2. The measures laid down in Article 6(1) and (2) shall not be taken in the contiguous zone of a Member State that is not participating in the sea operation without the authorisation of that Member State. The International Coordination Centre shall be informed of any communication with that Member State and of the subsequent course of action authorised by that Member State. If that Member State does not give its authorisation and where there are reasonable grounds to suspect that the vessel is carrying persons intending to reach the border of a Member State, Article 7(14) shall apply.

3. Where a stateless vessel is transiting the contiguous zone, Article 7(11) shall apply.

Article 9

Search and rescue situations

1. Member States shall observe their obligation to render assistance to any vessel or person in distress at sea and, during a sea operation, they shall ensure that their participating units comply with that obligation, in accordance with international law and respect for fundamental rights. They shall do so regardless of the nationality or status of such a person or the circumstances in which that person is found.

2. For the purpose of dealing with search and rescue situations that may occur during a sea operation, the operational plan shall contain, in accordance with relevant international law, including that on search and rescue, at least the following provisions:

(a) When, in the course of a sea operation, the participating units have reason to believe that they are facing a phase of uncertainty, alert or distress as regards a vessel or any person on board, they shall promptly transmit all available information to the Rescue Coordination Centre responsible for the search and rescue region in which the situation occurs and they shall place themselves at the disposal of that Rescue Coordination Centre.

(b) The participating units shall inform the International Coordination Centre as soon as possible of any contact with the Rescue Coordination Centre and of the course of action taken by them.

(c) A vessel or the persons on board shall be considered to be in a phase of uncertainty in particular:

(i) when a person has been reported as missing or a vessel is overdue; or

(ii) when a person or a vessel has failed to make an expected position or safety report.

- (d) A vessel or the persons on board shall be considered to be in a phase of alert in particular:
- (i) when, following a phase of uncertainty, attempts to establish contact with a person or a vessel have failed and inquiries addressed to other appropriate sources have been unsuccessful; or
 - (ii) when information has been received indicating that the operating efficiency of a vessel is impaired, but not to the extent that a distress situation is likely.
- (e) A vessel or the persons on board shall be considered to be in a phase of distress in particular:
- (i) when positive information is received that a person or a vessel is in danger and in need of immediate assistance; or
 - (ii) when, following a phase of alert, further unsuccessful attempts to establish contact with a person or a vessel and more widespread unsuccessful inquiries point to the probability that a distress situation exists; or
 - (iii) when information is received which indicates that the operating efficiency of a vessel has been impaired to the extent that a distress situation is likely.
- (f) Participating units shall, for the purpose of considering whether the vessel is in a phase of uncertainty, alert or distress, take into account and transmit all relevant information and observations to the responsible Rescue Coordination Centre including on:
- (i) the existence of a request for assistance, although such a request shall not be the sole factor for determining the existence of a distress situation;
 - (ii) the seaworthiness of the vessel and the likelihood that the vessel will not reach its final destination;
 - (iii) the number of persons on board in relation to the type and condition of the vessel;
 - (iv) the availability of necessary supplies such as fuel, water and food to reach a shore;
 - (v) the presence of qualified crew and command of the vessel;
 - (vi) the availability and capability of safety, navigation and communication equipment;
 - (vii) the presence of persons on board in urgent need of medical assistance;
 - (viii) the presence of deceased persons on board;
 - (ix) the presence of pregnant women or of children on board;
 - (x) the weather and sea conditions, including weather and marine forecasts.
- (g) While awaiting instructions from the Rescue Coordination Centre, participating units shall take all appropriate measures to ensure the safety of the persons concerned.

- (h) Where a vessel is considered to be in a situation of uncertainty, alert or distress but the persons on board refuse to accept assistance, the participating unit shall inform the responsible Rescue Coordination Centre and follow its instructions. The participating unit shall continue to fulfil a duty of care by surveying the vessel and by taking any measure necessary for the safety of the persons concerned, while avoiding to take any action that might aggravate the situation or increase the chances of injury or loss of life.
- (i) Where the Rescue Coordination Centre of a third country responsible for the search and rescue region does not respond to the information transmitted by the participating unit, the latter shall contact the Rescue Coordination Centre of the host Member State unless that participating unit considers that another internationally recognised Rescue Coordination Centre is better able to assume coordination of the search and rescue situation.

The operational plan may contain details adapted to the circumstances of the sea operation concerned.

- 3. Where the search and rescue situation has been concluded, the participating unit shall, in consultation with the International Coordination Centre, resume the sea operation.

Article 10

Disembarkation

- 1. The operational plan shall contain, in accordance with international law and respect for fundamental rights, at least the following modalities for the disembarkation of the persons intercepted or rescued in a sea operation:
 - (a) in the case of interception in the territorial sea or the contiguous zone as laid down in Article 6(1), (2) or (6) or in Article 8(1) or (2), disembarkation shall take place in the coastal Member State, without prejudice to point (b) of Article 6(2);
 - (b) in the case of interception on the high seas as laid down in Article 7, disembarkation may take place in the third country from which the vessel is assumed to have departed. If that is not possible, disembarkation shall take place in the host Member State;
 - (c) in the case of search and rescue situations as laid down in Article 9 and without prejudice to the responsibility of the Rescue Coordination Centre, the host Member State and the participating Member States shall cooperate with the responsible Rescue Coordination Centre to identify a place of safety and, when the responsible Rescue Coordination Centre designates such a place of safety, they shall ensure that disembarkation of the rescued persons is carried out rapidly and effectively.

If it is not possible to arrange for the participating unit to be released of its obligation referred to in Article 9(1) as soon as reasonably practicable, taking into account the safety of the rescued persons and that of the participating unit itself, it shall be authorised to disembark the rescued persons in the host Member State.

Those modalities for disembarkation shall not have the effect of imposing obligations on Member States not participating in the sea operation unless they expressly provide authorisation for measures to be taken in their territorial sea or contiguous zone in accordance with Article 6(6) or Article 8(2).

The operational plan may contain details adapted to the circumstances of the sea operation concerned.

- 2. The participating units shall inform the International Coordination Centre of the presence of any persons within the meaning of Article 4, and the International Coordination Centre shall transmit that information to the competent national authorities of the country where disembarkation takes place.

The operational plan shall contain the contact details of those competent national authorities, which shall take appropriate follow-up measures.

*Article 11***Amendment to Regulation (EC) No 2007/2004**

In Articles 3a(1) and 8e(1) of Regulation (EC) No 2007/2004, at the end of point (j) respectively, the following sentence is added:

In that regard the operational plan shall be established in accordance with Regulation (EU) No 656/2014 of the European Parliament and of the Council (*).

(*) Regulation (EU) No 656/2014 of the European Parliament and of the Council of 15 May 2014 establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Members States of the European Union (OJ L 189, 27.6.2014, p. 93).

*Article 12***Solidarity mechanisms**

1. A Member State faced with a situation of urgent and exceptional pressure at its external border shall be able to request:

- (a) the deployment of European Border Guard Teams in accordance with Article 8a of Regulation (EC) No 2007/2004 to provide rapid operational assistance to that Member State;
- (b) the Agency for technical and operational assistance in accordance with Article 8 of Regulation (EC) No 2007/2004 in order to obtain assistance on matters of coordination between Members States and/or the deployment of experts to support the competent national authorities;
- (c) emergency assistance under Article 14 of Regulation (EU) No 515/2014 of the European Parliament and of the Council ⁽¹⁾ to address urgent and specific needs in the event of an emergency situation.

2. A Member State subject to strong migratory pressure which places urgent demands on its reception facilities and asylum systems shall be able to request:

- (a) the European Asylum Support Office for the deployment of an asylum support team in accordance with Article 13 of Regulation (EU) No 439/2010 of the European Parliament and of the Council ⁽²⁾ to provide expertise, such as in relation to interpreting services, information on countries of origin and knowledge of the handling and management of asylum cases;
- (b) emergency assistance under Article 21 of Regulation (EU) No 516/2014 of the European Parliament and of the Council ⁽³⁾ to address urgent and specific needs in the event of an emergency situation.

*Article 13***Report**

1. The Agency shall submit a report to the European Parliament, the Council and the Commission on the practical application of this Regulation by 18 July 2015 and every year thereafter.

⁽¹⁾ Regulation (EU) No 515/2014 of the European Parliament and of the Council of 16 April 2014 establishing, as part of the Internal Security Fund, the instrument for financial support for external borders and visa and repealing Decision No 574/2007/EC (OJ L 150, 20.5.2014, p. 143).

⁽²⁾ Regulation (EU) No 439/2010 of the European Parliament and of the Council of 19 May 2010 establishing a European Asylum Support Office (OJ L 132, 29.5.2010, p. 11).

⁽³⁾ Regulation (EU) No 516/2014 of the European Parliament and of the Council of 16 April 2014 establishing the Asylum, Migration and Integration Fund, amending Council Decision 2008/381/EC and repealing Decisions No 573/2007/EC and No 575/2007/EC of the European Parliament and of the Council and Council Decision 2007/435/EC (OJ L 150, 20.5.2014, p. 168).

2. The report shall include a description of the procedures put in place by the Agency to apply this Regulation during sea operations and information on the application of this Regulation in practice, including detailed information on compliance with fundamental rights and the impact on those rights, and any incidents which may have taken place.

CHAPTER IV

FINAL PROVISIONS

Article 14

Effects of Decision 2010/252/EU

Decision 2010/252/EU ceases to produce effects from the date of entry into force of this Regulation.

Article 15

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

REGULATION (EU) No 657/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
amending Council Regulation (EC) No 2173/2005 as regards the delegated and implementing
powers to be conferred on the Commission

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 2173/2005 ⁽²⁾ confers powers upon the Commission in order to implement some of the provisions of that Regulation.
- (2) As a consequence of the entry into force of the Treaty of Lisbon, the powers conferred on the Commission under Regulation (EC) No 2173/2005 should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).
- (3) In order to apply some of the provisions of Regulation (EC) No 2173/2005, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to Annexes I, II and III to that Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (4) In order to ensure uniform conditions for the implementation of Regulation (EC) No 2173/2005, implementing powers should be conferred on the Commission to assess and approve existing schemes that guarantee the legality and reliable tracking of timber products exported from partner countries with a view to becoming the basis of a Forest Law Enforcement, Governance and Trade (FLEGT) licence, and to adopt modalities of a practical nature and documents of a standard format, including their possible means (electronic or paper format) in relation to the FLEGT licensing scheme. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽³⁾.
- (5) Regulation (EC) No 2173/2005 should therefore be amended accordingly,

⁽¹⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.

⁽²⁾ Council Regulation (EC) No 2173/2005 of 20 December 2005 on the establishment of a FLEGT licensing scheme for imports of timber into the European Community (OJ L 347, 30.12.2005, p. 1).

⁽³⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2173/2005 is amended as follows:

(1) in Article 4, paragraphs 2 and 3 are replaced by the following:

'2. In order to provide the necessary assurance as to the legality of the timber products concerned, the Commission shall assess existing schemes that guarantee the legality and reliable tracking of timber products exported from partner countries, and adopt implementing acts to approve them. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 11(3).

The schemes approved by the Commission may form the basis of a FLEGT licence.

3. Timber products of species listed in Annexes A, B and C to Council Regulation (EC) No 338/97 (*) shall be exempt from the requirement laid down in paragraph 1 of this Article.

The Commission shall review that exemption, taking into account market developments and the experience gained in the implementation of this Regulation, shall report on its findings to the European Parliament and to the Council and, if necessary, shall come forward with appropriate legislative proposals.

(*) Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade (OJ L 61, 3.3.1997, p. 1).;

(2) in Article 5, paragraph 9 is replaced by the following:

'9. In order to ensure uniform conditions for the implementation of this Article, the Commission shall, by means of implementing acts, adopt the procedural modalities and the documents of a standard format, including their possible means. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 11(3).;

(3) Article 10 is replaced by the following:

'Article 10

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 11a to amend the list of partner countries and their designated licensing authorities as set out in Annex I.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 11a to amend the list of timber products as set out in Annex II to which the FLEGT licensing scheme applies. In adopting those amendments, the Commission shall take into account the implementation of the FLEGT Partnership Agreements. Such amendments shall comprise commodity codes, at four-digit heading level or six-digit subheading level of the current version of Annex I to the Harmonised Commodity Description and Coding System.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 11a to amend the list of timber products as set out in Annex III to which the FLEGT licensing scheme applies. In adopting those amendments, the Commission shall take into account the implementation of the FLEGT Partnership Agreements. Such amendments shall comprise commodity codes, at four-digit heading level or six-digit subheading level of the current version of Annex I to the Harmonised Commodity Description and Coding System and shall only apply in relation to the corresponding partner countries as set out in Annex III.;

(4) Article 11 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Commission shall be assisted by the Forest Law Enforcement Governance and Trade (FLEGT) Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).

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

(b) paragraph 2 is deleted;

(c) paragraph 3 is replaced by the following:

‘3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.’;

(d) paragraph 4 is deleted;

(5) the following Article is inserted:

‘Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 10(1), (2) and (3) shall be conferred on the Commission for a period of five years from 30 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 10(1), (2) and (3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 10(1), (2) and (3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by four months at the initiative of the European Parliament or of the Council.’.

Article 2

This Regulation shall enter into force on the third day following that of 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 Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

STATEMENT BY THE COMMISSION

In the context of this Regulation, the Commission recalls the commitment it has made in paragraph 15 of the Framework Agreement on relations between the European Parliament and the European Commission to provide to the Parliament full information and documentation on its meetings with national experts within the framework of its work on the preparation of delegated acts.

REGULATION (EU) No 658/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014

on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities
in respect of medicinal products for human use

(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 and point (c) of Article 168(4) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

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

Whereas:

- (1) The revenue of the European Medicines Agency (the 'Agency') consists of a contribution from the Union and fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services as referred to in Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽³⁾.
- (2) The provisions on pharmacovigilance relating to medicinal products for human use ('medicinal products') laid down in Regulation (EC) No 726/2004 and in Directive 2001/83/EC of the European Parliament and of the Council ⁽⁴⁾ were amended by Directive 2010/84/EU of the European Parliament and of the Council ⁽⁵⁾, Regulation (EU) No 1235/2010 of the European Parliament and of the Council ⁽⁶⁾, Directive 2012/26/EU of the European Parliament and of the Council ⁽⁷⁾ and Regulation (EU) No 1027/2012 of the European Parliament and of the Council ⁽⁸⁾. Those amendments provide for new pharmacovigilance tasks for the Agency, including pharmacovigilance procedures carried out at Union level, the monitoring of literature cases and the improved use of information technology tools. Furthermore, those amendments provide that the Agency should be enabled to fund those activities from fees charged to marketing authorisation holders. New types of fees should therefore be created to cover the new and specific tasks of the Agency.

⁽¹⁾ OJ C 67, 6.3.2014, p. 92.

⁽²⁾ Position of the European Parliament of 16 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.

⁽³⁾ 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 (OJ L 136, 30.4.2004, p. 1).

⁽⁴⁾ 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 (OJ L 311, 28.11.2001, p. 67).

⁽⁵⁾ Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, p. 74).

⁽⁶⁾ Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1).

⁽⁷⁾ Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1).

⁽⁸⁾ Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38).

- (3) In order to enable the Agency to charge fees for those new pharmacovigilance tasks, and pending an overall legislative revision of the fees regimes in the medicinal products sector, this Regulation should be adopted. The fees provided for in this Regulation should be applicable without prejudice to the fees laid down in Council Regulation (EC) No 297/95 ⁽¹⁾.
- (4) This Regulation should be based on the dual legal basis of Article 114 and point (c) of Article 168(4) of the Treaty on the Functioning of the European Union (TFEU). It is aimed at financing pharmacovigilance activities that contribute to achieving an internal market as regards medicinal products, taking as a basis a high level of protection of health. At the same time, this Regulation aims to ensure financial resources to support the activities addressing common safety concerns, in order to maintain high standards of quality, safety and efficacy of medicinal products. Both objectives are pursued simultaneously and are inseparably linked, so that one is not secondary to the other.
- (5) The structure and amounts of the fees for pharmacovigilance collected by the Agency, as well as the rules for their payment, should be established. The structure of the fees should be as simple as possible to apply in order to minimise the related administrative burden.
- (6) In line with the Joint Statement of the European Parliament, the Council of the EU and the European Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, the fees set out in this Regulation should be based on an evaluation of the Agency's estimations and forecasts as regards its workload and related costs, and on the basis of an evaluation of the costs of the work carried out by the national competent authorities of the Member States which act as rapporteurs and, where applicable, co-rapporteurs in accordance with Articles 61(6) and 62(1) of Regulation (EC) No 726/2004 and Articles 107e, 107j and 107q of Directive 2001/83/EC.
- (7) The fees established in this Regulation should be transparent, fair and proportionate to the work carried out. Information on those fees should be publicly available. Any future revisions of the pharmacovigilance fees or other fees levied by the Agency should be based on a transparent and independent evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities.
- (8) This Regulation should only regulate fees which are to be levied by the Agency, whereas the competence to decide on possible fees levied by the national competent authorities should remain with the Member States, including in relation to signal detection tasks. Marketing authorisation holders should not be charged twice for the same pharmacovigilance activity. Member States should therefore not levy fees for the activities which are covered by this Regulation.
- (9) For reasons of predictability and clarity, the amounts of the fees should be provided in euro.
- (10) Two different types of fees should be levied under this Regulation in order to take account of the diversity of the tasks of the Agency and of the rapporteurs and, where applicable, co-rapporteurs. First, fees for the pharmacovigilance procedures carried out at Union level should be charged to those marketing authorisation holders whose medicinal products are part of the procedure. Those procedures relate to the assessment of periodic safety update reports, the assessment of post-authorisation safety studies and assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data. Second, an annual fee should be charged for other pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the Eudravigilance database referred to in Article 24 of Regulation (EC) No 726/2004, and the monitoring of selected medical literature.

⁽¹⁾ Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

- (11) Marketing authorisation holders for medicinal products authorised under Regulation (EC) No 726/2004 already pay an annual fee to the Agency for the maintenance of their authorisations, which includes pharmacovigilance activities that are covered by the annual fee established by this Regulation. In order to avoid double charging for those pharmacovigilance activities of the Agency, the annual fee established by this Regulation should not be charged for marketing authorisations granted under Regulation (EC) No 726/2004.
- (12) The work carried out at Union level in respect of the assessment of non-interventional post-authorisation safety studies imposed by the Agency or the national competent authority to be conducted in more than one Member State and of which the protocol has to be endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of those studies, including the assessment of the draft protocol and the assessment of the final study reports. Therefore, the fee levied for that procedure should cover all the work relating to the study. As the legislation on pharmacovigilance encourages the conduct of joint post-authorisation safety studies, marketing authorisation holders should share the applicable fee in cases where a joint study is submitted. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of such post-authorisation safety studies should be exempted from any other fee charged by the Agency or a national competent authority for the submission of those studies.
- (13) For their assessments, rapporteurs rely on the scientific evaluations and resources of national competent authorities, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States. In view of that, and to ensure the existence of adequate resources for the scientific assessments relating to the pharmacovigilance procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and, where applicable, co-rapporteurs appointed by Member States as members of the Pharmacovigilance Risk Assessment Committee referred to in point (aa) of Article 56(1) of Regulation (EC) No 726/2004 or, where relevant, provided by rapporteurs and co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based exclusively on estimations of the workload involved and should be taken into account in setting the level of the fees for pharmacovigilance procedures carried out at Union level. It is recalled that as a matter of good practice, in the context of referrals initiated as a result of the evaluation of pharmacovigilance data, the Pharmacovigilance Risk Assessment Committee generally seeks to avoid appointing as rapporteur the member nominated by the Member State that initiated the referral procedure.
- (14) Fees should be levied on all marketing authorisation holders on a fair basis. Therefore, a chargeable unit should be established, irrespective of the procedure under which the medicinal product has been authorised, either under Regulation (EC) No 726/2004 or under Directive 2001/83/EC, and of the way in which authorisation numbers are assigned by the Member States or the Commission. That objective is met by establishing the chargeable unit on the basis of the active substance(s) and the pharmaceutical form of the medicinal products that are subject to the obligation to be registered in the database referred to in point (l) of the second subparagraph of Article 57(1) of Regulation (EC) No 726/2004, based on information from the list of all medicinal products authorised in the Union referred to in Article 57(2) thereof. The active substance(s) should not be taken into account when establishing the chargeable unit in respect of authorised homeopathic medicinal products or authorised herbal medicinal products.
- (15) In order to take into account the scope of the marketing authorisations of medicinal products granted to marketing authorisation holders, the number of chargeable units corresponding to those authorisations should take into account the number of Member States in which the marketing authorisation is valid.
- (16) In line with the policy of the Union to support small and medium-sized enterprises, reduced fees should apply to small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC⁽¹⁾. Such fees should be established on a basis which takes due account of the ability of small and medium-sized enterprises to pay. Consistent with that policy, micro enterprises within the meaning of that Recommendation should be exempted from all fees under this Regulation.

⁽¹⁾ Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

- (17) Generic medicinal products, medicinal products authorised under the provisions relating to well-established medicinal use, authorised homeopathic medicinal products and authorised herbal medicinal products should be subject to a reduced annual fee, as those medicinal products generally have a well-established safety profile. However, in cases where those medicinal products are part of any of the pharmacovigilance procedures carried out at Union level, the full fee should be charged in view of the work involved.
- (18) Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC should be excluded from the scope of this Regulation as the pharmacovigilance activities for those medicinal products are carried out by the Member States. Medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC should also be excluded from the scope of this Regulation.
- (19) In order to avoid a disproportionate administrative workload for the Agency, the fee reductions and the fee exemption provided for in this Regulation should be applied on the basis of a declaration of the marketing authorisation holder claiming to be entitled to such a fee reduction or exemption. The submission of incorrect information should be discouraged by means of the application of an increase in the amount of the applicable fee in such circumstances.
- (20) For reasons of consistency, deadlines for the payment of fees levied under this Regulation should be established, taking due account of the deadlines of the procedures relating to pharmacovigilance provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC.
- (21) The amounts of the fees and of the remuneration for the rapporteurs and co-rapporteurs provided for under this Regulation should be adjusted, where appropriate, to take account of inflation. For that purpose, the European Index of Consumer Prices published by Eurostat pursuant to Council Regulation (EC) No 2494/95 ⁽¹⁾ should be used. For the purpose of such an adjustment, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (22) Since the objective of this Regulation, namely to ensure adequate funding of pharmacovigilance activities carried out at Union level, cannot sufficiently be achieved by the Member States but can rather, by reason of the scale of the measure, 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.
- (23) For reasons of predictability, legal certainty and proportionality, the annual fee for the information technology systems and literature monitoring should be levied for the first time on 1 July 2015,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation shall apply to fees for pharmacovigilance activities relating to medicinal products for human use ('medicinal products') authorised in the Union under Regulation (EC) No 726/2004 and Directive 2001/83/EC which shall be levied by the European Medicines Agency (the 'Agency') on marketing authorisation holders.

⁽¹⁾ Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices (OJ L 257, 27.10.1995, p. 1).

2. Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC, and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, shall be excluded from the scope of this Regulation.
3. This Regulation establishes the pharmacovigilance activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees to the Agency, and the amounts of remuneration by the Agency for the services provided by the rapporteurs and, where applicable, the co-rapporteurs.
4. Micro enterprises shall be exempted from the payment of any fee under this Regulation.
5. The fees laid down in this Regulation shall apply without prejudice to the fees laid down in Regulation (EC) No 297/95.

Article 2

Definitions

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

- (1) 'chargeable unit' means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in points (b) and (c) of Article 57(2) of Regulation (EC) No 726/2004 to submit such information to the database referred to in point (l) of the second subparagraph of Article 57(1) of that Regulation:
 - (a) name of the medicinal product, as defined in point 20 of Article 1 of Directive 2001/83/EC;
 - (b) marketing authorisation holder;
 - (c) the Member State in which the marketing authorisation is valid;
 - (d) active substance or a combination of active substances; and
 - (e) pharmaceutical form.

Point (d) of the first subparagraph is not applicable in the case of authorised homeopathic medicinal products or authorised herbal medicinal products, as defined, respectively, in points 5 and 30 of Article 1 of Directive 2001/83/EC;
- (2) 'medium-sized enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;
- (3) 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;
- (4) 'micro enterprise' means a micro enterprise within the meaning of Recommendation 2003/361/EC.

Article 3

Types of fees

1. The fees for pharmacovigilance activities shall consist of the following:
 - (a) fees for procedures carried out at Union level as provided for in Articles 4, 5 and 6;

(b) an annual fee as provided for in Article 7.

2. Where a fee is levied by the Agency in accordance with point (a) of paragraph 1 of this Article, the Agency shall pay remuneration, in accordance with Article 9, to the national competent authorities:

(a) for the services provided by the rapporteurs and, where applicable, the co-rapporteurs in the Pharmacovigilance Risk Assessment Committee appointed as members of that Committee by Member States;

(b) for the work carried out by the Member States which act as the rapporteurs and, where applicable, co-rapporteurs in the coordination group.

Article 4

Fee for assessment of periodic safety update reports

1. The Agency shall levy a fee for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004.

2. The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part I of the Annex.

3. Where only one marketing authorisation holder is subject to the obligation to submit a periodic safety update report in the context of the procedures referred to in paragraph 1, the Agency shall levy the total amount of the applicable fee on that marketing authorisation holder.

4. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in paragraph 1, the Agency shall divide the total amount of the fee among those marketing authorisation holders in accordance with point 2 of Part I of the Annex.

5. Where the marketing authorisation holder referred to in paragraphs 3 and 4 is a small or medium-sized enterprise, the amount payable by the marketing authorisation holder shall be reduced as laid down in point 3 of Part I of the Annex.

6. The Agency shall levy the fee under this Article by issuing an invoice to each marketing authorisation holder concerned. The fee shall be due at the date of the start of the procedure for the assessment of the periodic safety update report. Fees due under this Article shall be paid to the Agency within 30 calendar days from the date of the invoice.

Article 5

Fee for assessment of post-authorisation safety studies

1. The Agency shall levy a fee for the assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies referred to in point (b) of Article 21a and point (a) of Article 22a(1) of Directive 2001/83/EC, and in point (cb) of Article 9(4) and point (a) of Article 10a(1) of Regulation (EC) No 726/2004 that are conducted in more than one Member State.

2. The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part II of the Annex.

3. Where the obligation to conduct a post-authorisation safety study is imposed on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the amount payable by each marketing authorisation holder shall be levied as laid down in point 2 of Part II of the Annex.

4. Where the obligation to conduct a post-authorisation safety study is imposed on a marketing authorisation holder which is a small or medium-sized enterprise, the amount payable by the marketing authorisation holder shall be reduced as laid down in point 3 of Part II of the Annex.

5. The Agency shall levy the fee by issuing two invoices to each marketing authorisation holder concerned, one for the assessment of the draft protocol and one for the assessment of the final study report. The relevant part of the fee shall be due at the start of the procedure for the assessment of the draft protocol and at the start of the procedure for the assessment of the final study report, and shall be paid to the Agency within 30 calendar days from the date of the respective invoice.

6. Marketing authorisation holders who are charged the fee under this Article shall be exempted from the payment of any other fee charged by the Agency or a national competent authority for the submission of the studies referred to in paragraph 1.

Article 6

Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data

1. The Agency shall levy a fee for the assessment carried out in the context of a procedure initiated as a result of the evaluation of pharmacovigilance data under the second subparagraph of Article 31(1), Article 31(2) and Articles 107i to 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004.

2. The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part III of the Annex.

3. Where only one marketing authorisation holder is involved in the procedure referred to in paragraph 1 of this Article, the Agency shall levy the total amount of the fee on that marketing authorisation holder, as laid down in point 1 of Part III of the Annex, except in the cases specified in paragraph 5 of this Article.

4. Where two or more marketing authorisation holders are involved in the procedure referred to in paragraph 1 of this Article, the Agency shall divide the total amount of the fee among those marketing authorisation holders in accordance with point 2 of Part III of the Annex.

5. Where the procedure referred to in paragraph 1 of this Article involves one substance or one combination of substances and one marketing authorisation holder, the Agency shall levy a reduced amount of the fee on that marketing authorisation holder and shall remunerate the national competent authority for the services provided by the rapporteur or the co-rapporteur as laid down in point 3 of Part III of the Annex. Where that marketing authorisation holder is a small or medium-sized enterprise, the amount payable shall be reduced as laid down in point 3 of Part III of the Annex.

6. Where the marketing authorisation holder referred to in paragraphs 3 and 4 of this Article is a small or medium-sized enterprise, the amount payable by that marketing authorisation holder shall be reduced as laid down in point 4 of Part III of the Annex.

7. The Agency shall levy the fee by issuing a separate invoice to each marketing authorisation holder involved in the procedure. The fee shall be due at the date of the start of the procedure. Fees due under this Article shall be paid to the Agency within 30 calendar days from the date of the invoice.

*Article 7***Annual fee for information technology systems and literature monitoring**

1. For its pharmacovigilance activities relating to information technology systems under Article 24, Article 25a, Article 26, point (l) of the second subparagraph of Article 57(1) and Article 57(2) of Regulation (EC) No 726/2004 and the monitoring of selected medical literature under Article 27 thereof, the Agency shall levy once per year a fee as laid down in point 1 of Part IV of the Annex (the 'annual fee').

2. The annual fee shall be levied on holders of marketing authorisations for all medicinal products authorised in the Union in accordance with Directive 2001/83/EC, on the basis of the chargeable units corresponding to those medicinal products. Chargeable units corresponding to medicinal products authorised in accordance with Regulation (EC) No 726/2004 shall not be subject to the annual fee.

The total payable amount of the annual fee for each marketing authorisation holder shall be calculated by the Agency on the basis of the chargeable units which correspond to the information recorded on 1 July of each year. That amount shall cover the period from 1 January to 31 December of the year concerned.

3. Where the marketing authorisation holder is a small or medium-sized enterprise, the amount of the annual fee payable by that marketing authorisation holder shall be reduced as laid down in point 2 of Part IV of the Annex.

4. An annual fee which has been reduced as laid down in point 3 of Part IV of the Annex shall apply in respect of medicinal products referred to in Article 10(1) and Article 10a of Directive 2001/83/EC, and in respect of authorised homeopathic medicinal products and authorised herbal medicinal products.

5. Where the marketing authorisation holder of medicinal products referred to in paragraph 4 is a small or medium-sized enterprise, only the fee reduction set out in paragraph 3 shall apply.

6. The annual fee shall be due on 1 July of every year in respect of that calendar year.

The fees due under this Article shall be paid within 30 calendar days from the date of the invoice.

7. The Agency shall retain the fee revenue from the annual fee.

*Article 8***Fee reductions and fee exemption**

1. Any marketing authorisation holder claiming to be a small or medium-sized enterprise entitled to a fee reduction under Article 4(5), Article 5(4), Article 6(5), Article 6(6) or Article 7(3), shall make a declaration to that effect to the Agency within 30 calendar days from the date of the invoice from the Agency. The Agency shall apply the fee reduction on the basis of that declaration.

2. Any marketing authorisation holder claiming to be a micro enterprise entitled to the fee exemption under Article 1(4) shall make a declaration to that effect to the Agency within 30 calendar days from the date of the invoice from the Agency. The Agency shall apply the exemption on the basis of that declaration.

3. Any marketing authorisation holder claiming to be entitled to a reduced annual fee under Article 7(4) shall make a declaration to that effect to the Agency. The Agency shall publish guidance on how that declaration is to be formulated by the marketing authorisation holder. The Agency shall apply the fee reduction on the basis of that declaration. Where the declaration is made by the marketing authorisation holder after the receipt of the invoice from the Agency, the declaration shall be made within 30 calendar days from the date of that invoice.

4. The Agency may at any time request evidence that the conditions for a fee reduction or fee exemption are fulfilled. In such a case, the marketing authorisation holder claiming or having claimed to be entitled to a fee reduction or fee exemption under this Regulation shall submit to the Agency, within 30 calendar days from receipt of the Agency's request, the information necessary to enable the Agency to verify that those conditions are fulfilled.

5. Where a marketing authorisation holder claiming or having claimed to be entitled to a fee reduction or fee exemption under this Regulation fails to demonstrate that it is entitled to such a reduction or exemption, the amount of the fee laid down in the Annex shall be increased by 10 % and the Agency shall levy the resulting full applicable amount or, as appropriate, the balance of the resulting full applicable amount.

Article 9

Payment of remuneration by the Agency to national competent authorities

1. The Agency shall remunerate the national competent authorities for the services provided by rapporteurs and, where applicable, co-rapporteurs in accordance with Article 3(2) in the following cases:

- (a) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the assessment of the periodic safety update reports referred to in Article 4;
- (b) where the coordination group has appointed a Member State which acts as rapporteur and, where applicable, co-rapporteur in the context of the assessment of the periodic safety update reports referred to in Article 4;
- (c) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the assessment of the post-authorisation safety studies referred to in Article 5;
- (d) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the referrals referred to in Article 6.

Where the Pharmacovigilance Risk Assessment Committee or the coordination group decides to appoint a co-rapporteur, the remuneration for the rapporteur and the co-rapporteur shall be determined in accordance with Parts I, II and III of the Annex.

2. The corresponding amounts of the remuneration for each of the activities listed in the first subparagraph of paragraph 1 of this Article are laid down in Parts I, II and III of the Annex.

3. The remuneration provided for in points (a), (b) and (d) of the first subparagraph of paragraph 1 shall be paid only after the final assessment report for a recommendation, which is intended for adoption by the Pharmacovigilance Risk Assessment Committee, has been made available to the Agency. The remuneration for the assessment of post-authorisation safety studies referred to in point (c) of the first subparagraph of paragraph 1 shall be paid in two instalments. The first instalment, relating to the assessment of the draft protocol, and the second instalment, relating to the assessment of the final study report, shall be paid after the respective final assessment reports have been submitted to the Pharmacovigilance Risk Assessment Committee.

4. The remuneration for the services provided by the rapporteur and the co-rapporteur and any related scientific and technical support shall be without prejudice to the obligation of Member States to refrain from giving the members and experts of the Pharmacovigilance Risk Assessment Committee instructions incompatible with the individual tasks of those members and experts in their capacity as rapporteur or co-rapporteur, or incompatible with the tasks and responsibilities of the Agency.

5. The remuneration shall be paid in accordance with the written contract referred to in the first subparagraph of Article 62(3) of Regulation (EC) No 726/2004. Any bank charges related to the payment of that remuneration shall be borne by the Agency.

Article 10

Method of payment of the fee

1. The fees shall be paid in euro.
2. Payment of the fees shall be made only after the marketing authorisation holder has received an invoice issued by the Agency.
3. Payment of the fees shall be made by means of a transfer to the bank account of the Agency. Any bank charges related to that payment shall be borne by the marketing authorisation holder.

Article 11

Identification of the payment of the fee

In every payment the marketing authorisation holder shall indicate the invoice reference number. For payments made via the on-line payment system, the reference number shall be the number automatically generated by the Agency's invoicing system.

Article 12

Date of payment of the fee

The date on which the full amount of the payment is received in the bank account held by the Agency shall be considered to be the date on which the payment has been made. A deadline for payment shall be considered to have been complied with only if the full amount of the fee due has been paid in time.

Article 13

Refund of fee amounts paid in excess

Any amount paid in excess of a fee amount due shall be refunded by the Agency to the marketing authorisation holder, unless otherwise explicitly agreed with the marketing authorisation holder. However, where such an excess amount is less than EUR 100 and the marketing authorisation holder concerned has not expressly requested a refund, the excess amount shall not be refunded.

Article 14

Provisional estimate of Agency budget

The Agency shall, when producing an estimate of revenue and expenditure for the following financial year in accordance with Article 67(6) of Regulation (EC) No 726/2004, include detailed information on income from fees relating to pharmacovigilance activities. That information shall distinguish between the annual fee and the fees for each procedure referred to in point (a) of Article 3(1). The Agency shall also provide specific analytical information on its revenue and expenditure related to pharmacovigilance activities, allowing the annual fee and the fees for each procedure referred to in point (a) of Article 3(1) to be distinguished.

*Article 15***Transparency and monitoring**

1. The amounts and rates laid down in Parts I to IV of the Annex shall be published on the website of the Agency.
2. The Executive Director of the Agency shall provide, as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, the information on the components that may have a bearing on the costs to be covered by the fees provided for in this Regulation. That information shall include a cost breakdown related to the previous year and a forecast for the following year. The Agency shall also publish an overview of that information in its annual report.
3. The Executive Director of the Agency shall also provide the Commission and the Management Board once per year with the performance information set out in Part V of the Annex based on the performance indicators referred to in paragraph 4 of this Article.
4. By 18 July 2015 the Agency shall adopt a set of performance indicators taking into account the information listed in Part V of the Annex.
5. The inflation rate, measured by means of the European Index of Consumer prices published by Eurostat pursuant to Regulation (EC) No 2494/95, shall be monitored in relation to the amounts set out in the Annex. The monitoring shall take place for the first time after this Regulation has been applied during a full calendar year, and thereafter it shall take place annually.
6. Where justified in light of the monitoring referred to in paragraph 5 of this Article, the Commission shall adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs referred to in Parts I to IV of the Annex. Where the delegated act enters into force before 1 July, those adjustments shall take effect as from 1 July. Where the delegated act enters into force after 30 June, they shall take effect as from the date of entry into force of the delegated act.

*Article 16***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 15(6) shall be conferred on the Commission for a period of five years from 17 July 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Article 15(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 15(6) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 17***Transitional provisions**

The fees referred to in Articles 4, 5 and 6 shall not apply to those procedures carried out at Union level for which the assessment has started before 26 August 2014.

*Article 18***Entry into force and application**

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. The annual fee referred to in Article 7 shall be levied as from 1 July 2015.

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

Done at Brussels, 15 May 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

ANNEX

PART I

FEE FOR ASSESSMENT OF PERIODIC SAFETY UPDATE REPORTS REFERRED TO IN ARTICLE 4

1. The fee for the assessment of periodic safety update reports shall be EUR 19 500 per procedure. From that amount, the remuneration for the rapporteur shall be EUR 13 100. That remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).
2. For the purpose of calculating the amount to be levied on each marketing authorisation holder in application of Article 4(4), the Agency shall calculate the proportion of chargeable units held by each marketing authorisation holder concerned of the total number of chargeable units held by all marketing authorisation holders involved in the procedure.

The share payable by each marketing authorisation holder shall be calculated by:

- (a) dividing the total amount of the fee among the marketing authorisation holders concerned proportionately to the number of chargeable units; and
 - (b) subsequently applying the fee reduction as set out in point 3 of this Part and the fee exemption referred to in Article 1(4), where relevant.
3. In application of Article 4(5), small and medium-sized enterprises shall pay 60 % of the applicable amount.
 4. Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally.

PART II

FEE FOR ASSESSMENT OF A POST-AUTHORISATION SAFETY STUDIES REFERRED TO IN ARTICLE 5

1. The fee for the assessment of each post-authorisation safety study shall be EUR 43 000 to be paid in two instalments as follows:
 - (a) EUR 17 200 shall be due at the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; from that amount, the remuneration for the rapporteur shall be EUR 7 280, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s);
 - (b) EUR 25 800 shall be due at the date of the start of the procedure for the assessment of the final study report by the Pharmacovigilance Risk Assessment Committee as referred to in Article 107p of Directive 2001/83/EC; from that amount, the remuneration for the rapporteur shall be EUR 10 920, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).
2. Where marketing authorisation holders conduct a joint post-authorisation safety study as referred to in Article 5(3), the amount payable by each marketing authorisation holder shall be levied by the Agency by evenly dividing the total amount of the fee among those marketing authorisation holders. Where relevant, the fee reduction laid down in point 3 of this Part or, where appropriate, the fee exemption referred to in Article 1(4), shall be applied to the share payable by the marketing authorisation holder.
3. In application of Article 5(4), small and medium-sized enterprises shall pay 60 % of the applicable amount.

4. Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally.

PART III

FEE FOR ASSESSMENT IN THE CONTEXT OF REFERRALS INITIATED AS A RESULT OF THE EVALUATION OF PHARMACOVIGILANCE DATA REFERRED TO IN ARTICLE 6

1. The fee for the assessment of the procedure referred to in Article 6(1) shall be EUR 179 000 where one or two active substances and/or combinations of active substances are included in the assessment. That fee shall be increased by EUR 38 800 per each additional active substance or combination of active substances as of the third active substance or combination of substances. That fee shall not exceed EUR 295 400 irrespective of the number of active substances and/or combinations of active substances.

From the amount of the fee, the total amount of remuneration for the rapporteur and the co-rapporteur(s) shall be as follows:

- (a) EUR 119 333 where one or two active substances and/or combinations of active substances are included in the assessment;
- (b) EUR 145 200 where three active substances and/or combinations of active substances are included in the assessment;
- (c) EUR 171 066 where four active substances and/or combinations of active substances are included in the assessment;
- (d) EUR 196 933 where five or more active substances and/or combinations of active substances are included in the assessment.

Where one or two active substances and/or combinations of active substances are included in the assessment, the Agency shall remunerate the national competent authorities for the services provided by the rapporteur and co-rapporteur(s) by dividing equally the total amount of the remuneration.

Where three or more active substances and/or combinations of active substances are included in the assessment, the Agency shall remunerate the national competent authorities for the services provided by the rapporteur and co-rapporteur(s) by:

- (a) dividing the total amount of the remuneration equally between the national competent authorities; and
 - (b) subsequently increasing the resulting amount of the remuneration for the rapporteur by EUR 1 000 where three substances and/or combinations of active substances are included, by EUR 2 000 where four substances and/or combinations of active substances are included and by EUR 3 000 where five or more active substances and/or combinations of active substances are included. That increase shall be paid from the parts of the fee attributed to the Agency and the co-rapporteur(s), each of which shall contribute the same amount.
2. For the purpose of calculating the amount to be levied on each marketing authorisation holder in application of Article 6(4), the Agency shall calculate the proportion of chargeable units held by each marketing authorisation holder concerned of the total number of chargeable units held by all marketing authorisation holders involved in the procedure.

The amount payable by each marketing authorisation holder shall be calculated by:

- (a) dividing the total amount of the fee among the marketing authorisation holders proportionately to the number of chargeable units; and

- (b) subsequently applying the fee reduction laid down in point 4 of this Part and the fee exemption referred to in Article 1(4), where relevant.

Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and co-rapporteur(s) shall be adapted proportionally.

3. In application of Article 6(5), the amount payable by the marketing authorisation holder shall be two thirds of the applicable fee laid down in point 1 of this Part. Small and medium-sized enterprises shall pay 60 % of that amount.

The total amount of remuneration for the rapporteur and the co-rapporteur(s) from either of the reduced amounts of the fee referred to in the first subparagraph shall correspond to the same proportion as the total amount of remuneration for the rapporteur and the co-rapporteur(s) from the fee laid down in point 1 of this Part for assessments involving one or two active substances and/or combinations of active substances. The Agency shall divide that amount equally between the national competent authorities for the services provided by the rapporteur and the co-rapporteur(s).

4. In application of Article 6(6), small and medium-sized enterprises shall pay 60 % of the applicable amount.

PART IV

ANNUAL FEE FOR INFORMATION TECHNOLOGY SYSTEMS AND LITERATURE MONITORING REFERRED TO IN ARTICLE 7

1. The annual fee shall be EUR 67 per chargeable unit.
2. In application of Article 7(3), small and medium-sized enterprises shall pay 60 % of the applicable amount.
3. Holders of marketing authorisations for medicinal products referred to in Article 7(4) shall pay 80 % of the amount applicable to the chargeable units corresponding to those medicinal products.

PART V

PERFORMANCE INFORMATION

The following information shall relate to each calendar year:

Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of hours outsourced to third parties with specification of the activities concerned and cost incurred.
Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of procedures relating to the assessment of periodic safety update reports, as well as number of marketing authorisation holders and number of chargeable units per procedure; number of reports submitted per procedure and number of marketing authorisation holders that have submitted a joint periodic safety update report.
Number of procedures relating to the assessment of draft protocols and of final reports of post-authorisation safety studies; number of marketing authorisation holders having submitted a draft protocol; number of marketing authorisation holders having submitted a final study report; number of marketing authorisation holders that have submitted a joint study.

Number of procedures relating to the referrals initiated as a result of the evaluation of pharmacovigilance data as well as number of marketing authorisation holders and number of chargeable units involved per marketing authorisation holder and per procedure.

Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure; number of marketing authorisation holders whose claim has been denied.

Number of marketing authorisation holders that have claimed a micro enterprise status; number of marketing authorisation holders whose claim for fee exemption has been denied.

Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees; number of chargeable units per marketing authorisation holder concerned.

Number of invoices sent out and annual fees charged in respect of the annual fee and average and overall amount invoiced to marketing authorisation holders.

Number of marketing authorisation holders that have claimed a small and medium-sized enterprise or a micro enterprise status for each application of the annual fee; number of marketing authorisation holders whose claim has been denied.

Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.

Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

REGULATION (EU) No 659/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014

amending Regulation (EC) No 638/2004 on Community statistics relating to trading of goods between Member States as regards conferring delegated and implementing powers on the Commission for the adoption of certain measures, the communication of information by the customs administration, the exchange of confidential data between Member States and the definition of statistical value

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 338(1) 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) As a consequence of the entry into force of the Treaty on the Functioning of the European Union (TFEU), powers conferred on the Commission should be aligned with Articles 290 and 291 TFEU.
- (2) In connection with the adoption of Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽²⁾, the Commission has committed itself to reviewing, in the light of the criteria laid down in the TFEU, legislative acts which currently contain references to the regulatory procedure with scrutiny.
- (3) Regulation (EC) No 638/2004 of the European Parliament and of the Council⁽³⁾ confers powers on the Commission in order to implement some of its provisions.
- (4) In order to align Regulation (EC) No 638/2004 with Articles 290 and 291 TFEU, implementing powers conferred on the Commission by that Regulation should be replaced by powers to adopt delegated and implementing acts.
- (5) In order to provide a satisfactory response to users' needs for statistical information without imposing excessive burdens on economic operators, to take into account changes necessary for methodological reasons and the necessity to set up an efficient system for the collection of data and the compilation of statistics, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the adoption of different or specific rules applying to specific goods or movements, the adaptation of the Intrastat coverage rates, the specification of the conditions for defining the thresholds referred to in Article 10(4) of Regulation (EC) No 638/2004, the specification of the conditions for simplifying the information to be provided for small individual transactions and the definition of the aggregated data.

⁽¹⁾ Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 6 May 2014.

⁽²⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽³⁾ Regulation (EC) No 638/2004 of the European Parliament and of the Council of 31 March 2004 on Community statistics relating to the trading of goods between Member States and repealing Council Regulation (EEC) No 3330/91 (OJ L 102, 7.4.2004, p. 1).

- (6) When adopting delegated acts, it is particularly important for the Commission to carry out appropriate consultations during its preparatory work, including at expert level. When preparing and drawing up delegated acts, the Commission should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. The Commission should also ensure that the delegated acts provided for in the legislative acts do not impose a significant additional burden on the Member States or on the respondents and that they remain as economical as possible.
- (7) In order to ensure uniform conditions for the implementation of Regulation (EC) No 638/2004, implementing powers should be conferred on the Commission enabling it to adopt the arrangements for collecting information, particularly concerning the codes to be used, the determination of the breakdown of the estimates, technical provisions for compiling annual statistics on trade by business characteristics and any measures necessary to ensure that the quality of the statistics transmitted meets the quality standards. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.
- (8) The Committee for the statistics on the trading of goods between Member States (the 'Intrastat Committee') referred to in Article 14 of Regulation (EC) No 638/2004 provides advice to the Commission and assists it in exercising its implementing powers.
- (9) Under the strategy for a new European Statistical System (ESS) structure intended to improve coordination and partnership in a clear pyramid structure within the ESS, the European Statistical System Committee (ESSC), established by Regulation (EC) No 223/2009 of the European Parliament and of the Council ⁽¹⁾, should have an advisory role and should assist the Commission in exercising its implementing powers. Improving coordination between national authorities and the Commission (Eurostat) is key to producing higher quality statistics in the Union.
- (10) Regulation (EC) No 638/2004 should be amended by replacing the reference to the Intrastat Committee with a reference to the ESSC.
- (11) Simplifications of customs clearance schemes have led to the non-availability, at customs level, of statistical information about goods under customs processing procedures. To assure coverage of the data, movements of those goods should be included in the Intrastat system.
- (12) The exchange of confidential data relating to intra-Union trade statistics should be allowed between Member States with a view to increasing the efficiency of the development, production and dissemination or to improving the quality of those statistics. Such exchanges of confidential data should be voluntary, be treated carefully and not per se entail an increased administrative burden on undertakings.
- (13) The definition of statistical value should be clarified and aligned with the definition of that data element under the extra-Union trade statistics in order to enable better comparability between intra-Union and extra-Union trade statistics. Uniform definitions are essential for the harmonised recording of cross-border trade and are especially important as a prerequisite to enable national authorities to make concordant interpretations of rules having an impact on the cross-border activities of businesses.
- (14) In accordance with the principle of proportionality, it is necessary and appropriate to lay down harmonised rules on the communication of information by the customs administration, the exchange of confidential data between Member States and the definition of statistical value in the domain of intra-Union trade statistics. This Regulation does not go beyond what is necessary to achieve that objective, in accordance with Article 5(4) of the Treaty on European Union.

⁽¹⁾ Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

- (15) Data transmission by the national authorities should be free of charge for the Member States and for the Union institutions and agencies.
- (16) It is important to guarantee the security of the modes of transmission of sensitive statistical data, including economic data.
- (17) To ensure legal certainty, procedures for the adoption of measures which have been initiated but not completed before the entry into force of this Regulation should not be affected by this Regulation.
- (18) Regulation (EC) No 638/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 638/2004 is amended as follows:

- (1) in Article 3, paragraph 4 is replaced by the following:

‘4. The Commission shall be empowered to adopt delegated acts in accordance with Article 13a relating to different or specific rules applying to specific goods or movements.’;

- (2) Article 5 is amended as follows:

- (a) in paragraph 1, the word ‘Community’ is deleted;

- (b) paragraph 2 is replaced by the following:

‘2. The statistical information on dispatches and arrivals of goods which are the subject of a single administrative document for customs or fiscal purposes shall be provided directly by customs to the national authorities, at least once a month.’;

- (c) the following paragraph is inserted:

‘2a. The customs administration responsible in each Member State shall, on its own initiative or at the request of the national authority, provide the national authority with any available information to identify the person who carries out dispatches and arrivals of goods covered by the customs procedures of inward processing or processing under customs control.’;

- (3) Article 6 is replaced by the following:

‘Article 6

Reference period

The reference period for the information to be provided in accordance with Article 5 shall be:

- (a) the calendar month of dispatch or arrival of the goods;
- (b) the calendar month during which the chargeable event occurs for the Community goods on which VAT becomes chargeable on intra-Community acquisitions and supplies; or

(c) the calendar month during which the declaration is accepted by customs where the customs declaration is used as data sources.;

(4) in Article 9(1), the second subparagraph is replaced by the following:

‘Definitions of the statistical data referred to in points (e) to (h) are laid down in the Annex. The Commission shall adopt, by means of implementing acts, the arrangements to collect that information, in particular the codes and the format to be employed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).;

(5) the following Article is inserted:

‘Article 9a

Exchange of confidential data

The exchange of confidential data, as defined in Article 3(7) of Regulation (EC) No 223/2009 of the European Parliament and of the Council (*), may take place for statistical purposes only, between the national authorities responsible in each Member State, where the exchange serves the efficient development, production and dissemination of European statistics relating to the trading of goods between Member States or improves their quality.

National authorities that have obtained confidential data shall treat that information confidentially and shall use it exclusively for statistical purposes in accordance with Chapter V of Regulation (EC) No 223/2009.

(*) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).;

(6) Article 10 is amended as follows:

(a) in paragraph 3, the second subparagraph is replaced by the following:

‘The Commission shall be empowered to adopt delegated acts in accordance with Article 13a to adapt those Intrastat coverage rates to technical and economic developments whenever it is possible to reduce them, while maintaining statistics which meet the quality indicators and standards in force.;

(b) in paragraph 4, the second subparagraph is replaced by the following:

‘The Commission shall be empowered to adopt delegated acts in accordance with Article 13a to specify the conditions for defining those thresholds.;

(c) paragraph 5 is replaced by the following:

‘5. Member States may, under certain conditions that meet quality requirements, simplify the information to be provided for small individual transactions provided that such simplification has no detrimental effects on the quality of the statistics. The Commission shall be empowered to adopt delegated acts in accordance with Article 13a to specify those conditions.;

(7) Article 12 is amended as follows:

(a) in paragraph 1, point (a) is replaced by the following:

'(a) 40 calendar days after the end of the reference month for the aggregated data to be defined by the Commission. The Commission shall be empowered to adopt delegated acts in accordance with Article 13a to define those aggregated data. Those delegated acts shall take into account the relevant economic and technical developments.';

(b) paragraph 2 is replaced by the following:

'2. Member States shall provide the Commission (Eurostat) with monthly results which cover their total trade in goods by using estimates, where necessary. The Commission shall by means of implementing acts, determine the breakdown for such estimates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).';

(c) in paragraph 4, the third subparagraph is replaced by the following:

The Commission shall adopt, by means of implementing acts, technical provisions for compiling those statistics in the most economical way.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).';

(8) in Article 13, paragraph 4 is replaced by the following:

'4. The Commission shall adopt, by means of implementing acts, any measures necessary to ensure the quality of the statistics transmitted in accordance with the quality criteria, avoiding excessive costs for the national authorities.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).';

(9) the following Article is inserted:

'Article 13a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. When exercising the power delegated in Article 3(4), Article 10(3), (4) and (5) and point (a) of Article 12(1) of this Regulation, the Commission shall act in accordance with Article 14(3) of Regulation (EC) No 223/2009, ensuring, inter alia, that the delegated acts do not impose a significant additional burden on the Member States and on the respondents.

It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The power to adopt delegated acts referred to in Article 3(4), Article 10(3), (4) and (5) and point (a) of Article 12(1) shall be conferred on the Commission for a period of five years from 17 July 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

4. The delegation of power referred to in Article 3(4), Article 10(3), (4) and (5) and point (a) of Article 12(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

6. A delegated act adopted pursuant to Article 3(4), Article 10(3), (4) and (5) and point (a) of Article 12(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or the Council.;

(10) Article 14 is replaced by the following:

‘Article 14

Committee procedure

1. The Commission shall be assisted by the European Statistical System Committee established by Regulation (EC) No 223/2009. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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

(11) in the Annex, point 3(b) is replaced by the following:

‘(b) the statistical value, which is the value calculated at the national borders of the Member States. It shall be based on the taxable amount or, where applicable, the value replacing it. It includes only incidental expenses (freight, insurance) incurred, in the case of dispatches, in the part of the journey located on the territory of the Member State of dispatch and, in the case of arrivals, in the part of the journey located outside the territory of the Member State of arrival. It is said to be a fob value (free on board) for dispatches, and a cif value (cost, insurance, freight) for arrivals.’

Article 2

This Regulation shall not affect the procedures for the adoption of measures provided for in Regulation (EC) No 638/2004 that have been initiated but not completed before the entry into force of this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of 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 Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

REGULATION (EU) No 660/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
amending Regulation (EC) No 1013/2006 on shipments of waste

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 192(1) thereof,

Having regard to the proposal from the European Commission,

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

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

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

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

Whereas:

- (1) In order to protect the environment, Regulation (EC) No 1013/2006 of the European Parliament and of the Council ⁽⁴⁾ lays down requirements for shipments of waste both within the Union and between the Member States and third countries. However, divergences and gaps have been identified in the enforcement and inspections carried out by the authorities involved in inspections in Member States.
- (2) Adequate planning of inspections of shipments of waste is necessary to establish the capacity needed for inspections and to effectively prevent illegal shipments. The provisions relating to enforcement and inspections laid down in Article 50 of Regulation (EC) No 1013/2006 should therefore be strengthened with a view to ensuring regular and consistent planning of such inspections. Inspection plans should be established for inspections carried out in accordance with those provisions. Inspection plans should be based on a risk assessment and should include a number of key elements, namely objectives, priorities, the geographical area covered, information on planned inspections, the tasks assigned to authorities involved in inspections, arrangements for cooperation between those authorities involved in inspections in a Member State, in different Member States, as well as, where appropriate, between those authorities in Member States and in third countries, and information on the training of inspectors as well as on the human, financial and other resources for the implementation of the inspection plan concerned.
- (3) Inspection plans may either be drawn up separately or as a clearly defined part of other plans.
- (4) As inspection plans are covered by Directive 2003/4/EC of the European Parliament and of the Council ⁽⁵⁾, the provisions of that Directive, including, where applicable, the exceptions in Article 4 thereof, apply to such plans.

⁽¹⁾ Not yet published in the Official Journal.

⁽²⁾ Not yet published in the Official Journal.

⁽³⁾ Position of the European Parliament of 17 April 2014 (not yet published in the Official Journal) and decision of the Council of 6 May 2014.

⁽⁴⁾ Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).

⁽⁵⁾ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

- (5) The outcome of inspections and the measures taken, including any penalties imposed, should be made available to the public, including electronically via the internet.
- (6) Diverging rules exist throughout the Union as regards the power of, and possibility for, authorities involved in inspections in Member States to require evidence to ascertain the legality of shipments. Such evidence could concern, inter alia, whether the substance or object is waste within the meaning of Regulation (EC) No 1013/2006, whether the waste has been correctly classified, and whether the waste will be shipped to environmentally sound facilities in accordance with Article 49 of that Regulation. Article 50 of Regulation (EC) No 1013/2006 should therefore provide the possibility for authorities involved in inspections in Member States to require such evidence. Such evidence may be requested on the basis of general provisions or on a case-by-case basis. Where such evidence is not made available or is considered to be insufficient, the carriage of the substance or object concerned, or the shipment of waste concerned should be considered as an illegal shipment and should be dealt with in accordance with the relevant provisions of Regulation (EC) No 1013/2006.
- (7) Illegal shipments of waste frequently stem from uncontrolled collection, sorting and storage. Carrying out inspections of shipments of waste in a systematic manner should therefore contribute to identifying and addressing those uncontrolled activities, thereby promoting the implementation of Regulation (EC) No 1013/2006.
- (8) In order to allow sufficient time for Member States to prepare for the application of the measures required under Article 50 of Regulation (EC) No 1013/2006, as amended by this Regulation, it is appropriate that the first inspection plans be adopted by 1 January 2017.
- (9) As a consequence of the entry into force of the Lisbon Treaty, the power conferred on the Commission under Regulation (EC) No 1013/2006 should be aligned with Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).
- (10) The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the amendment of certain non-essential elements of Regulation (EC) No 1013/2006. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (11) In order to ensure uniform conditions for the implementation of Regulation (EC) No 1013/2006, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (12) Regulation (EC) No 1013/2006 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1013/2006 is amended as follows:

- (1) in Article 2, the following points are added:

‘7a. “re-use” is as defined in Article 3(13) of Directive 2008/98/EC of the European Parliament and of the Council (*).

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

35a. “inspection” means actions undertaken by the authorities involved to ascertain whether an establishment, an undertaking, a broker, a dealer, a shipment of waste or the related recovery or disposal complies with the relevant requirements set out in this Regulation.

(*) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).;

(2) in Article 26, paragraph 4 is replaced by the following:

‘4. Subject to the agreement of the competent authorities concerned and of the notifier, the information and documents listed in paragraph 1 may be submitted and exchanged by means of electronic data interchange with electronic signature or electronic authentication in accordance with Directive 1999/93/EC of the European Parliament and of the Council (*), or a comparable electronic authentication system which provides the same level of security.

With a view to facilitating the implementation of the first subparagraph, the Commission shall, where feasible, adopt implementing acts establishing the technical and organisational requirements for the practical implementation of electronic data interchange for the submission of documents and information. The Commission shall take into consideration any relevant international standards, and shall ensure that those requirements are in conformity with Directive 1999/93/EC or provide at least the same level of security as provided for under that Directive. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59a(2).

(*) Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures (OJ L 13, 19.1.2000, p. 12).;

(3) Article 50 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. Member States shall, by way of measures for the enforcement of this Regulation, provide, inter alia, for inspections of establishments, undertakings, brokers and dealers in accordance with Article 34 of Directive 2008/98/EC, and for inspections of shipments of waste and of the related recovery or disposal.’;

(b) the following paragraph is inserted:

‘2a. By 1 January 2017, Member States shall ensure that, in respect of their entire geographical territory, one or more plans are established, either separately or as a clearly defined part of other plans, for inspections carried out pursuant to paragraph 2 (“inspection plan”). Inspection plans shall be based on a risk assessment covering specific waste streams and sources of illegal shipments and considering, if available and where appropriate, intelligence-based data such as data on investigations by police and customs authorities and analyses of criminal activities. That risk assessment shall aim, inter alia, to identify the minimum number of inspections required, including physical checks on establishments, undertakings, brokers, dealers and shipments of waste or on the related recovery or disposal. An inspection plan shall include the following elements:

(a) the objectives and priorities of the inspections, including a description of how those priorities have been identified;

(b) the geographical area covered by that inspection plan;

(c) information on planned inspections, including on physical checks;

- (d) the tasks assigned to each authority involved in inspections;
- (e) arrangements for cooperation between authorities involved in inspections;
- (f) information on the training of inspectors on matters relating to inspections; and
- (g) information on the human, financial and other resources for the implementation of that inspection plan.

An inspection plan shall be reviewed at least every three years and, where appropriate, updated. That review shall evaluate to which extent the objectives and other elements of that inspection plan have been implemented.;

- (c) paragraph 3 is replaced by the following:

‘3. Inspections of shipments may take place in particular:

- (a) at the point of origin, carried out with the producer, holder or notifier;
- (b) at the point of destination, including interim and non-interim recovery or disposal, carried out with the consignee or the facility;
- (c) at the frontiers of the Union; and/or
- (d) during the shipment within the Union.’;

- (d) paragraph 4 is replaced by the following:

‘4. Inspections of shipments shall include the verification of documents, the confirmation of identity and, where appropriate, physical checking of the waste.’;

- (e) the following paragraphs are inserted:

‘4a. In order to ascertain that a substance or object being carried by road, rail, air, sea or inland waterway is not waste, the authorities involved in inspections may, without prejudice to Directive 2012/19/EU of the European Parliament and of the Council (*), require the natural or legal person who is in possession of the substance or object concerned, or who arranges the carriage thereof, to submit documentary evidence:

- (a) as to the origin and destination of the substance or object concerned; and
- (b) that it is not waste, including, where appropriate, evidence of functionality.

For the purpose of the first subparagraph, the protection of the substance or object concerned against damage during transportation, loading and unloading, such as adequate packaging and appropriate stacking, shall also be ascertained.

4b. The authorities involved in inspections may conclude that the substance or object concerned is waste where:

- the evidence referred to in paragraph 4a or required under other Union legislation to ascertain that a substance or object is not waste, has not been submitted within the period specified by them, or
- they consider the evidence and information available to them to be insufficient to reach a conclusion, or they consider the protection provided against damage referred to in the second subparagraph of paragraph 4a to be insufficient.

In such circumstances, the carriage of the substance or object concerned or the shipment of waste concerned shall be considered as an illegal shipment. Consequently, it shall be dealt with in accordance with Articles 24 and 25 and the authorities involved in inspections shall, without delay, inform the competent authority of the country where the inspection concerned took place accordingly.

4c. In order to ascertain whether a shipment of waste complies with this Regulation, the authorities involved in inspections may require the notifier, the person who arranges the shipment, the holder, the carrier, the consignee and the facility that receives the waste to submit relevant documentary evidence to them within a period specified by them.

In order to ascertain whether a shipment of waste falling under the general information requirements of Article 18 is destined for recovery operations which are in accordance with Article 49, the authorities involved in inspections may require the person who arranges the shipment to submit relevant documentary evidence, provided by the interim and non-interim recovery facility and, if necessary, approved by the competent authority of destination.

4d. Where the evidence referred to in paragraph 4c has not been submitted to the authorities involved in inspections within the period specified by them, or they consider the evidence and information available to them to be insufficient to reach a conclusion, the shipment concerned shall be considered as an illegal shipment. Consequently, it shall be dealt with in accordance with Articles 24 and 25 and the authorities involved in inspections shall, without delay, inform the competent authority of the country where the inspection concerned took place accordingly.

4e. By 18 July 2015, the Commission shall adopt, by means of implementing acts, a preliminary correlation table between the codes of the combined nomenclature, provided for in Council Regulation (EEC) No 2658/87 (**), and the entries of waste listed in Annexes III, IIIA, IIIB, IV, IVA and V to this Regulation. The Commission shall maintain that correlation table up-to-date in order to reflect changes to that nomenclature and to the entries listed in those Annexes, as well as to include any new waste-related codes of the Harmonised System Nomenclature that the World Customs Organisation may adopt.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59a(2).

(*) Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (OJ L 197, 24.7.2012, p. 38).

(**) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).;

(f) paragraph 5 is replaced by the following:

‘5. Member States shall cooperate, bilaterally and multilaterally, with one another in order to facilitate the prevention and detection of illegal shipments. They shall exchange relevant information on shipments of waste, flows of waste, operators and facilities and share experience and knowledge on enforcement measures, including the risk assessment carried out pursuant to paragraph 2a of this Article, within established structures, in particular, through the network of correspondents designated in accordance with Article 54.’;

(4) in Article 51, paragraph 2 is replaced by the following:

'2. Before the end of each calendar year, Member States shall also draw up a report for the previous year, based on the additional reporting questionnaire in Annex IX, and shall send it to the Commission. Within a month of transmission of that report to the Commission, Member States shall also make the section of that report relating to Article 24 and Article 50(1), (2) and (2a), including Table 5 of Annex IX, publicly available, including electronically via the internet, together with any explanation that the Member States consider to be appropriate. The Commission shall compile a list of the Member States' hyperlinks referred to in the section relating to Article 50(2) and (2a) in Annex IX and make it publicly available on its website.'

(5) Article 58 is replaced by the following:

'Article 58

Amendment of the Annexes

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 58a to amend the following:

- (a) Annexes IA, IB, IC, II, III, IIIA, IIIB, IV, V, VI and VII to take account of changes agreed under the Basel Convention and the OECD Decision;
- (b) Annex V to reflect agreed changes to the list of waste adopted in accordance with Article 7 of Directive 2008/98/EC;
- (c) Annex VIII to reflect decisions taken under relevant international conventions and agreements.'

(6) the following Article is inserted:

'Article 58a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 58 shall be conferred on the Commission for a period of five years from 17 July 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 58 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 58 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'

(7) Article 59 is deleted;

(8) Article 59a is replaced by the following:

'Article 59a

Committee procedure

1. The Commission shall be assisted by the committee established by Article 39 of Directive 2008/98/EC. That committee is a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.;

(9) in Article 60, the following paragraph is added:

'2a. By 31 December 2020, the Commission shall, taking into account, inter alia, the reports drawn up in accordance with Article 51, carry out a review of this Regulation and submit a report on the results thereof to the European Parliament and to the Council, accompanied, if appropriate, by a legislative proposal. In that review, the Commission shall consider, in particular, the effectiveness of Article 50(2a) in combating illegal shipments, taking into account environmental, social and economic aspects.;

(10) Annex IX is amended as follows:

(a) the section relating to Article 50(2) is replaced by the following:

'Summary information on the outcome of the inspections carried out pursuant to Article 50(2), including:

- number of inspections, including physical checks, of establishments, undertakings, brokers and dealers, related to shipments of waste:
- number of inspections of shipments of waste, including physical checks:
- number of supposed illegalities concerning establishments, undertakings, brokers and dealers, related to shipments of waste:
- number of supposed illegal shipments ascertained during the inspections:

Additional remarks:;

(b) the following section relating to Article 50(2a) is inserted:

'Article 50(2a)

Information on the inspection plan(s)

Number of inspection plan(s) for the entire geographical territory:

The date of adoption of the inspection plan(s) and the period covered by them:

The latest review date of the inspection plan(s):

The authorities involved in inspections and the cooperation amongst those authorities:

Indicate the persons or bodies to which concerns or irregularities can be reported*;

(c) the following section relating to Article 50(2) and (2a) is inserted:

'The link where the information made publicly available via the internet by Member States in accordance with Article 51(2) can be accessed electronically*;

(11) in Annex IX, Table 5, the heading of the last column is replaced by the following:

'Measures taken, including any penalties imposed'.

Article 2

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

It shall apply from 1 January 2016.

Notwithstanding the second paragraph, point (4) of Article 1 shall apply from 1 January 2018.

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

Done at Brussels, 15 May 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

REGULATION (EU) No 661/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
amending Council Regulation (EC) No 2012/2002 establishing the European Union Solidarity Fund

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 the third paragraph of Article 175 and Article 212(2) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social 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) The European Union Solidarity Fund ('the Fund') was established by Council Regulation (EC) No 2012/2002 ⁽⁴⁾.
- (2) It is important for the Union to have at its disposal a sound and flexible instrument to allow it to show solidarity, send a clear political signal and provide genuine assistance to citizens affected by major natural disasters that have serious repercussions on economic and social development.
- (3) The Union's declared intention to assist candidate countries on the path towards stability and sustainable economic and political development through a clear European perspective should not be set back by the adverse effects of major natural disasters. The Union should, therefore, continue to show solidarity with the third countries that are involved in accession negotiations with it, and with which an intergovernmental accession conference has been opened. The inclusion of those countries in the scope of this Regulation entails, as a consequence, recourse to Article 212 of the Treaty on the Functioning of the European Union (TFEU) as an additional legal basis.
- (4) The Commission should be in a position to take a rapid decision to commit specific financial resources and to mobilise them as quickly as possible. Administrative procedures should be adjusted accordingly and limited to the minimum necessary. To that end, the European Parliament, the Council and the Commission concluded the Interinstitutional Agreement of 2 December 2013 on budgetary discipline, on cooperation in budgetary matters and on sound financial management ⁽⁵⁾.

⁽¹⁾ Opinion of 10 December 2013 (not yet published in the Official Journal).

⁽²⁾ Opinion of 28 November 2013 (not yet published in the Official Journal).

⁽³⁾ Position of the European Parliament of 16 April 2014 (not yet published in the Official Journal) and decision of the Council of 6 May 2014.

⁽⁴⁾ Council Regulation (EC) No 2012/2002 of 11 November 2012 establishing the European Union Solidarity Fund (OJ L 311, 14.11.2012, p. 3).

⁽⁵⁾ Interinstitutional Agreement between the European Parliament, the Council and the Commission of 2 December 2013 on budgetary discipline, on cooperation in budgetary matters and on sound financial management (OJ C 373, 20.12.2013, p. 1).

- (5) The terminology contained in, and procedures laid down under, Regulation (EC) No 2012/2002 should be aligned with the provisions of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ⁽¹⁾.
- (6) The definition of a natural disaster, which determines the scope of Regulation (EC) No 2012/2002, should be unambiguous.
- (7) Damage caused by other types of disaster that through a cascading effect are the direct consequence of a natural disaster should, for the purposes of Regulation (EC) No 2012/2002, be considered to be part of the direct damage caused by that natural disaster.
- (8) In order to codify established practice and to ensure equal treatment of applications financial contributions from the Fund should be awarded in respect of direct damage only.
- (9) A major natural disaster within the meaning of Regulation (EC) No 2012/2002 should be further defined as a disaster that has caused direct damage above a threshold expressed in financial terms. Such damage should be expressed in the prices of a reference year, or as a percentage of the gross national income (GNI) of the State concerned.
- (10) In order to better take into account the specific nature of natural disasters which, although having serious repercussions for the economic and social development of the regions concerned, do not reach the minimum scale required to benefit from a financial contribution from the Fund, the criteria for regional natural disasters should be determined based on the damage calculable by reference to regional gross domestic product (GDP), whereby the specific structural social and economic situation, compounded by the special features of Guadeloupe, French Guiana, Martinique, Réunion, Mayotte, Saint-Martin, the Azores, Madeira and the Canary Islands, as outermost regions within the meaning of Article 349 TFEU, justifies the establishment for them of a special threshold of 1 % of the GDP as a derogation. Those criteria should be determined in a clear and simple manner in order to reduce the possibility of applications being submitted which do not meet the requirements set out in Regulation (EC) No 2012/2002.
- (11) For the purposes of determining direct damage, data with a harmonised format, provided by Eurostat, should be used in order to allow an equitable treatment of applications.
- (12) The Fund should contribute to the restoration of infrastructure to working order, to the cleaning up of disaster-stricken areas and to the costs of rescue services and temporary accommodation for the population concerned during the whole implementation period. The meaning of restoration of infrastructure to working order should be defined, and the extent to which the Fund will be able to contribute to the corresponding costs clarified. The time-frame during which it is possible to consider the accommodation of people made homeless by a natural disaster to be temporary should also be defined.
- (13) The provisions of Regulation (EC) No 2012/2002 should be aligned with the general Union funding policy in relation to value added tax.
- (14) It should also be specified to what extent it is possible for eligible operations to include expenditure for technical assistance.
- (15) In order to preclude beneficiary States from making a net profit from an intervention through the Fund, the conditions under which operations financed by the Fund are able to generate revenue should be specified.

⁽¹⁾ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

- (16) Certain types of natural disaster, such as, inter alia, droughts, develop over an extended period of time before their effects are felt. Provisions should be laid down in order to allow the use of the Fund also in such cases.
- (17) It is important to ensure that eligible States make the requisite efforts to prevent natural disasters from occurring and to mitigate their effects, including by full implementation of relevant Union legislation on disaster risk prevention and management and the use of available Union funding for relevant investments. Provisions should therefore be laid down to make it possible for a failure, as established by a final judgment of the Court of Justice of the European Union, by a Member State to comply with relevant Union legislation on disaster risk prevention and management after having received a financial contribution from the Fund for an earlier natural disaster, to result in the rejection of the application or a reduction of the amount of the financial contribution in the event of a further application in relation to a natural disaster of the same nature.
- (18) It is possible that Member States require financial support in response to a natural disaster more rapidly than is possible through the normal procedure. For this purpose, it is appropriate to provide for the possibility of making an advance payment upon request by the Member State concerned shortly after the application for a financial contribution from the Fund has been submitted to the Commission. The advance should not exceed a certain amount and it should be accounted for when the final amount of the financial contribution is paid out. Unduly paid advances should be repaid by the Member State within a determined short period of time. The payment of an advance should not prejudice the outcome of the final decision on the mobilisation of the Fund.
- (19) Administrative procedures for the payment of a financial contribution should be as simple and time-efficient as possible. Detailed provisions on the implementation of the financial contribution from the Fund should therefore be contained, for Member States, in the implementing acts awarding that financial contribution. However, for beneficiary States which are not yet Member States, separate implementation agreements should be maintained for legal reasons.
- (20) The Commission should issue guidance in order to assist the Member States on how to effectively access and use the Fund, and how to apply in the simplest way for assistance from the Fund.
- (21) Regulation (EU, Euratom) No 966/2012 introduced changes in shared and indirect management, including specific reporting requirements which should be taken into account. Reporting obligations should reflect the short implementation period of the Fund operations. The procedures for the designation of the bodies responsible for the management and control of Union funds should reflect the nature of the instrument and not delay the payment of the financial contribution from the Fund. It is therefore necessary to derogate from Regulation (EU, Euratom) No 966/2012.
- (22) Provisions should be laid down to avoid double financing of operations financed by the Fund with other financial instruments of the Union or international legal instruments relating to the compensation of specific damage.
- (23) Declaring expenditure that countries have made from a financial contribution from the Fund should be as simple as possible. A single exchange rate should therefore be used throughout the implementation of the financial contribution for countries that are not members of the euro area.
- (24) In order to ensure uniform conditions for the implementation of Regulation (EC) No 2012/2002, implementing powers should be conferred on the Commission with respect to decisions on particular financial contributions or on any advance payments from the Fund to eligible States.
- (25) The provisions laid down in Regulation (EC) No 2012/2002 governing the protection of financial interests of the Union should be made more specific so as to clearly identify measures for the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used.

- (26) Since the objectives of this Regulation, namely to ensure Union-wide solidarity action to support natural disaster-stricken States, cannot be sufficiently achieved by the Member States on an ad-hoc basis, but can rather, by reason of applying a systematic, regular and equitable method of granting financial support involving all Member States according to their capacity, 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 to achieve those objectives.
- (27) Regulation (EC) No 2012/2002 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments

Regulation (EC) No 2012/2002 is amended as follows:

- (1) Article 2 is replaced by the following:

Article 2

1. At the request of a Member State or of a country involved in accession negotiations with the Union, hereinafter referred to as “eligible State”, assistance from the Fund may be mobilised when serious repercussions on living conditions, the natural environment or the economy occur in one or more regions of that eligible State as a consequence of a major or regional natural disaster having taken place on the territory of the same eligible State or of a neighbouring eligible State. Direct damage caused as the direct consequence of a natural disaster shall be regarded as part of the damage caused by that natural disaster.

2. For the purposes of this Regulation, a “major natural disaster” means any natural disaster resulting, in an eligible State, in direct damage estimated either at over EUR 3 000 000 000 in 2011 prices, or more than 0,6 % of its GNI.

3. For the purposes of this Regulation, a “regional natural disaster” means any natural disaster resulting, in a region at NUTS level 2 of an eligible State, in direct damage in excess of 1,5 % of that region’s gross domestic product (GDP).

By way of derogation from the first subparagraph, where the region concerned, in which a natural disaster has occurred, is an outermost region within the meaning of Article 349 of the Treaty on the Functioning of the European Union, “regional natural disaster” means any natural disaster resulting in direct damage in excess of 1 % of that region’s GDP.

Where the natural disaster concerns several regions at NUTS level 2, the threshold shall be applied to the average GDP of those regions weighted according to the share of total damage in each region.

4. Assistance from the Fund may also be mobilised for any natural disaster in an eligible State which is also a major natural disaster in a neighbouring eligible State.

5. For the purpose of this Article harmonised statistical data provided by Eurostat shall be used.;

(2) Article 3 is amended as follows:

(a) paragraphs 1, 2 and 3 are replaced by the following:

‘1. The assistance shall take the form of a financial contribution from the Fund. For each natural disaster a single financial contribution shall be awarded to an eligible State.

2. The aim of the Fund is to complement the efforts of the States concerned and to cover part of their public expenditure in order to help the eligible State to carry out, depending on the type of natural disaster, the following essential emergency and recovery operations:

(a) restoring the working order of infrastructure and plant in the fields of energy, water and waste water, telecommunications, transport, health and education;

(b) providing temporary accommodation and funding rescue services to meet the needs of the population concerned;

(c) securing preventive infrastructure and measures of protection of cultural heritage;

(d) cleaning up disaster-stricken areas, including natural zones, in line with, where appropriate, eco-system based approaches, as well as immediate restoration of affected natural zones to avoid immediate effects from soil erosion.

For the purposes of point (a), “restoring the working order” means restoring infrastructure and plant to their condition prior to the occurrence of the natural disaster. Where it is not legally possible or economically justified to restore the condition prior to the occurrence of the natural disaster, or where the beneficiary State decides to relocate or improve the functionality of the infrastructure or plant affected in order to improve its capacity to withstand future natural disasters, the Fund may contribute to the cost of restoration only up to the estimated cost of returning to its status quo ante.

Costs in excess of the level of cost referred to in the second subparagraph shall be financed by the beneficiary State from its own or, where possible, from other Union funds.

For the purposes of point (b), “temporary accommodation” means accommodation that lasts until the population concerned are able to return to their original homes following their repair or reconstruction.

3. Payments from the Fund are limited to financing measures alleviating non-insurable damage and shall be recovered if the cost of repairing the damage is subsequently met by a third party in accordance with Article 8(4).;

(b) the following paragraphs are added:

‘4. Value added tax (VAT) shall not constitute eligible expenditure of an operation, unless it is non-recoverable under national VAT legislation.

5. Technical assistance for management, monitoring, information and communication, complaint resolution, and control and auditing, shall not be eligible for a financial contribution from the Fund.

Costs relating to the preparation and implementation of the operations referred to in paragraph 2, including costs relating to essential technical expertise, shall be eligible as part of project costs.

6. Where revenue is generated from the operations referred to in paragraph 2 with a financial contribution from the Fund, the total financial contribution from the Fund shall not exceed the total net costs of emergency and recovery operations borne by the beneficiary State. The beneficiary State shall include a statement to that effect in the report on the implementation of the financial contribution from the Fund pursuant to Article 8(3).

7. On 1 October each year, at least one-quarter of the annual amount of the Fund should remain available in order to cover needs arising until the end of the year.;

(3) Article 4 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. As soon as possible and no later than 12 weeks after the first occurrence of damage as a consequence of a natural disaster, the responsible national authorities of an eligible State may submit an application for a financial contribution from the Fund to the Commission providing, as a minimum, all available information on:

- (a) the total direct damage caused by the natural disaster and its impact on the population, the economy and the environment concerned;
- (b) the estimated cost of the operations referred to in Article 3(2);
- (c) any other sources of Union funding;
- (d) any other sources of national or international funding, including public and private insurance coverage which might contribute to the costs of repairing the damage;
- (e) a short description of the implementation of Union legislation on disaster risk prevention and management related to the nature of the natural disaster.;

(b) the following paragraphs are inserted:

‘1a. In justified cases the responsible national authorities may submit, after the deadline referred to in paragraph 1, additional information in order to complete or update their application.

1b. The Commission shall prepare guidance on how to access and implement the Fund effectively. The guidance shall be drawn up by 30 September 2014 and shall provide detailed information on the procedures for drafting the application, including requirements for the information to be submitted to the Commission. The guidance shall be made public on the websites of the relevant Directorate Generals of the Commission and the Commission shall ensure its wider dissemination to eligible States.

1c. In the event of a progressively unfolding natural disaster, the deadline referred to in paragraph 1 shall run from the date on which the public authorities of the eligible State take official action for the first time against the effects of the natural disaster or from the date they declare a state of emergency.;

(c) paragraphs 2 to 5 are replaced by the following:

2. On the basis of the information referred to in paragraph 1, and any clarifications to be provided by the eligible State, the Commission shall assess whether the conditions for mobilising the Fund are met and shall determine the amount of any possible financial contribution from the Fund as quickly as possible and no later than six weeks after receipt of the application, counting from the date of receipt of the complete application and excluding the time needed for translation, within the limits of the financial resources available.

If the Commission decides on a financial contribution from the Fund based on an application received after 28 June 2014 for a natural disaster falling under the scope of this Regulation, it may reject a further application for a financial contribution relating to a natural disaster of the same nature or reduce the amount to be made available where the Member State is the subject of infringement proceedings and the Court of Justice of the European Union has delivered a final judgment that the Member State concerned has failed to implement Union legislation on disaster risk prevention and management, which is directly linked to the nature of the natural disaster suffered.

The Commission shall treat all applications for a financial contribution from the Fund in an equitable manner.

3. When the Commission has concluded that the conditions are met for providing a financial contribution from the Fund, the Commission shall without delay submit to the European Parliament and the Council the necessary proposals for mobilisation of the Fund and to authorise the corresponding appropriations. Those proposals shall include:

- (a) all available information, as referred to in paragraph 1;
- (b) all other relevant information in the possession of the Commission;
- (c) a demonstration that the conditions of Article 2 are met; and
- (d) a justification of the amounts proposed.

The decision to mobilise the Fund shall be taken jointly by the European Parliament and the Council as soon as possible after the submission of the proposal by the Commission.

Both the Commission, on the one hand, and the European Parliament and the Council, on the other hand, shall endeavour to minimise the time taken to mobilise the Fund.

4. Once the appropriations are made available by the European Parliament and the Council, the Commission shall adopt a decision, by means of an implementing act, awarding the financial contribution from the Fund and shall pay that financial contribution immediately and in a single instalment to the beneficiary State. If an advance has been paid pursuant to Article 4a only the balance shall be paid.

5. The eligibility period for expenditure shall begin on the date of the first occurrence of damage as referred to in paragraph 1. In the event of a progressively unfolding natural disaster, the eligibility period for expenditure shall begin on the date on which the public authorities of the eligible State take action for the first time or from the date they declare a state of emergency, as referred to in paragraph 1c.;

(4) the following Article is inserted:

'Article 4a

1. When submitting an application for a financial contribution from the Fund to the Commission, a Member State may request the payment of an advance. The Commission shall make a preliminary assessment of whether the application fulfils the conditions laid down in Article 4(1) and verify the availability of budgetary resources. Where those conditions are fulfilled and sufficient resources are available, the Commission may adopt a decision, by means of an implementing act, awarding the advance and pay it out without delay before the decision referred to in Article 4(4) has been taken. The payment of an advance shall be made without prejudice to the final decision on the mobilisation of the Fund.

2. The amount of the advance shall not exceed 10 % of the amount of the financial contribution anticipated and shall in no case exceed EUR 30 000 000. Once the definitive amount of the financial contribution has been determined, the Commission shall take into account the sum of the advance prior to the balance of the financial contribution being paid. The Commission shall recover unduly paid advances.

3. Any repayment due to be made to the general budget of the Union shall be effected before the due date indicated in the order for recovery drawn up in accordance with the Article 78 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (*). The due date shall be the last day of the second month following the issue of the order.

4. When adopting the draft general budget of the Union for a given financial year, the Commission shall, where necessary in order to ensure the timely availability of budgetary resources, propose to the European Parliament and the Council to mobilise the Fund in an amount up to a maximum of EUR 50 000 000 for the payment of advances and propose to enter the corresponding appropriations into the general budget of the Union.

The budgetary arrangements shall comply with the ceilings referred to in Article 10(1) of Council Regulation (EU, Euratom) No 1311/2013 (**).

(*) Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

(**) Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884);

(5) Article 5 is replaced by the following:

'Article 5

1. An implementing act adopted pursuant to Article 4(4) shall contain in its Annex detailed provisions for the implementation of the financial contribution from the Fund.

Those provisions shall describe, in particular, the type and location of operations to be financed by the Fund following a proposal by the eligible State.

2. Before paying out a financial contribution from the Fund to an eligible State that is not a Member State, the Commission shall conclude a delegation agreement with that State laying down detailed provisions for the implementation of the financial contribution from the Fund referred to in paragraph 1 in accordance with Regulation (EU, Euratom) No 966/2012 and Commission Delegated Regulation (EU) No 1268/2012 (*), as well as the obligations relating to natural disaster risk prevention and management.

3. Responsibility for selecting individual operations and implementing the financial contribution from the Fund shall lie with the beneficiary State, in accordance with this Regulation, in particular Article 3(2) and (3), the implementing act referred to in Article 4(4) and, where applicable, the delegation agreement referred to in paragraph 2 of this Article.

4. The financial contribution from the Fund to a Member State shall be implemented within the framework of shared management in accordance with Regulation (EU, Euratom) No 966/2012. The financial contribution from the Fund to an eligible State that is not a Member State shall be implemented within the framework of indirect management in accordance with that Regulation.

5. Without prejudice to the Commission's responsibility for implementing the general budget of the Union, beneficiary States shall take responsibility for the management of operations supported by the Fund and the financial control of the operations. The measures they take shall include:

- (a) verifying that management and control arrangements have been set up and are being implemented in such a way as to ensure that Union funds are being used efficiently and correctly, in accordance with the principles of sound financial management;
- (b) verifying that the financed actions have been properly carried out;
- (c) ensuring that expenditure funded is based on verifiable supporting documents, and is correct and regular;
- (d) preventing, detecting and correcting irregularities and recovering amounts unduly paid together with interest on late payments where appropriate. They shall notify any such irregularities to the Commission, and keep the Commission informed of the progress of administrative and legal proceedings.

6. Beneficiary States shall designate bodies responsible for the management and control of the operations supported by the Fund in accordance with Articles 59 and 60 of Regulation (EU, Euratom) No 966/2012. In doing so they shall take into account criteria on internal environment, control activities, information and communication, and monitoring. Member States may designate the bodies already designated under Regulation (EU) No 1303/2013 of the European Parliament and of the Council (**).

Those designated bodies shall provide the Commission with the information set out in Article 59(5) or Article 60(5) of Regulation (EU, Euratom) No 966/2012 covering the whole of the implementation period when submitting the report and the statement referred to in Article 8(3) of this Regulation.

7. The beneficiary State shall make the financial corrections required where an irregularity is ascertained. The corrections made by the beneficiary State shall consist of cancelling all or part of the financial contribution from the Fund. The beneficiary State shall recover any amount lost as a result of an irregularity detected.

8. Without prejudice to the powers of the Court of Auditors or the checks carried out by the beneficiary State in accordance with national laws, regulations and administrative provisions, the Commission may carry out on-the-spot checks on the operations financed by the Fund. The Commission shall give notice to the beneficiary State with a view to obtaining all the assistance necessary. Officials or other servants of the Member State concerned may take part in such checks.

9. The beneficiary State shall ensure that all supporting documents regarding expenditure incurred are kept available for the Commission and the Court of Auditors for a period of three years following the closure of the assistance from the Fund.

(*) Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

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

(6) Article 6 is replaced by the following:

'Article 6

1. The beneficiary State shall be responsible for coordinating the financial contribution from the Fund to the operations referred to in Article 3, on the one hand, with assistance from the European Structural and Investment Funds, the European Investment Bank and other Union financing instruments, on the other.

2. The beneficiary State shall ensure that expenditure reimbursed in accordance with this Regulation shall not be reimbursed through other Union financing instruments in particular through instruments of cohesion, agricultural or fisheries policy.

3. Damage repaired under Union or international instruments relating to the compensation of specific damage shall not be eligible for assistance from the Fund for the same purpose.;

(7) Article 7 is replaced by the following:

'Article 7

Operations financed by the Fund shall be compatible with the provisions of the Treaty and instruments adopted under it, with Union policies and measures, in particular in the fields of financial management, public procurement, environmental protection, natural disaster risk prevention and management, climate change adaptation including, where appropriate, eco-system based approaches, and with pre-accession assistance instruments. Where applicable, operations financed by the Fund shall contribute to the objectives of Union in those fields.;

(8) Articles 8 and 9 are replaced by the following:

'Article 8

1. The financial contribution from the Fund shall be used within eighteen months from the date on which the Commission has disbursed the full amount of the assistance. Any part of the financial contribution remaining unused by that deadline or found to be used for ineligible operations shall be recovered by the Commission from the beneficiary State.

2. Beneficiary States shall seek all possible compensation from third parties.

3. No later than six months after the expiry of the eighteen months period referred to in paragraph 1, the beneficiary State shall present a report on the implementation of the financial contribution from the Fund with a statement justifying the expenditure, indicating any other source of funding received for the operations concerned, including insurance settlements and compensation from third parties.

The implementation report shall detail:

- (a) the preventive measures, taken or proposed by the beneficiary State to limit future damage and to avoid, to the extent possible, a recurrence of similar natural disasters, including the use of Union Structural and Investment Funds for this purpose;
- (b) the state of implementation of relevant Union legislation on disaster risk prevention and management;
- (c) the experience gained from the natural disaster and the measures taken or proposed to ensure environmental protection and resilience in relation to climate change and natural disasters; and
- (d) any other relevant information on prevention and mitigation measures taken related to the nature of the natural disaster.

The implementation report shall be accompanied by an opinion of an independent audit body, drawn up in accordance with internationally accepted audit standards, establishing that the statement justifying the expenditure gives a true and fair view and that the financial contribution from the Fund is legal and regular, in line with Article 59(5) and Article 60(5) of Regulation (EU, Euratom) No 966/2012.

At the end of the procedure referred to in the first subparagraph, the Commission shall carry out a closure of the assistance from the Fund.

4. Where the cost of repairing the damage is subsequently met by a third party, the Commission shall require the beneficiary State to reimburse a corresponding amount of the financial contribution from the Fund.

Article 9

Applications for a financial contribution from the Fund and the implementing acts referred to in Article 4(4), as well as the delegation agreement, reports and any other related documents shall express all amounts in euros.

Amounts of expenditure incurred in national currencies shall be converted into euros at the exchange rates published in the C series of the *Official Journal of the European Union* for the day on which the related implementing act has been adopted by the Commission. Where no exchange rate is published in the *Official Journal of the European Union* for the day on which the related implementing act has been adopted by the Commission, conversion shall be made at the average of the monthly accounting rates established by the Commission, determined over that period. This single exchange rate shall be used throughout the implementation of the financial contribution from the Fund and as the basis for the final implementation report and the statement on the implementation and the elements required under Article 59(5) or Article 60(5) of Regulation (EU, Euratom) No 966/2012 of the financial contribution.';

(9) in Article 10, paragraph 2 is replaced by the following:

'2. In the event of a significantly lower valuation of the damage incurred, as shown by new elements, the beneficiary State shall reimburse the corresponding amount of the financial contribution from the Fund to the Commission.';

(10) Article 11 is replaced by the following:

Article 11

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all funding beneficiaries, contractors, subcontractors who have received Union funds under this Regulation.

3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council (*) and Council Regulation (Euratom, EC) No 2185/96 (**) with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a contract concerning Union funding.

4. Without prejudice to paragraphs 1, 2 and 3, delegation agreements with third countries, contracts and decisions awarding a financial contribution from the Fund resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

(*) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

(**) 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's financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).;

(11) Articles 13 and 14 are deleted.

Article 2

Entry into force

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

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

Done at Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

REGULATION (EU) No 662/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
amending Regulation (EU) No 525/2013 as regards the technical implementation of the Kyoto
Protocol to the United Nations Framework Convention on Climate Change
(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 192(1) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

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

Whereas:

- (1) On 8 December 2012, at its eighth session, the Conference of the Parties to the United Nations Framework Convention on Climate Change (UNFCCC) serving as the meeting of the Parties to the Kyoto Protocol, adopted the Doha Amendment, establishing a second commitment period of the Kyoto Protocol, starting on 1 January 2013 and ending on 31 December 2020 (the 'Doha Amendment').
- (2) Article 4 of the Kyoto Protocol provides for the possibility for Parties to fulfil their commitments under Article 3 of the Kyoto Protocol jointly. At the time of adoption of the Doha Amendment, the Union and its Member States, together with Croatia and Iceland, stated that the quantified emission limitation and reduction commitments for the Union, its Member States, Croatia and Iceland for the second commitment period under the Kyoto Protocol are based on the understanding that these will be fulfilled jointly in accordance with Article 4 of the Kyoto Protocol. That statement is reflected in the Report of the Conference and was endorsed by the Council on 17 December 2012.
- (3) The Kyoto Protocol requires Parties that have reached an agreement to fulfil their commitments under Article 3 of the Kyoto Protocol jointly to set out in that agreement the respective emission level allocated to each of them. The Kyoto Protocol requires the Parties to a joint fulfilment agreement to notify the UNFCCC Secretariat of the terms of that agreement on the date of deposit of their instruments of acceptance.
- (4) The conclusion of the Doha Amendment, the implementation of accompanying decisions of the Conference of the Parties to the UNFCCC serving as the meeting of the Parties to the Kyoto Protocol and a joint fulfilment agreement will require the establishment of rules to ensure the technical implementation of the second commitment period of

⁽¹⁾ Opinion of 26 February 2014 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 16 April 2014 (not yet published in the Official Journal) and decision of the Council of 13 May 2014.

the Kyoto Protocol in the Union, including the transition from the first to the second commitment period, to enable the effective operation of a joint fulfilment agreement, and to ensure its alignment with the operation of the Union's Emissions Trading System (the 'EU ETS') established by Directive 2003/87/EC of the European Parliament and of the Council ⁽¹⁾ and Decision 406/2009/EC of the European Parliament and of the Council ⁽²⁾.

- (5) During the first commitment period of the Kyoto Protocol, the internationally agreed requirements for the accounting and management of emissions and units and the joint fulfilment by the Union and its Member States were implemented pursuant to Decision No 280/2004/EC of the European Parliament and of the Council ⁽³⁾, Commission Regulation (EC) No 2216/2004 ⁽⁴⁾ and Commission Regulation (EU) No 920/2010 ⁽⁵⁾. Regulations (EC) No 2216/2004 and (EU) No 920/2010 have been replaced by Commission Regulation (EU) No 389/2013 ⁽⁶⁾, which contains provisions on unit management related to the implementation and operation of the EU ETS and Decision No 406/2009/EC. The recently adopted Regulation (EU) No 525/2013 of the European Parliament and of the Council ⁽⁷⁾, which repealed and replaced Decision No 280/2004/EC, does not contain the legal basis that would enable the Commission to adopt the necessary technical implementation rules for the second commitment period of the Kyoto Protocol in accordance with the terms of the Doha Amendment, the decisions of the Conference of the Parties to the UNFCCC serving as the meeting of the Parties to the Kyoto Protocol and a joint fulfilment agreement.
- (6) Where a Member State is seriously disadvantaged by a specific and exceptional situation, including accounting inconsistencies in matching the implementation of Union legislation with the rules agreed under the Kyoto Protocol, without prejudice to the fulfilment of the Member State's obligations under Decision No 406/2009/EC, the Commission should, subject to the availability of units at the end of the second commitment period of the Kyoto Protocol, adopt measures to address that situation, by means of a transfer of certified emission reductions (CERs), emission reduction units (ERUs) or assigned amount units (AAUs) held in the Union registry to the registry of that Member State.
- (7) In order to ensure uniform conditions for the implementation of Article 10(7) of Regulation (EU) No 525/2013, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽⁸⁾.
- (8) Decision 1/CMP.8 of the Conference of the Parties to the UNFCCC serving as the meeting of the Parties to the Kyoto Protocol ('Decision 1/CMP.8') amends the rules for the establishment of eligibility to participate in the flexible mechanisms during the second commitment period of the Kyoto Protocol. It also sets limits on the carry-over of units from the first to the second commitment period, and includes a requirement for each Party to establish an account for the previous period surplus reserve. Moreover, that Decision provides for a 2 % share of the proceeds to be levied on the first international transfers of AAUs and on the issuance of ERUs for joint implementation projects immediately upon the conversion to ERUs of AAUs or of removal units (RMUs) previously held by Parties. Further rules for the implementation of the second commitment period of the Kyoto Protocol are currently being negotiated.

⁽¹⁾ Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC (OJ L 275, 25.10.2003, p. 32).

⁽²⁾ Decision No 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020 (OJ L 140, 5.6.2009, p. 136).

⁽³⁾ Decision No 280/2004/EC of the European Parliament and of the Council of 11 February 2004 concerning a mechanism for monitoring Community greenhouse gas emissions and for implementing the Kyoto Protocol (OJ L 49, 19.2.2004, p. 1).

⁽⁴⁾ Commission Regulation (EC) No 2216/2004 of 21 December 2004 for a standardised and secured system of registries pursuant to Directive 2003/87/EC of the European Parliament and of the Council and Decision No 280/2004/EC of the European Parliament and of the Council (OJ L 386, 29.12.2004, p. 1).

⁽⁵⁾ Commission Regulation (EU) No 920/2010 of 7 October 2010 establishing a Union Registry for the periods ending 31 December 2012 of the Union emissions trading scheme pursuant to Directive 2003/87/EC of the European Parliament and of the Council and Decision No 280/2004/EC of the European Parliament and of the Council (OJ L 270, 14.10.2010, p. 1).

⁽⁶⁾ Commission Regulation (EU) No 389/2013 of 2 May 2013 establishing a Union Registry pursuant to Directive 2003/87/EC of the European Parliament and of the Council, Decisions No 280/2004/EC and No 406/2009/EC of the European Parliament and of the Council and repealing Commission Regulations (EU) No 920/2010 and (EU) No 1193/2011 (OJ L 122, 3.5.2013, p. 1).

⁽⁷⁾ Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change and repealing Decision No 280/2004/EC (OJ L 165, 18.6.2013, p. 13).

⁽⁸⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (9) In the delegated acts to be adopted in accordance with this Regulation, the Commission should provide for a clearing process at the end of the second commitment period of the Kyoto Protocol, whereby any net transfers of annual emission allocations in accordance with Decision No 406/2009/EC, and any net transfers of allowances with third countries participating in the EU ETS which are not part of a joint fulfilment agreement with the Union and its Member States, are followed by a transfer of a corresponding number of AAUs.
- (10) The relevant international rules governing the accounting for emissions and progress towards achievement of commitments are expected to be adopted at the next climate conference to be held in Lima in December 2014. The Union and its Member States should work with third countries to help ensure this.
- (11) Pursuant to Decision 1/CMP.8, which requires Parties to revisit their commitment for the second commitment period at the latest by 2014, cancelling a number of AAUs, CERs and ERUs in order to increase the ambition of their commitment could be considered.
- (12) In order to establish coherent rules to ensure the technical implementation of the second commitment period of the Kyoto Protocol in the Union, including the transition from the first to the second commitment period, to enable the effective operation of the joint fulfilment of the commitments of the Union, its Member States and Iceland for the second commitment period, and to ensure its alignment with the operation of the EU ETS and Decision No 406/2009/EC, the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, from the date of conclusion by the Union of the Doha Amendment to the end of the additional period for fulfilling commitments under the second commitment period of the Kyoto Protocol. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council, as well as their consistency with internationally agreed accounting requirements, a joint fulfilment agreement concluded between the Union, its Member States and third countries under Articles 3 and 4 of the Kyoto Protocol, and relevant Union legislation.
- (13) The Council conclusions of 9 March 2012 state that the Union's quantified emission limitation or reduction objective during the second commitment period is determined on the basis of the Union's total greenhouse gas emissions allowed during the period 2013-20 under its climate and energy legislative package, thus reflecting the Union's unilateral commitment to a 20 % reduction by 2020, and in this context confirm that with this approach, the emission reduction obligations of individual Member States should not exceed their obligations agreed in Union legislation.
- (14) Compliance with the limits established by the relevant decisions of the UNFCCC or Kyoto Protocol bodies on the carry-over of ERUs and CERs from the first to the second commitment period should be ensured.
- (15) Regulation (EU) No 525/2013 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 525/2013 is amended as follows:

- (1) the following points are inserted in Article 3:

'(13a) "commitment period reserve" or "CPR" means the reserve established pursuant to the Annex to Decision 11/CMP.1 or other relevant decisions of the UNFCCC or Kyoto Protocol bodies;

- (13b) “previous period surplus reserve” or “PPSR” means the account established pursuant to Decision 1/CMP.8 of the Conference of the Parties to the UNFCCC serving as the meeting of the Parties to the Kyoto Protocol (“Decision 1/CMP.8”) or other relevant decisions of the UNFCCC or Kyoto Protocol bodies;
- (13c) “joint fulfilment agreement” means the terms of an agreement, in accordance with Article 4 of the Kyoto Protocol, between the Union, its Member States and any third country to fulfil their commitments under Article 3 of the Kyoto Protocol, for the second commitment period, jointly;”;

(2) Article 10 is amended as follows:

(a) in paragraph 1, the following subparagraph is added:

‘The Union and the Member States shall each, in their respective registries set up pursuant to the first subparagraph, account for their respective assigned amounts in the second commitment period of the Kyoto Protocol and perform the transactions referred to in the first subparagraph, in accordance with Decision 1/CMP.8 or other relevant decisions of the UNFCCC or Kyoto Protocol bodies and with a joint fulfilment agreement. To that effect, the Union and each Member State shall each in their respective registries:

- set up and manage party holding accounts, including a deposit account, and issue an amount of AAUs corresponding to their respective assigned amounts for the second commitment period of the Kyoto Protocol into those party holding accounts,
- account for the issue, holding, transfer, acquisition, cancellation, retirement, replacement or change of expiry date of AAUs, RMUs, ERUs, CERs, tCERs and ICERs, as relevant, held in their respective registries for the second commitment period of the Kyoto Protocol,
- establish and maintain a commitment period reserve,
- carry over AAUs, CERs and ERUs held in their respective registries from the first to the second commitment period of the Kyoto Protocol, and establish a previous period surplus reserve and manage AAUs held therein,
- account for the transfer of AAUs or ERUs, as a share of proceeds following the issue of ERUs and on the first international transfer of AAUs.;

(b) the following paragraphs are added:

‘5. The Commission shall also be empowered to adopt delegated acts in accordance with Article 25 in order to give effect, by means of the registries of the Union and of the Member States, to the necessary technical implementation of the Kyoto Protocol pursuant to Decision 1/CMP.8 or other relevant decisions of the UNFCCC or Kyoto Protocol bodies and a joint fulfilment agreement, in accordance with paragraph 1.

6. The Commission shall also be empowered to adopt delegated acts in accordance with Article 25 to ensure that:

- any net transfers of annual emission allocations in accordance with Decision No 406/2009/EC and any net transfers of allowances with third countries participating in the scheme established for greenhouse gas emissions trading within the Union by Directive 2003/87/EC which are not parties to a joint fulfilment agreement, are followed by a transfer of a corresponding number of AAUs through a clearing process at the end of the second commitment period of the Kyoto Protocol,

- those transactions which are necessary to align the application of the limits established by decisions of the UNFCCC or Kyoto Protocol bodies on the carry-over of ERUs and CERs from the first to the second commitment period of the Kyoto Protocol with the implementation of Article 11a of Directive 2003/87/EC are performed; such transactions shall be without prejudice to the ability of Member States to carry over further ERUs and CERs from the first to the second commitment period for other purposes, provided that the limits for the carry-over of ERUs and CERs from the first to the second commitment period of the Kyoto Protocol are not exceeded.

7. Where a Member State is seriously disadvantaged by a specific and exceptional situation, including accounting inconsistencies in matching the implementation of Union legislation with the rules agreed under the Kyoto Protocol, the Commission may, subject to the availability of units at the end of the second commitment period of the Kyoto Protocol, adopt measures to address that situation. For that purpose, the Commission shall be empowered to adopt implementing acts to transfer CERs, ERUs or AAUs held in the Union registry to the registry of that Member State. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 26(2). The power to adopt those implementing acts shall be conferred on the Commission from the date of conclusion by the Union of the Doha Amendment to the Kyoto Protocol.

8. When adopting the delegated acts under paragraphs 5 and 6, the Commission shall ensure consistency with Directive 2003/87/EC and Decision 406/2009/EC and a consistent implementation of internationally agreed accounting requirements, optimise transparency and ensure accuracy of the accounting of AAUs, RMUs, ERUs, CERs, tCERs and ICERs by the Union and the Member States, while avoiding, to the extent possible, administrative burdens and costs, including those relating to share of proceeds and IT development and maintenance. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.;

(3) in Article 11, the following paragraph is added:

'3. The Union and the Member States shall each, at the end of the second commitment period under the Kyoto Protocol, and in accordance with Decision 1/CMP.8 or other relevant decisions of the UNFCCC or Kyoto Protocol bodies and a joint fulfilment agreement, retire from their respective registries AAUs, RMUs, ERUs, CERs, tCERs or ICERs equivalent to the greenhouse gas emissions from sources and removals by sinks covered by their respective assigned amounts.;

(4) Article 25 is amended as follows:

(a) in paragraph 2, the first sentence is replaced by the following:

'The power to adopt delegated acts referred to in Articles 6, 7 and Article 10(4) shall be conferred on the Commission for a period of five years from 8 July 2013.;

(b) the following paragraph is inserted:

'2a. The power to adopt delegated acts referred to in Article 10(5) and (6) shall be conferred on the Commission from the date of conclusion by the Union of the Doha Amendment to the Kyoto Protocol to the end of the additional period for fulfilling commitments under the second commitment period of the Kyoto Protocol.;

(5) in Article 26, the following paragraph is added:

'3. In the case of Article 10(7), where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.;

Article 2

This Regulation shall enter into force on the twentieth day following that of 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 Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

DIRECTIVES

DIRECTIVE 2014/64/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 May 2014

amending Council Directive 64/432/EEC as regards computer databases which are part of the surveillance networks in the Member States

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),

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

- (1) Council Directive 64/432/EEC ⁽³⁾ applies to trade in bovine animals and swine within the Union. It provides that the competent authority in a Member State may introduce a system of surveillance networks. Those networks include a computer database which is to contain, as a minimum, a number of elements laid down in Directive 64/432/EEC, including the identification code of each animal.
- (2) Regulation (EC) No 1760/2000 of the European Parliament and of the Council ⁽⁴⁾ establishes a system for the identification and registration of bovine animals. It requires as a general rule that the two official means of identification allocated to an animal bear the same identification code. However, during the initial phase of adjustment to the use of electronic identifiers as an official means of identification, it could not be excluded that, in certain cases, technical limitations related to the configuration of an animal's original identification code could prevent the reproduction of that code on an electronic identifier. This could occur where the characters forming an animal's existing identification code prevent that code from being converted into an electronic format. Therefore, Regulation (EC) No 1760/2000 provides for specific transitory derogations to allow the application of an electronic identifier also to those animals, provided that full traceability is ensured and that the animals can be identified individually, including the holding on which they were born. The possibility of using such electronic identifiers should be reflected in the list of elements of the computer databases laid down in Directive 64/432/EEC.
- (3) In the interest of consistency of Union legislation, the type of electronic identifier, if applied to the animals, should also be added to the list of elements to be included in the computer databases laid down in Directive 64/432/EEC.

⁽¹⁾ OJ C 43, 15.2.2012, p. 64.

⁽²⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 6 May 2014.

⁽³⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64).

⁽⁴⁾ Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

(4) Directive 64/432/EEC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In part C of Article 14(3) of Directive 64/432/EEC, point (1) is replaced by the following:

‘(1) for each animal:

- the unique identification code or codes, as regards the cases set out in Articles 4(1), 4b, 4c(1) and 4d of Regulation (EC) No 1760/2000 of the European Parliament and of the Council (*),
- date of birth,
- sex,
- breed or colour of coat,
- identification code of the mother or, in the case of an animal imported from a third country, the unique identification code of the individual means of identification allocated to the animal by the Member State of destination in accordance with Regulation (EC) No 1760/2000,
- identification number of the holding where born,
- identification numbers of all holdings where the animal has been kept and the dates of each change of holding,
- date of death or slaughter,
- the type of electronic identifier, if applied to the animal.

(*) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).’

Article 2

1. By 18 January 2016, Member States shall bring into force, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those measures from 18 July 2019.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 May 2014
on the harmonisation of the laws of the Member States relating to the making available on the
market of pressure equipment
(recast)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

- (1) Directive 97/23/EC of the European Parliament and of the Council ⁽³⁾ has been substantially amended ⁽⁴⁾. Since further amendments are to be made, that Directive should be recast in the interests of clarity.
- (2) Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽⁵⁾ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (3) Decision No 768/2008/EC of the European Parliament and of the Council ⁽⁶⁾ lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 97/23/EC should therefore be adapted to that Decision.
- (4) This Directive covers pressure equipment and assemblies which are new to the Union market when they are placed on the market; that is to say they are either new pressure equipment or assemblies made by a manufacturer established in the Union or pressure equipment or assemblies, whether new or second-hand, imported from a third country.
- (5) This Directive should apply to all forms of supply, including distance selling.

⁽¹⁾ OJ C 67, 6.3.2014, p. 101.

⁽²⁾ Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 13 May 2014.

⁽³⁾ Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1).

⁽⁴⁾ See Annex V, Part A.

⁽⁵⁾ 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 and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

⁽⁶⁾ 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 and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

- (6) This Directive should apply to pressure equipment subject to a maximum allowable pressure PS greater than 0,5 bar. Pressure equipment subject to a pressure of not more than 0,5 bar does not pose a significant risk due to pressure. Therefore, there should not be any obstacle to its free movement within the Union.
- (7) This Directive should also apply to assemblies composed of several pieces of pressure equipment assembled to constitute an integrated and functional whole. Those assemblies may range from simple assemblies such as pressure cookers to complex assemblies such as water tube boilers. If the manufacturer of an assembly intends to place it on the market and put it into service as an assembly — and not in the form of its constituent non-assembled elements — that assembly should comply with this Directive. However, this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations.
- (8) This Directive should harmonise national provisions on risks due to pressure. The other risks which this equipment may present may fall within the scope of other Directives dealing with those risks.
- (9) However, some pressure equipment is covered by other Directives based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). The provisions laid down in some of those Directives deal also with the risk due to pressure. Those Directives are considered adequate to provide appropriate protection where the risk due to pressure associated with such equipment remains small. Therefore, such equipment should be excluded from the scope of this Directive.
- (10) For some pressure equipment covered by international agreements for its international transport, national transport and pressure hazards and risks are dealt with by Union Directives based on such agreements. Those Directives extend the application of those agreements to national transport, in order to ensure the free movement of dangerous goods whilst enhancing transport safety. Such equipment which is covered by Directive 2008/68/EC of the European Parliament and of the Council ⁽¹⁾ and by Directive 2010/35/EU of the European Parliament and of the Council ⁽²⁾ should be excluded from the scope of this Directive.
- (11) Certain types of pressure equipment, although subject to a maximum allowable pressure PS greater than 0,5 bar, do not present any significant risk due to pressure, and therefore the free movement of such equipment in the Union should not be hindered if it has been legally manufactured or placed on the market in a Member State. It is not necessary in order to ensure free movement of such equipment to include it within the scope of this Directive. Consequently it should be expressly excluded from its scope.
- (12) Other pressure equipment subject to a maximum allowable pressure greater than 0,5 bar and presenting a significant risk due to pressure, but in respect of which free movement and an appropriate level of safety are guaranteed, should be excluded from the scope of this Directive. Such exclusions should, however, be regularly reviewed in order to ascertain whether it is necessary to take action at Union level.
- (13) The scope of this Directive should be based on a general definition of the term 'pressure equipment' so as to allow for the technical development of products.
- (14) Compliance with the essential safety requirements is necessary in order to ensure the safety of pressure equipment. Those requirements should be subdivided into general and specific requirements that need to be met by pressure equipment. In particular the specific requirements should take account of particular types of pressure equipment. Certain types of pressure equipment in categories III and IV should be subject to a final assessment comprising final inspection and proof tests.

⁽¹⁾ Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

⁽²⁾ Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).

- (15) Member States should be in a position to allow the showing at trade fairs of pressure equipment which is not yet in conformity with the requirements of this Directive. During demonstrations, appropriate safety measures should be taken in accordance with the general safety rules of the Member State concerned to ensure the safety of persons.
- (16) Directive 97/23/EC provides for a classification of pressure equipment in categories, according to the ascending level of hazard. This includes the classification of the fluid contained in the pressure equipment as dangerous or not, according to Council Directive 67/548/EEC ⁽¹⁾. On 1 June 2015 Directive 67/548/EEC is to be repealed and replaced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾, which implements in the Union the Globally Harmonised System of Classification and Labelling of Chemicals that has been adopted at international level, within the United Nations structure. Regulation (EC) No 1272/2008 introduces new hazard classes and categories only partially corresponding to those provided for by Directive 67/548/EEC. Directive 97/23/EC should therefore be aligned to Regulation (EC) No 1272/2008 while maintaining the existing levels of protection provided for in that Directive.
- (17) Economic operators should be responsible for the compliance of pressure equipment and assemblies with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons, and the protection of domestic animals and of property, and to guarantee fair competition on the Union market.
- (18) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market pressure equipment and assemblies which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (19) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (20) In order to facilitate the communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (21) It is necessary to ensure that pressure equipment and assemblies from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that pressure equipment or those assemblies. Provision should therefore be made for importers to make sure that the pressure equipment or assembly they place on the market complies with the requirements of this Directive and that they do not place on the market pressure equipment or assemblies which do not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that marking of pressure equipment or assemblies and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (22) When placing pressure equipment or assemblies on the market, every importer should indicate on the pressure equipment or assembly his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the pressure equipment or assembly does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the pressure equipment or assembly.

⁽¹⁾ Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (23) The distributor makes pressure equipment or assemblies available on the market after they have been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the pressure equipment or assembly does not adversely affect the compliance of the pressure equipment or assembly with the requirements of this Directive.
- (24) Any economic operator that either places pressure equipment or assemblies on the market under his own name or trademark or modifies pressure equipment or assemblies in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (25) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the pressure equipment or assembly concerned.
- (26) Ensuring traceability of pressure equipment and assemblies throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant pressure equipment or assemblies available on the market.
- (27) When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with pressure equipment or an assembly or to whom they have supplied pressure equipment or an assembly.
- (28) This Directive should be limited to the expression of the essential safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for pressure equipment or assemblies which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁽¹⁾ for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, manufacture and testing of pressure equipment or assemblies.
- (29) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (30) Manufacturing of pressure equipment calls for the utilisation of safe materials. In the absence of harmonised standards the characteristics of the materials intended for repeated use should be established. Those characteristics should be established by European approvals for materials, such approvals being issued by one of the notified bodies specifically designated for that task. The materials conforming to the European approvals should benefit from a presumption of conformity with the essential safety requirements of this Directive.
- (31) In view of the nature of the risks involved in the use of pressure equipment and assemblies and in order to enable economic operators to demonstrate and the competent authorities to ensure that pressure equipment or assemblies made available on the market comply with the essential safety requirements, it is necessary to provide for conformity assessment procedures. Those procedures should be devised in the light of the level of hazard which is inherent in the pressure equipment or assembly. Therefore, for each category of pressure equipment

⁽¹⁾ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

there should be an adequate procedure or a choice between different procedures of equivalent stringency. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. The details added to those procedures are justified by the nature of the verification required for pressure equipment.

- (32) Member States should be in a position to authorise user inspectorates to carry out certain tasks for conformity assessment in the framework of this Directive. For that purpose this Directive should set out criteria for the authorisation of user inspectorates by Member States.
- (33) Under certain procedures for conformity assessment it should be possible for each item to be inspected and tested by a notified body or a user inspectorate as part of the final assessment of the pressure equipment or assembly. In other cases provision should be made to ensure that the final assessment may be monitored by a notified body by means of unexpected visits.
- (34) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of the pressure equipment or assembly with the requirements of this Directive and of other relevant Union harmonisation legislation.
- (35) To ensure effective access to information for market surveillance purposes, in cases where pressure equipment or an assembly is covered by several pieces of Union harmonisation legislation, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (36) A check on compliance with the essential safety requirements is necessary in order to provide effective protection for consumers, other users and third parties.
- (37) Pressure equipment and assemblies should, as a general rule, bear the CE marking. The CE marking, indicating the conformity of pressure equipment or assemblies, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (38) For pressure equipment defined in this Directive which presents only a minor pressure risk and for which certification procedures are therefore not justified, the CE marking should not be affixed.
- (39) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (40) Experience has shown that the criteria set out in Directive 97/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of those bodies throughout the Union. It is, however, essential that all conformity assessment bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (41) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.

- (42) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of conformity assessment bodies.
- (43) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (44) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (45) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the pressure equipment or assembly to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (46) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (47) Since conformity assessment bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (48) In the interests of competitiveness, it is crucial that conformity assessment bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between conformity assessment bodies.
- (49) Member States should take all appropriate measures to ensure that pressure equipment and assemblies may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Pressure equipment or assemblies should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (50) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred to the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.

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

- (51) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (52) The examination procedure should be used for the adoption of implementing acts with respect to European approvals for materials presenting shortcomings and whose references were already published in the *Official Journal of the European Union*, given that such decisions could have consequences on the presumption of conformity with the applicable essential requirements.
- (53) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant pressure equipment or assemblies which present a risk to the health or safety of persons, to domestic animals or to property, imperative grounds of urgency so require.
- (54) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (55) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (56) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant pressure equipment or assemblies are justified or not.
- (57) In order to take into account emerging very serious safety reasons, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to classification of pressure equipment or assemblies. The reclassification should be based on appropriate evidence and justification in each case. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (58) The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (59) Directive 97/23/EC provides for a transitional arrangement enabling pressure equipment and assemblies which comply with the national regulations in force on the date of application of Directive 97/23/EC to be put into service. For reasons of legal certainty, it is necessary to include that transitional arrangement also in this Directive.
- (60) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and the putting into service, without the need to comply with further product requirements, of pressure equipment and assemblies that have already been placed on the market in accordance with Directive 97/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply pressure equipment and assemblies that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (61) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

- (62) Since the objective of this Directive, namely to ensure that pressure equipment or assemblies on the market fulfil the requirements providing a high level of protection of health and safety of persons and protection of domestic animals or property while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, 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.
- (63) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (64) This Directive should be without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of the Directive set out in Annex V, Part B,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Scope

1. This Directive shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.
2. This Directive shall not apply to:
 - (a) pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines; this exclusion shall not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;
 - (b) networks for the supply, distribution and discharge of water and associated equipment and headraces such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;
 - (c) simple pressure vessels covered by Directive 2014/29/EU of the European Parliament and of the Council ⁽¹⁾;
 - (d) aerosol dispensers covered by Council Directive 75/324/EEC ⁽²⁾;
 - (e) equipment intended for the functioning of vehicles defined by the following legal acts:
 - (i) Directive 2007/46/EC of the European Parliament and of the Council ⁽³⁾;

⁽¹⁾ Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45).

⁽²⁾ Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40).

⁽³⁾ Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1).

- (ii) Regulation (EU) No 167/2013 of the European Parliament and of the Council ⁽¹⁾;
- (iii) Regulation (EU) No 168/2013 of the European Parliament and of the Council ⁽²⁾;
- (f) equipment classified as no higher than category I under Article 13 of this Directive and covered by one of the following Directives:
 - (i) Directive 2006/42/EC of the European Parliament and of the Council ⁽³⁾;
 - (ii) Directive 2014/33/EU of the European Parliament and of the Council ⁽⁴⁾;
 - (iii) Directive 2014/35/EU of the European Parliament and of the Council ⁽⁵⁾;
 - (iv) Council Directive 93/42/EEC ⁽⁶⁾;
 - (v) Directive 2009/142/EC of the European Parliament and of the Council ⁽⁷⁾;
 - (vi) Directive 2014/34/EU of the European Parliament and of the Council ⁽⁸⁾;
- (g) equipment covered by point (b) of Article 346(1) TFEU;
- (h) items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
- (i) well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure; this shall comprise the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;
- (j) equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; such equipment may include:
 - (i) engines including turbines and internal combustion engines;
 - (ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;

⁽¹⁾ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

⁽²⁾ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

⁽³⁾ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

⁽⁴⁾ Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).

⁽⁵⁾ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).

⁽⁶⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁽⁷⁾ Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10).

⁽⁸⁾ Directive 2014/34/EU of the European Parliament and the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309).

- (k) blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel, iron and non-ferrous metals;
- (l) enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;
- (m) pressurised pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;
- (n) ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;
- (o) pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;
- (p) exhaust and inlet silencers;
- (q) bottles or cans for carbonated drinks for final consumption;
- (r) vessels designed for the transport and distribution of drinks having a PS·V of not more than 500 bar·L and a maximum allowable pressure not exceeding 7 bar;
- (s) equipment covered by Directive 2008/68/EC and Directive 2010/35/EU and equipment covered by the International Maritime Dangerous Goods Code and the Convention on International Civil Aviation;
- (t) radiators and pipes in warm water heating systems;
- (u) vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.

Article 2

Definitions

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

- (1) 'pressure equipment' means vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs;
- (2) 'vessel' means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment; a vessel may be composed of more than one chamber;
- (3) 'piping' means piping components intended for the transport of fluids, when connected together for integration into a pressure system; piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components as appropriate; heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping;
- (4) 'safety accessories' means devices designed to protect pressure equipment against the allowable limits being exceeded, including devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid level switches and safety related measurement control and regulation (SRMCR) devices;

- (5) 'pressure accessories' means devices with an operational function and having pressure-bearing housings;
- (6) 'assemblies' means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;
- (7) 'pressure' means pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value;
- (8) 'maximum allowable pressure PS' means the maximum pressure for which the equipment is designed, as specified by the manufacturer, and defined at a location specified by him, being either the connection of protective and/or limiting devices, or the top of equipment or, if not appropriate, any point specified;
- (9) 'maximum/minimum allowable temperature TS' means the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer;
- (10) 'volume (V)' means the internal volume of a chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts;
- (11) 'nominal size (DN)' means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size; it is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions; the nominal size is designated by DN followed by a number;
- (12) 'fluids' means gases, liquids and vapours in pure phase as well as mixtures thereof; fluids may contain a suspension of solids;
- (13) 'permanent joints' means joints which cannot be disconnected except by destructive methods;
- (14) 'European approval for materials' means a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonised standard;
- (15) 'making available on the market' means any supply of pressure equipment or assemblies for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (16) 'placing on the market' means the first making available of pressure equipment or assemblies on the Union market;
- (17) 'putting into service' means the first use of pressure equipment or an assembly by its user;
- (18) 'manufacturer' means any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name or trademark or uses it for his own purposes;
- (19) '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;
- (20) 'importer' means any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market;

- (21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the market;
- (22) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by pressure equipment or assemblies;
- (24) 'harmonised standard' means harmonised standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012;
- (25) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (26) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (27) 'conformity assessment' means the process demonstrating whether the essential safety requirements of this Directive relating to pressure equipment or assemblies have been fulfilled;
- (28) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (29) 'recall' means any measure aimed at achieving the return of pressure equipment or assemblies that have already been made available to consumers or other users;
- (30) 'withdrawal' means any measure aimed at preventing pressure equipment or assemblies in the supply chain from being made available on the market;
- (31) 'CE marking' means a marking by which the manufacturer indicates that the pressure equipment or assembly is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (32) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

Article 3

Making available on the market and putting into service

1. Member States shall take all appropriate measures to ensure that pressure equipment and assemblies may be made available on the market and put into service only if they satisfy the requirements of this Directive when properly installed and maintained and used for the purposes for which they are intended.
2. This Directive shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment or assembly in question provided that this does not mean modifications to such equipment or assembly in a way not specified in this Directive.
3. At trade fairs, exhibitions, demonstrations and other similar events, Member States shall not prevent the showing of pressure equipment or assemblies which do not comply with this Directive, provided that a visible sign clearly indicates that such pressure equipment or assemblies may not be made available on the market and/or put into service until they are brought into conformity. During demonstrations, appropriate safety measures shall be taken in accordance with any requirements laid down by the competent authority of the Member State concerned in order to ensure the safety of persons.

*Article 4***Technical requirements**

1. The following pressure equipment shall satisfy the essential safety requirements set out in Annex I:
 - (a) vessels, except those referred to in point (b), for:
 - (i) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 25 bar·L, or with a pressure PS greater than 200 bar (Annex II, table 1),
 - for fluids in Group 2, with a volume greater than 1 L and a product of PS and V is greater than 50 bar·L, or with a pressure PS greater than 1 000 bar, and all portable extinguishers and bottles for breathing apparatus (Annex II, table 2);
 - (ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar·L, or with a pressure PS greater than 500 bar (Annex II, table 3),
 - for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10 000 bar·L, or with a pressure PS greater than 1 000 bar (Annex II, table 4);
 - (b) fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or superheated water at temperatures higher than 110 °C having a volume greater than 2 L, and all pressure cookers (Annex II, table 5);
 - (c) piping intended for:
 - (i) gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a DN greater than 25 (Annex II, table 6),
 - for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1 000 bar (Annex II, table 7);
 - (ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2 000 bar (Annex II, table 8),
 - for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5 000 bar (Annex II, table 9).
 - (d) safety and pressure accessories intended for equipment covered by points (a), (b), and (c) including where such equipment is incorporated into an assembly.

2. The following assemblies which include at least one item of pressure equipment covered by paragraph 1 shall satisfy the essential safety requirements set out in Annex I:

- (a) assemblies intended for generating steam or superheated water at a temperature higher than 110 °C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating;
- (b) assemblies other than those referred to in point (a), if the manufacturer intends them to be made available on the market and put into service as assemblies.

By way of derogation from the first subparagraph, assemblies intended for generating warm water at temperatures not greater than 110 °C which are manually fed with solid fuels and have a PS·V greater than 50 bar·L shall comply with the essential safety requirements referred to in points 2.10, 2.11, 3.4, 5 (a) and 5 (d) of Annex I.

3. Pressure equipment and assemblies below or equal to the limits set out in points (a), (b) and (c) of paragraph 1 and in paragraph 2 respectively shall be designed and manufactured in accordance with the sound engineering practice of a Member State in order to ensure safe use. Pressure equipment and assemblies shall be accompanied by adequate instructions for use.

Without prejudice to other applicable Union harmonisation legislation providing for its affixing, such equipment or assemblies shall not bear the CE marking referred to in Article 18.

Article 5

Free movement

1. Member States shall not, on grounds of the risks due to pressure, prohibit, restrict or impede the making available on the market or the putting into service under the conditions specified by the manufacturer of pressure equipment or assemblies which comply with this Directive.

Member States shall not, on grounds of the risks due to pressure, prohibit, restrict or impede the making available on the market or the putting into service of pressure equipment or assemblies which comply with Article 4(3).

2. When a Member State has designated a user inspectorate in accordance with the requirements set out in Article 25, it may not, on grounds of the risks due to pressure, prohibit, restrict or impede the placing on the market or putting into service under the conditions provided for in Article 16, of pressure equipment or assemblies the conformity of which has been assessed by a user inspectorate designated by another Member State in accordance with the requirements set out in Article 25.

3. Member States may require, to the extent that it is needed for safe and correct use of pressure equipment and assemblies, the information referred to in points 3.3 and 3.4 of Annex I to be provided in the official language(s) of the Union which may be determined by the Member State in which the equipment or assembly is made available on the market.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6

Obligations of manufacturers

1. When placing their pressure equipment or assemblies referred to in Article 4(1) and (2) on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.

When placing their pressure equipment or assemblies referred to in Article 4(3) on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the sound engineering practice of a Member State.

2. For the pressure equipment or assemblies referred to in Article 4(1) and (2), manufacturers shall draw up the technical documentation referred to in Annex III and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out.

Where compliance of the pressure equipment or assemblies referred to in Article 4(1) and (2) with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph of this paragraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after pressure equipment or assemblies have been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in design or characteristics of pressure equipment or assemblies and changes in the harmonised standards or in other technical specifications by reference to which conformity of pressure equipment or assemblies is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by pressure equipment or assemblies, manufacturers shall, to protect the health and safety of consumers and other users, carry out sample testing of pressure equipment or assemblies made available on the market, investigate, and, if necessary, keep a register of complaints of non-conforming pressure equipment and assemblies and recalls of such equipment, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their pressure equipment or assemblies bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment or assembly does not allow it, that the required information is provided on the packaging or in a document accompanying the equipment.

6. Manufacturers shall indicate on the pressure equipment or assembly their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on the packaging or in a document accompanying the equipment or assembly. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by consumers, other users and market surveillance authorities.

7. Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(1) and (2) is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.

Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(3) are accompanied by instructions and safety information in accordance with Article 4(3), in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that pressure equipment or assemblies which they have placed on the market are not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pressure equipment or those assemblies into conformity, to withdraw it or recall it, if appropriate. Furthermore, where pressure equipment or assemblies present a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made that pressure equipment or those assemblies available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. 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 pressure equipment or assembly with this Directive, in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment or assembly which they have placed on the market.

Article 7

Authorised representatives

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

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the pressure equipment or assembly has been placed on the market;
- (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 pressure equipment or assembly;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the pressure equipment or assembly covered by the authorised representative's mandate.

Article 8

Obligations of importers

1. Importers shall place only compliant pressure equipment or assemblies on the market.

2. Before placing on the market the pressure equipment or assemblies referred to in Article 4(1) and (2), importers shall ensure that the appropriate conformity assessment procedure in accordance with Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that pressure equipment or assemblies bear the CE marking and are accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Before placing on the market the pressure equipment or assemblies referred to in Article 4(3), importers shall ensure that the manufacturer has drawn up the technical documentation and that pressure equipment or assemblies are accompanied by adequate instructions for use and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that the pressure equipment or assembly is not in conformity with the essential safety requirements set out in Annex I, he shall not place the pressure equipment or assembly on the market until it has been brought into conformity. Furthermore, where the pressure equipment or assembly presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the pressure equipment or assembly, or, where that is not possible, on its packaging or in a document accompanying the equipment or assembly. The contact details shall be in a language easily understood by consumers, other users and market surveillance authorities.

4. Importers shall ensure that pressure equipment or assemblies referred to in Article 4(1) and (2) are accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.

Importers shall ensure that the pressure equipment or assembly referred to in Article 4(3) is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.

5. Importers shall ensure that, while pressure equipment or assemblies referred to in Article 4(1) and (2) are under their responsibility, storage or transport conditions do not jeopardise their compliance with the essential safety requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by pressure equipment or assemblies, importers shall, to protect the health and safety of consumers and other users, carry out sample testing of pressure equipment and assemblies made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pressure equipment or assemblies and recalls of such equipment, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that pressure equipment or assemblies which they have placed on the market are not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pressure equipment or assembly into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pressure equipment or assembly presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the pressure equipment or assembly available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the pressure equipment or assembly has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be 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 pressure equipment or an assembly in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pressure equipment or an assembly which they have placed on the market.

Article 9

Obligations of distributors

1. When making pressure equipment or assemblies available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making the pressure equipment or assemblies referred to in Article 4(1) and (2) available on the market distributors shall verify that the pressure equipment or assembly bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment or assembly is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that pressure equipment or assemblies are not in conformity with the essential safety requirements set out in Annex I, he shall not make the pressure equipment or assembly available on the market until it has been brought into conformity. Furthermore, where the pressure equipment or assembly presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making the pressure equipment or assembly referred to in Article 4(3) available on the market, distributors shall verify that that pressure equipment or assembly is accompanied by adequate instructions for use, in a language which can be easily understood by consumers and other users in the Member State in which that pressure equipment or assembly is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

3. Distributors shall ensure that, while the pressure equipment or assemblies referred to in Article 4(1) and (2) are under their responsibility, storage or transport conditions do not jeopardise their compliance with the essential safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that pressure equipment or assemblies which they have made available on the market are not in conformity with this Directive shall make sure that the corrective measures necessary to bring that equipment or assembly into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the pressure equipment or assembly presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the equipment or assembly available on the market to that effect, 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 pressure equipment or assemblies. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the pressure equipment or assemblies which they have made available on the market.

Article 10

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 Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places pressure equipment or an assembly on the market under his name or trademark or modifies pressure equipment or an assembly already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 11

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with pressure equipment or an assembly;
- (b) any economic operator to whom they have supplied pressure equipment or an assembly.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the pressure equipment or assembly and for 10 years after they have supplied the pressure equipment or assembly.

CHAPTER 3

CONFORMITY AND CLASSIFICATION OF PRESSURE EQUIPMENT AND ASSEMBLIES

Article 12

Presumption of conformity

1. Pressure equipment or assemblies referred to in Article 4(1) and (2) which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements covered by those standards or parts thereof, referred to in Annex I.

2. The materials used for the manufacture of pressure equipment or assemblies which are in conformity with European approvals for materials, the references of which have been published in the *Official Journal of the European Union* in accordance with Article 15(4), shall be presumed to be in conformity with the applicable essential safety requirements set out in Annex I.

Article 13

Classification of pressure equipment

1. Pressure equipment referred to in Article 4(1) shall be classified by category in accordance with Annex II, according to an ascending level of hazard.

For the purposes of such classification fluids shall be divided into the following two groups:

(a) group 1 consisting of substances and mixtures, as defined in points (7) and (8) of Article 2 of Regulation (EC) No 1272/2008, that are classified as hazardous in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to that Regulation:

- (i) unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;
- (ii) flammable gases, category 1 and 2;
- (iii) oxidising gases, category 1;
- (iv) flammable liquids, category 1 and 2;
- (v) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;
- (vi) flammable solids, category 1 and 2;
- (vii) self-reactive substances and mixtures, type A to F;
- (viii) pyrophoric liquids, category 1;
- (ix) pyrophoric solids, category 1;
- (x) substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;
- (xi) oxidising liquids, category 1, 2 and 3;
- (xii) oxidising solids, category 1, 2 and 3;
- (xiii) organic peroxides types A to F;
- (xiv) acute oral toxicity, category 1 and 2;
- (xv) acute dermal toxicity, category 1 and 2;
- (xvi) acute inhalation toxicity, category 1, 2 and 3;
- (xvii) specific target organ toxicity – single exposure, category 1.

Group 1 comprises also substances and mixtures contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid;

(b) group 2 consisting of substances and mixtures not referred to in point (a).

2. Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

Article 14

Conformity assessment procedures

1. The conformity assessment procedures to be applied to an item of pressure equipment shall be determined by the category, as set out in Article 13, in which the equipment is classified.

2. The conformity assessment procedures to be applied for the various categories are the following:

(a) category I:

— Module A

(b) category II:

— Module A2

— Module D1

— Module E1

(c) category III:

— Modules B (design type) + D

— Modules B (design type) + F

— Modules B (production type) + E

— Modules B (production type) + C2

— Module H

(d) category IV:

— Modules B (production type) + D

— Modules B (production type) + F

— Module G

— Module H1

The conformity assessment procedures are set out in Annex III.

3. Pressure equipment shall be subject to one of the conformity assessment procedures which may be chosen by the manufacturer among those laid down for the category in which it is classified. The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

4. In the framework of quality assurance procedures for pressure equipment in categories III and IV referred to in point (i) of point (a) of Article 4(1), first indent of point (ii) of point (a) of Article 4(1) and point (b) of Article 4(1), the notified body shall, when performing unexpected visits, take a sample of equipment from the manufacturing or storage premises in order to perform, or have performed, the final assessment as referred to in Annex I, point 3.2. To this end, the manufacturer shall inform the notified body of the intended schedule of production. The notified body shall carry out at least two visits during the first year of manufacturing. The frequency of subsequent visits shall be determined by the notified body on the basis of the criteria set out in point 4.4 of modules D, E and H and point 5.4 of module H1.

5. In the case of one-off production of vessels and pressure equipment in category III referred to in point (b) of Article 4(1) under the module H procedure, the notified body shall perform or have performed the final assessment, as referred to in point 3.2 of Annex I, for each unit. To this end, the manufacturer shall communicate the intended schedule of production to the notified body.

6. Assemblies referred to in Article 4(2) shall be subject to a global conformity assessment procedure comprising the following assessments:

- (a) the assessment of each item of pressure equipment making up the assembly and referred to in Article 4(1) which has not been previously subjected to a conformity assessment procedure and to a separate CE marking; the assessment procedure shall be determined by the category of each item of equipment;
- (b) the assessment of the integration of the various components of the assembly as referred to in points 2.3, 2.8 and 2.9 of Annex I which shall be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories;
- (c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in points 2.10 and 3.2.3 of Annex I shall be conducted in the light of the highest category applicable to the items of equipment to be protected.

7. By way of derogation from paragraphs 1 and 2 of this Article, the competent authorities may, where justified, allow the making available on the market and putting into service in the territory of the Member State concerned of individual pressure equipment items and assemblies referred to in Article 2, in respect of which the procedures referred to in paragraphs 1 and 2 of this Article have not been applied and the use of which is in the interests of experimentation.

8. The records and correspondence relating to conformity assessment procedures shall be drafted in an official language of the Member State where the body responsible for carrying out these conformity assessment procedures is established, or in a language accepted by that body.

Article 15

European approval for materials

1. European approval for materials shall be issued at the request of one or more manufacturers of materials or equipment, by one of the notified bodies referred to in Article 20 specifically designated for that task. The notified body shall determine and perform, or arrange for the performance of, the appropriate inspections and tests to certify the conformity of the types of material with the corresponding requirements of this Directive. In the case of materials recognised as being safe to use before 29 November 1999, the notified body shall take account of the existing data when certifying such conformity.

2. Before issuing a European approval for materials, the notified body shall notify the Member States and the Commission by sending them the appropriate information. Within three months, a Member State or the Commission may provide comments giving its reasons. The notified body may issue the European approval for materials taking into account the comments submitted.
3. A copy of the European approval for materials shall be sent to the Member States, the notified bodies and the Commission.
4. When the European approval for materials satisfies the requirements which it covers and which are set out in Annex I, the Commission shall publish the references of that approval. The Commission shall keep up to date a list of such approvals in the *Official Journal of the European Union*.
5. The notified body which issued the European approval for materials shall withdraw that approval if it finds that it should not have been issued or if the type of materials is covered by a harmonised standard. It shall immediately inform the other Member States, the notified bodies and the Commission of any withdrawal of an approval.
6. When a Member State or the Commission considers that a European approval for materials whose references have been published in the *Official Journal of the European Union*, does not entirely satisfy the essential safety requirements which it covers and which are set out in Annex I, the Commission shall decide by means of implementing acts whether to withdraw the references of that European approval for materials from the *Official Journal of the European Union*.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 16

User inspectorates

1. By way of derogation from the provisions relating to the tasks carried out by the notified bodies, Member States may authorise on their territory the placing on the market and the putting into service by users, of pressure equipment or assemblies of which conformity with the essential safety requirements has been assessed by a user inspectorate designated in accordance with paragraph 7.
2. Pressure equipment and assemblies the conformity of which has been assessed by a user inspectorate shall not bear the CE marking.
3. The pressure equipment or assemblies referred to in paragraph 1 may be used only in establishments operated by the group of which the inspectorate is part. The group shall apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies.
4. The user inspectorates shall act exclusively for the group of which they are part.
5. The conformity assessment procedures applicable by user inspectorates shall be modules A2, C2, F and G, set out in Annex III.
6. Member States shall notify the other Member States and the Commission which user inspectorates they have authorised, the tasks for which they have been designated and, for each inspectorate, a list of the establishments satisfying the provisions of paragraph 3.
7. In designating the user inspectorates, the Member States shall apply the requirements set out in Article 25 and ensure that the group of which the inspectorate is part applies the criteria referred to in the second sentence of paragraph 3 of this Article.

*Article 17***EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of essential safety requirements set out in Annex I has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in Annex IV and shall contain the elements specified in the relevant conformity assessment procedures set out in Annex III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in whose market the pressure equipment or assembly is placed or made available on the market.
3. Where pressure equipment or an assembly is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the pressure equipment or assembly with the requirements laid down in this Directive.

*Article 18***General principles of the CE marking**

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

*Article 19***Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to any of the following:
 - (a) each item of pressure equipment referred to in Article 4(1) or its dataplate;
 - (b) each assembly referred to in Article 4(2) or its dataplate.

Where the affixing of the CE marking is not possible or not warranted on account of the nature of the equipment or assembly, it shall be affixed to the packaging and to the accompanying documents.

The item or assembly referred to in points (a) and (b) of the first subparagraph shall be complete or shall be in a state permitting final assessment as described in point 3.2 of Annex I.

2. It is not necessary for the CE marking to be affixed to each individual item of pressure equipment making up an assembly. Individual items of pressure equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking.
3. The CE marking shall be affixed before the item of pressure equipment or the assembly is placed on the market.
4. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

5. The CE marking and, where applicable, the identification number referred to in paragraph 4 may be followed by any other mark indicating a special risk or use.

6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20

Notification

Member States shall notify the Commission and the other Member States of the notified bodies and the user inspectorates authorised to carry out conformity assessment tasks in accordance with Article 14, Article 15 or Article 16 and of the third-party organisations they have recognised, for the purposes of the tasks referred to in points 3.1.2 and 3.1.3 of Annex I.

Article 21

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 conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, including compliance with Article 27.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body 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 22. In addition it shall have arrangements to cover liabilities arising out of its activities.

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

Article 22

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

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

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

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

*Article 23***Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 24***Requirements relating to notified bodies and recognised third-party organisations**

1. For the purposes of notification, a notified body or recognised third party organisation shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under national law of a Member State and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the pressure equipment or assembly 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 pressure equipment or assemblies which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment or assembly which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed pressure equipment or assemblies that are necessary for the operations of the conformity assessment body or the use of such equipment for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment or assembly, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 14 or Article 15, or points 3.1.2 and 3.1.3 of Annex I and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a conformity assessment body and other activities;
- (c) procedures for the performance of 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 conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 14, Article 15, or under points 3.1.2 and 3.1.3 of Annex I or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25

Requirements relating to user inspectorates

1. For the purposes of notification, a user inspectorate shall meet the requirements laid down in paragraphs 2 to 11.
2. A user inspectorate shall be established under national law of a Member State and have legal personality.
3. A user inspectorate shall be organisationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality.
4. A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment or assembly which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed pressure equipment or assemblies that are necessary for the operations of the user inspectorate or the use of such equipment for personal purposes.

A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment or assembly, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

5. User inspectorates and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
6. A user inspectorate shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 16 and in relation to which it has been notified, whether those tasks are carried out by the user inspectorate itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified, the user inspectorate shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a user inspectorate and other activities;
- (c) procedures for the performance of 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 user inspectorate shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:
- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
8. The impartiality of the user inspectorates, their top level management and of the personnel responsible for carrying out conformity assessment tasks shall be guaranteed. User inspectorates must not engage in any activities that might conflict with its independence of judgement and integrity in relation to its inspection activities.

The remuneration of the top level management and personnel responsible for carrying out conformity assessment tasks of a user inspectorate shall not depend on the number of assessments carried out or on the results of those assessments.

9. User inspectorates shall take out liability insurance unless liability is assumed by the group of which they are part.
10. The personnel of user inspectorates shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 16 or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
11. User inspectorates shall participate in, or ensure that their personnel responsible for carrying out conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 26

Presumption of conformity of conformity assessment bodies

Where a conformity assessment body 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* it shall be presumed to comply with the requirements set out in Article 24 or Article 25 in so far as the applicable harmonised standards cover those requirements.

Article 27

Subsidiaries of and subcontracting by conformity assessment bodies

1. Where a notified body, a user inspectorate or a recognised third-party organisation subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 or Article 25 and shall inform the notifying authority accordingly.
2. Notified bodies, user inspectorates and recognised third-party organisations 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. Notified bodies, user inspectorates and recognised third-party organisations shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 14, Article 15, Article 16 or points 3.1.2 and 3.1.3 of Annex I.

Article 28

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the pressure equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24 or Article 25.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24 or Article 25.

Article 29

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24 or Article 25.

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

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the pressure equipment concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment 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 24 or Article 25.

5. The body concerned may perform the activities of a notified body, a recognised third-party organisation or a user inspectorate only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body, a recognised third-party organisation or a user inspectorate for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

*Article 30***Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a 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 the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

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

*Article 31***Lists of recognised third-party organisations and user inspectorates**

The Commission shall make publicly available the list of the recognised third-party organisations and of the user inspectorates under this Directive and the tasks for which they have been recognised.

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

*Article 32***Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body or a recognised third-party organisation no longer meets the requirements laid down in Article 24 or that it is failing to fulfil its obligations, the notifying authority shall, as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

Where a notifying authority has ascertained or has been informed that a user inspectorate no longer meets the requirements laid down in Article 25, or that it is failing to fulfil its obligations, the notifying authority shall as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

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

*Article 33***Challenge of the competence of notified bodies, recognised third party organisations and user inspectorates**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body, a recognised third-party organisation or a user inspectorate, or the continued fulfilment by a notified body, a recognised third-party organisation or a user inspectorate of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the conformity assessment 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, a recognised third-party organisation or a user inspectorate does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

Article 34

Operational obligations of notified bodies, user inspectorates and recognised third party organisations

1. Notified bodies, user inspectorates and recognised third-party organisations shall carry out conformity assessments in accordance with the conformity assessment tasks provided for in Article 14, Article 15, Article 16, or in points 3.1.2 and 3.1.3 of Annex I.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the pressure equipment or assembly technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the pressure equipment with the requirements of this Directive.

3. Where a conformity assessment body finds that essential safety requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a conformity assessment body finds that pressure equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

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

Article 35

Appeal against decisions of notified bodies, recognised third party organisations and user inspectorates

Member States shall ensure that appeal procedures against decisions of notified bodies, recognised third-party organisations and user inspectorates are available.

Article 36

Information obligation on notified bodies, recognised third party organisations and user inspectorates

1. Notified bodies, recognised third-party organisations and user inspectorates shall inform the notifying authority of the following:

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

(b) any circumstances affecting the scope of or conditions for notification;

- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies, recognised third-party organisations and user inspectorates shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37

Exchange of experience

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

Article 38

Coordination of notified bodies, recognised third-party organisations and user inspectorates

The Commission shall ensure that appropriate coordination and cooperation between the conformity assessment bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of conformity assessment bodies.

Member States shall ensure that the conformity assessment bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

CHAPTER 5

UNION MARKET SURVEILLANCE, CONTROL OF PRESSURE EQUIPMENT AND ASSEMBLIES ENTERING THE UNION MARKET, AND UNION SAFEGUARD PROCEDURE

Article 39

Union market surveillance and control of pressure equipment and assemblies entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to pressure equipment and assemblies covered by Article 1 of this Directive.

Article 40

Procedure for dealing with pressure equipment or assemblies presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reasons to believe that pressure equipment or assemblies covered by this Directive present a risk to the health or safety of persons or to domestic animals or property, they shall carry out an evaluation in relation to the pressure equipment or assembly concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

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

The market surveillance authorities shall inform the relevant notified body accordingly.

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 non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the pressure equipment and assemblies concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the equipment's or assembly's being made available on their national market, to withdraw the equipment or assembly 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 the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant equipment or assembly, the origin of the equipment or assembly, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and 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 equipment or assembly to meet requirements relating to the health or safety of persons or to the protection of domestic animals or property; or

(b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article 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 equipment or assembly concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

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

Article 41

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 40(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 or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

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

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

3. Where the national measure is considered justified and the non-compliance of the equipment or assembly is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 42

Compliant pressure equipment or assemblies which present a risk

1. Where, having carried out an evaluation under Article 40(1), a Member State finds that although pressure equipment or an assembly is in compliance with this Directive, it presents a risk to the health or safety of persons, to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the equipment or assembly concerned, when placed on the market, no longer presents that risk, to withdraw the equipment or assembly from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the equipment or assemblies concerned that he 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 equipment or assembly concerned, the origin and the supply chain of the equipment or assembly, 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 or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, or of domestic animals or of property, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

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

Article 43

Formal non-compliance

1. Without prejudice to Article 40, 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 violation of Article 30 of Regulation (EC) No 765/2008 or of Article 19 of this Directive;

- (b) the CE marking has not been affixed;
- (c) the identification number of the notified body involved in the production control phase, has been affixed in violation of Article 19 or has not been affixed;
- (d) the marking and labelling referred to in point 3.3. of Annex I have not been affixed or have been affixed in violation of Article 19 or point 3.3 of Annex I;
- (e) the EU declaration of conformity has not been drawn up;
- (f) the EU declaration of conformity has not been drawn up correctly;
- (g) the technical documentation is either not available or not complete;
- (h) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;
- (i) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the equipment or assembly being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER 6

COMMITTEE PROCEDURE AND DELEGATED ACTS

Article 44

Committee procedure

1. The Commission shall be assisted by the Committee on Pressure Equipment. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.
5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

Article 45

Delegated power

1. In order to take into account emerging very serious safety reasons, the Commission shall be empowered to adopt delegated acts in accordance with Article 46 reclassifying pressure equipment or assemblies so as to:
 - (a) make an item or family of pressure equipment referred to in Article 4(3) subject to the requirements of Article 4(1);

- (b) make an assembly or family of assemblies referred to in Article 4(3) subject to the requirements of Article 4(2);
- (c) classify an item or family of pressure equipment, by way of derogation from the requirements of Annex II, in another category.

2. A Member State having concerns about the safety of pressure equipment or assemblies shall immediately inform the Commission of its concerns and provide reasons in support.

3. Prior to adopting a delegated act the Commission shall carry out a thorough assessment of the risks that require reclassification.

Article 46

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 45 shall be conferred on the Commission for a period of five years from 1 June 2015. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 45 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 45 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER 7

TRANSITIONAL AND FINAL PROVISIONS

Article 47

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. Such rules may include criminal penalties for serious infringements.

The penalties referred to in the first paragraph shall be effective, proportionate and dissuasive.

Article 48

Transitional provisions

1. Member States shall not impede the putting into service of pressure equipment and assemblies which comply with the regulations in force in their territory at the date of application of Directive 97/23/EC and were placed on the market until 29 May 2002.

2. Member States shall not impede the making available on the market and/or the putting into service of pressure equipment or assemblies covered by Directive 97/23/EC which are in conformity with that Directive and which were placed on the market before 1 June 2015.
3. Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under this Directive.

Article 49

Transposition

1. Member States shall adopt and publish, by 28 February 2015, the laws, regulations and administrative provisions necessary to comply with Article 13. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 1 June 2015.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to Article 9 of Directive 97/23/EC shall be construed as references to Article 13 of this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall adopt and publish, by 18 July 2016, the laws, regulations and administrative provisions necessary to comply with Article 2(15) to (32), Articles 6 to 12, 14, 17 and 18, Article 19(3) to (5), Articles 20 to 43, 47 and 48 and Annexes I, II, III and IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 19 July 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive.

Article 50

Repeal

Article 9 of Directive 97/23/EC is deleted with effect from 1 June 2015, without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of that Article, set out in Annex V, Part B.

Directive 97/23/EC, as amended by the acts listed in Annex V, Part A, is repealed with effect from 19 July 2016, without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of the Directive set out in Annex V, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

*Article 51***Entry into force and application**

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

Article 1, points 1 to 14 of Article 2, Articles 3, 4, 5, 14, 15 and 16, Article 19(1) and (2), and Articles 44, 45 and 46 shall apply from 19 July 2016.

*Article 52***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 15 May 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

ANNEX I

ESSENTIAL SAFETY REQUIREMENTS

PRELIMINARY OBSERVATIONS

1. The obligations arising from the essential safety requirements listed in this Annex for pressure equipment also apply to assemblies where the corresponding hazard exists.
2. The essential safety requirements laid down in this Directive are compulsory. The obligations following from those essential safety requirements apply only if the corresponding hazard exists for the pressure equipment in question when it is used under conditions which are reasonably foreseeable by the manufacturer.
3. The manufacturer is under an obligation to analyse the hazards and risks in order to identify those which apply to his equipment on account of pressure; he shall then design and construct it taking account of his analysis.
4. The essential safety requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.

1. GENERAL

- 1.1. Pressure equipment shall be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.
- 1.2. In choosing the most appropriate solutions, the manufacturer shall apply the principles set out below in the following order:
 - eliminate or reduce hazards as far as is reasonably practicable;
 - apply appropriate protection measures against hazards which cannot be eliminated;
 - where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use.
- 1.3. Where the potential for misuse is known or can be clearly foreseen, the pressure equipment shall be designed to prevent risks from such misuse or, if that is not possible, adequate warning given that the pressure equipment shall not be used in that way.

2. DESIGN

2.1. **General**

The pressure equipment shall be properly designed taking all relevant factors into account in order to ensure that the equipment will be safe throughout its intended life.

The design shall incorporate appropriate safety coefficients using comprehensive methods which are known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.

2.2. **Design for adequate strength**

- 2.2.1. The pressure equipment shall be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors shall be taken into account:
 - internal/external pressure,

- ambient and operational temperatures,
- static pressure and mass of contents in operating and test conditions,
- traffic, wind, earthquake loading,
- reaction forces and moments which result from the supports, attachments, piping, etc.,
- corrosion and erosion, fatigue, etc.,
- decomposition of unstable fluids.

Various loadings which can occur at the same time shall be considered, taking into account the probability of their simultaneous occurrence.

2.2.2. Design for adequate strength shall be based on either of the following:

- as a general rule, a calculation method, as described in point 2.2.3, and supplemented if necessary by an experimental design method as described in point 2.2.4,
- an experimental design method without calculation, as described in point 2.2.4, when the product of the maximum allowable pressure PS and the volume V is less than 6 000 bar·L or the product PS·DN less than 3 000 bar.

2.2.3. *Calculation method*

(a) *Pressure containment and other loading aspects*

The allowable stresses for pressure equipment shall be limited having regard to reasonably foreseeable failure modes under operating conditions. To this end, safety factors shall be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models and the properties and behaviour of the material.

These calculation methods shall provide sufficient safety margins consistent, where applicable, with the requirements of point 7.

The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:

- design by formula,
- design by analysis,
- design by fracture mechanics.

(b) *Resistance*

Appropriate design calculations shall be used to establish the resistance of the pressure equipment concerned.

In particular:

- the calculation pressures shall not be less than the maximum allowable pressures and take into account static head and dynamic fluid pressures and the decomposition of unstable fluids. Where a vessel is separated into individual pressure-containing chambers, the partition wall shall be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber,

- the calculation temperatures shall allow for appropriate safety margins,
- the design shall take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
- the maximum stresses and peak stress concentrations shall be kept within safe limits,
- the calculation for pressure containment shall utilise the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in point 4 together with appropriate safety factors. Material characteristics to be considered, where applicable, include:
 - yield strength, 0,2 % or 1,0 % proof strength as appropriate at calculation temperature,
 - tensile strength,
 - time-dependent strength, i.e. creep strength,
 - fatigue data,
 - Young's modulus (modulus of elasticity),
 - appropriate amount of plastic strain,
 - bending rupture energy,
 - fracture toughness.
- appropriate joint factors shall be applied to the material properties depending, for example, on the type of non-destructive testing, the materials joined and the operating conditions envisaged,
- the design shall take appropriate account of all reasonably foreseeable degradation mechanisms (e.g. corrosion, creep, fatigue) commensurate with the intended use of the equipment. Attention shall be drawn, in the instructions referred to in point 3.4, to particular features of the design which are relevant to the life of the equipment, for example:
 - for creep: design hours of operation at specified temperatures,
 - for fatigue: design number of cycles at specified stress levels,
 - for corrosion: design corrosion allowance.

(c) *Stability aspects*

Where the calculated thickness does not allow for adequate structural stability, the necessary measures shall be taken to remedy the situation taking into account the risks from transport and handling.

2.2.4. *Experimental design method*

The design of the equipment may be validated, in all or in part, by an appropriate test programme carried out on a sample representative of the equipment or the category of equipment.

The test programme shall be clearly defined prior to testing and accepted by the notified body responsible for the design conformity assessment module, where it exists.

This programme shall define test conditions and criteria for acceptance or refusal. The actual values of the essential dimensions and characteristics of the materials which constitute the equipment tested shall be measured before the test.

Where appropriate, during tests, it shall be possible to observe the critical zones of the pressure equipment with adequate instrumentation capable of registering strains and stresses with sufficient precision.

The test programme shall include:

- (a) A pressure strength test, the purpose of which is to check that, at a pressure with a defined safety margin in relation to the maximum allowable pressure, the equipment does not exhibit significant leaks or deformation exceeding a determined threshold.

The test pressure shall be determined on the basis of the differences between the values of the geometrical and material characteristics measures under test conditions and the values used for design purposes; it shall take into account the differences between the test and design temperatures;

- (b) where the risk of creep or fatigue exists, appropriate tests determined on the basis of the service conditions laid down for the equipment, for instance hold time at specified temperatures, number of cycles at specified stress-levels;
- (c) where necessary, additional tests concerning other factors referred to in point 2.2.1 such as corrosion, external damage.

2.3. Provisions to ensure safe handling and operation

The method of operation specified for pressure equipment shall be such as to preclude any reasonably foreseeable risk in operation of the equipment. Particular attention shall be paid, where appropriate, to:

- closures and openings,
- dangerous discharge of pressure relief blow-off,
- devices to prevent physical access whilst pressure or a vacuum exists,
- surface temperature taking into consideration the intended use,
- decomposition of unstable fluids.

In particular, pressure equipment fitted with an access door shall be equipped with an automatic or manual device enabling the user easily to ascertain that the opening will not present any risk. Furthermore, where the opening can be operated quickly, the pressure equipment shall be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a risk.

2.4. Means of examination

- (a) Pressure equipment shall be designed and constructed so that all necessary examinations to ensure safety can be carried out;
- (b) Means of determining the internal condition of the equipment shall be available, where it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be carried out safely and ergonomically;
- (c) Other means of ensuring the safe condition of the pressure equipment may be applied in any of the following situations:
 - where it is too small for physical internal access,

- where opening the pressure equipment would adversely affect the inside,
- where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.

2.5. Means of draining and venting

Adequate means shall be provided for the draining and venting of pressure equipment where necessary:

- to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions. All stages of operation and testing, particularly pressure testing, shall be considered,
- to permit cleaning, inspection and maintenance in a safe manner.

2.6. Corrosion or other chemical attack

Where necessary, adequate allowance or protection against corrosion or other chemical attack shall be provided, taking due account of the intended and reasonably foreseeable use.

2.7. Wear

Where severe conditions of erosion or abrasion may arise, adequate measures shall be taken to:

- minimise that effect by appropriate design, e.g. additional material thickness, or by the use of liners or cladding materials,
- permit replacement of parts which are most affected,
- draw attention, in the instructions referred to in point 3.4, to measures necessary for continued safe use.

2.8. Assemblies

Assemblies shall be so designed that:

- the components to be assembled together are suitable and reliable for their duty,
- all the components are properly integrated and assembled in an appropriate manner.

2.9. Provisions for filling and discharge

Where appropriate, the pressure equipment shall be so designed and provided with accessories, or provision made for their fitting, as to ensure safe filling and discharge in particular with respect to risks such as:

(a) on filling:

- overfilling or overpressurisation having regard in particular to the filling ratio and to vapour pressure at the reference temperature,
- instability of the pressure equipment;

(b) on discharge: the uncontrolled release of the pressurised fluid;

(c) on filling or discharge: unsafe connection and disconnection.

2.10. Protection against exceeding the allowable limits of pressure equipment

Where, under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment shall be fitted with, or provision made for the fitting of, suitable protective devices, unless the equipment is intended to be protected by other protective devices within an assembly.

The suitable device or combination of such devices shall be determined on the basis of the particular characteristics of the equipment or assembly.

Suitable protective devices and combinations thereof comprise:

- (a) safety accessories as defined in point 4 of Article 2,
- (b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits.

2.11. Safety accessories

2.11.1. Safety accessories shall:

- be so designed and constructed as to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable,
- be independent of other functions, unless their safety function cannot be affected by such other functions,
- comply with appropriate design principles in order to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.

2.11.2. *Pressure limiting devices*

These devices shall be so designed that the pressure will not permanently exceed the maximum allowable pressure PS; however a short duration pressure surge in keeping with the specifications laid down in point 7.3 is allowable, where appropriate.

2.11.3. *Temperature monitoring devices*

These devices shall have an adequate response time on safety grounds, consistent with the measurement function.

2.12. External fire

Where necessary, pressure equipment shall be so designed and, where appropriate, fitted with suitable accessories, or provision made for their fitting, to meet damage-limitation requirements in the event of external fire, having particular regard to its intended use.

3. MANUFACTURING

3.1. Manufacturing procedures

The manufacturer shall ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with a view to the aspects set out below.

3.1.1. *Preparation of the component parts*

Preparation of the component parts (e.g. forming and chamfering) shall not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.

3.1.2. *Permanent joining*

Permanent joints and adjacent zones shall be free of any surface or internal defects detrimental to the safety of the equipment.

The properties of permanent joints shall meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account in the design calculations.

For pressure equipment, permanent joining of components which contribute to the pressure resistance of equipment and components which are directly attached to them shall be carried out by suitably qualified personnel according to suitable operating procedures.

For pressure equipment in categories II, III and IV, operating procedures and personnel shall be approved by a competent third party which, at the manufacturer's discretion, may be:

- a notified body,
- a third-party organisation recognised by a Member State as provided for in Article 20.

To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or equivalent examinations and tests or shall have them performed.

3.1.3. *Non-destructive tests*

For pressure equipment, non-destructive tests of permanent joints shall be carried out by suitable qualified personnel. For pressure equipment in categories III and IV, the personnel shall be approved by a third-party organisation recognised by a Member State pursuant to Article 20.

3.1.4. *Heat treatment*

Where there is a risk that the manufacturing process will change the material properties to an extent which would impair the safety of the pressure equipment, suitable heat treatment shall be applied at the appropriate stage of manufacture.

3.1.5. *Traceability*

Suitable procedures shall be established and maintained for identifying the material making up the components of the equipment which contribute to pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.

3.2. **Final assessment**

Pressure equipment shall be subjected to final assessment as described below.

3.2.1. *Final inspection*

Pressure equipment shall undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of this Directive. Test carried out during manufacture may be taken into account. As far as is necessary on safety grounds, the final inspection shall be carried out internally and externally on every part of the equipment, where appropriate in the course of manufacture (e.g. where examination during the final inspection is no longer possible).

3.2.2. *Proof test*

Final assessment of pressure equipment shall include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test at a pressure at least equal, where appropriate, to the value laid down in point 7.4.

For category I series-produced pressure equipment, this test may be performed on a statistical basis.

Where the hydrostatic pressure test is harmful or impractical, other tests of a recognised value may be carried out. For tests other than the hydrostatic pressure test, additional measures, such as non-destructive tests or other methods of equivalent validity, shall be applied before those tests are carried out.

3.2.3. *Inspection of safety devices*

For assemblies, the final assessment shall also include a check of the safety devices intended to check full compliance with the requirements referred to in point 2.10.

3.3. **Marking and labelling**

In addition to the CE marking referred to in Articles 18 and 19 and the information to be provided in accordance with Article 6(6) and Article 8(3), the following information shall be provided:

(a) for all pressure equipment:

- the year of manufacture,
- identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number,
- essential maximum/minimum allowable limits.

(b) depending on the type of pressure equipment, further information necessary for safe installation, operation or use and, where applicable, maintenance and periodic inspection such as:

- the volume V of the pressure equipment in L,
- the nominal size for piping DN,
- the test pressure P_T applied in bar and date,
- safety device set pressure in bar,
- output of the pressure equipment in kW,
- supply voltage in V (volts),
- intended use,
- filling ratio kg/L,
- maximum filling mass in kg,
- tare mass in kg,
- the fluid group.

- (c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

The information referred to in points (a), (b) and (c) shall be given on the pressure equipment or on a dataplate firmly attached to it, with the following exceptions:

- where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly,
- where the pressure equipment is too small, e.g. accessories, this information may be given on a label attached to that pressure equipment,
- labelling or other adequate means may be used for the mass to be filled and the warnings referred to in point (c), provided it remains legible for the appropriate period of time.

3.4. **Operating instructions**

- (a) When pressure equipment is made available on the market, it shall be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:
- mounting including assembling of different pieces of pressure equipment,
 - putting into service,
 - use,
 - maintenance including checks by the user.
- (b) Instructions shall cover information affixed to the pressure equipment in accordance with point 3.3, with the exception of serial identification, and shall be accompanied, where appropriate, by the technical documents, drawings and diagrams necessary for a full understanding of these instructions.
- (c) If appropriate, these instructions shall also refer to risks arising from misuse in accordance with point 1.3 and particular features of the design in accordance with point 2.2.3.

4. MATERIALS

Materials used for the manufacture of pressure equipment shall be suitable for such application during the scheduled lifetime unless replacement is foreseen.

Welding consumables and other joining materials need to fulfil only the relevant requirements of points 4.1, 4.2(a) and the first paragraph of point 4.3, in an appropriate way, both individually and in a joined structure.

4.1. Materials for pressurised parts shall:

- (a) have appropriate properties for all operating conditions which are reasonably foreseeable and for all test conditions, and in particular they should be sufficiently ductile and tough. Where appropriate, the characteristics of the materials shall comply with the requirements of point 7.5. Moreover, due care should be exercised in particular in selecting materials in order to prevent brittle-type fracture where necessary; where for specific reasons brittle material has to be used appropriate measures shall be taken;
- (b) be sufficiently chemically resistant to the fluid contained in the pressure equipment; the chemical and physical properties necessary for operational safety shall not be significantly affected within the scheduled lifetime of the equipment;

- (c) not be significantly affected by ageing;
- (d) be suitable for the intended processing procedures;
- (e) be selected in order to avoid significant undesirable effects when the various materials are put together.

4.2. The pressure equipment manufacturer shall:

- (a) define in an appropriate manner the values necessary for the design calculations referred to in point 2.2.3 and the essential characteristics of the materials and their treatment referred to in point 4.1;
- (b) provide in his technical documentation elements relating to compliance with the materials specifications of this Directive in one of the following forms:
 - by using materials which comply with harmonised standards,
 - by using materials covered by a European approval of pressure equipment materials in accordance with Article 15,
 - by a particular material appraisal;
- (c) for pressure equipment in categories III and IV, a specific assessment of the particular material appraisal shall be performed by the notified body in charge of conformity assessment procedures for the pressure equipment.

4.3. The equipment manufacturer shall take appropriate measures to ensure that the material used conforms with the required specification. In particular, documentation prepared by the material manufacturer affirming compliance with a specification shall be obtained for all materials.

For the main pressure-bearing parts of equipment in categories II, III and IV, this shall take the form of a certificate of specific product control.

Where a material manufacturer has an appropriate quality-assurance system, certified by a competent body established within the Union and having undergone a specific assessment for materials, certificates issued by the manufacturer are presumed to certify conformity with the relevant requirements of this point.

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS

In addition to the applicable requirements of points 1 to 4, the following requirements apply to the pressure equipment covered by points 5 and 6.

5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING AS REFERRED TO IN ARTICLE 4(1)

This pressure equipment includes:

- steam and hot-water generators as referred to in Article 4(1)(b), such as fired steam and hot-water boilers, superheaters and reheaters, waste-heat boilers, waste incineration boilers, electrode or immersion-type electrically heated boilers, pressure cookers, together with their accessories and where applicable their systems for treatment of feedwater and for fuel supply,
- process-heating equipment for other than steam and hot water generation falling under Article 4(1)(a), such as heaters for chemical and other similar processes and pressurised food-processing equipment.

This pressure equipment shall be calculated, designed and constructed so as to avoid or minimise risks of a significant loss of containment from overheating. In particular it shall be ensured, where applicable, that:

- (a) appropriate means of protection are provided to restrict operating parameters such as heat input, heat take-off and, where applicable, fluid level so as to avoid any risk of local and general overheating;
- (b) sampling points are provided where required to allow evaluation of the properties of the fluid so as to avoid risks related to deposits and/or corrosion;
- (c) adequate provisions are made to eliminate risks of damage from deposits;
- (d) means of safe removal of residual heat after shutdown are provided;
- (e) steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air, or flame blowback.

6. PIPING AS REFERRED TO IN ARTICLE 4(1)(c)

Design and construction shall ensure:

- (a) that the risk of overstressing from inadmissible free movement or excessive forces being produced, e.g. on flanges, connections, bellows or hoses, is adequately controlled by means such as support, constraint, anchoring, alignment and pre-tension;
- (b) that where there is a possibility of condensation occurring inside pipes for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion;
- (c) that due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of point 2.7 are applicable;
- (d) that due consideration is given to the risk of fatigue due to vibrations in pipes;
- (e) that, where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate 'take-off' pipes the size of which represents a significant risk;
- (f) that the risk of inadvertent discharge is minimised; the take-off points shall be clearly marked on the permanent side, indicating the fluid contained;
- (g) that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

7. SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT

The following provisions apply as a general rule. However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards are applied, the manufacturer shall demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.

The provisions laid down in this section supplement the essential safety requirements of points 1 to 6 for the pressure equipment to which they apply.

7.1. Allowable stresses

7.1.1. Symbols

$R_{e/t}$, yield limit, indicates the value at the calculation temperature of:

- the upper flow limit for a material presenting upper and lower flow limits,
- the 1,0 % proof strength of austenitic steel and non-alloyed aluminium,
- the 0,2 % proof strength in other cases.

$R_{m/20}$ indicates the minimum value of the ultimate tensile strength at 20 °C.

$R_{m/t}$ designates the ultimate tensile strength at the calculation temperature.

7.1.2. The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant shall not exceed the smaller of the following values, according to the material used:

- in the case of ferritic steel including normalised (normalised rolled) steel and excluding fine-grained steel and specially heat-treated steel, $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$,
- in the case of austenitic steel:
 - if its elongation after rupture exceeds 30 %, $\frac{2}{3}$ of $R_{e/t}$
 - or, alternatively, and if its elongation after rupture exceeds 35 %, $\frac{5}{6}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/t}$,
- in the case of non-alloy or low-alloy cast steel, $\frac{10}{19}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/20}$,
- in the case of aluminium, $\frac{2}{3}$ of $R_{e/t}$,
- in the case of aluminium alloys excluding precipitation hardening alloys $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$.

7.2. Joint coefficients

For welded joints, the joint coefficient shall not exceed the following values:

- for equipment subject to destructive and non-destructive tests which confirm that the whole series of joints show no significant defects: 1,
- for equipment subject to random non-destructive testing: 0,85,
- for equipment not subject to non-destructive testing other than visual inspection: 0,7.

If necessary, the type of stress and the mechanical and technological properties of the joint shall also be taken into account.

7.3. Pressure limiting devices, particularly for pressure vessels

The momentary pressure surge referred to in point 2.11.2 shall be kept to 10 % of the maximum allowable pressure.

7.4. Hydrostatic test pressure

For pressure vessels, the hydrostatic test pressure referred to in point 3.2.2 shall be no less than either of the following:

- that corresponding to the maximum loading to which the pressure equipment may be subject in service taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1,25,
- the maximum allowable pressure multiplied by the coefficient 1,43, whichever is the greater.

7.5. Material characteristics

Unless other values are required in accordance with other criteria that shall be taken into account, a steel is considered as sufficiently ductile to satisfy point 4.1(a) if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14 % and its bending rupture energy measured on an ISO V test-piece is no less than 27 J, at a temperature not greater than 20 °C but not higher than the lowest scheduled operating temperature.

ANNEX II

CONFORMITY ASSESSMENT TABLES

1. The references in the tables to categories of modules are the following:

I	=	Module A
II	=	Modules A2, D1, E1
III	=	Modules B (design type) + D, B (design type) + F, B (production type) + E, B (production type) + C2, H
IV	=	Modules B (production type) + D, B (production type) + F, G, H1

2. The safety accessories defined in point 4 of Article 2, and referred to in Article 4(1)(d), are classified in category IV. However, by way of exception, safety accessories manufactured for specific equipment may be classified in the same category as the equipment they protect.

3. The pressure accessories defined in point 5 of Article 2, and referred to in Article 4(1)(d), are classified on the basis of:

- their maximum allowable pressure PS,
- their volume V or their nominal size DN, as appropriate,
- the group of fluids for which they are intended.

The appropriate table for vessels or piping is to be used to determine the conformity assessment category.

Where both the volume and the nominal size are considered appropriate in the second indent of the first subparagraph, the pressure accessory shall be classified in the highest category.

4. The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

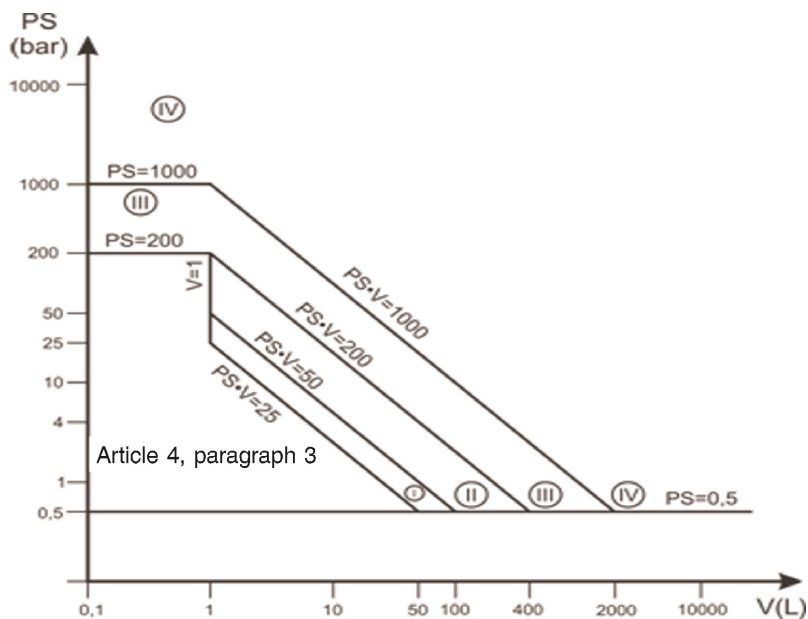


Table 1

Vessels referred to in Article 4(1)(a)(i), first indent

Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of table 1 shall be classified in category III.

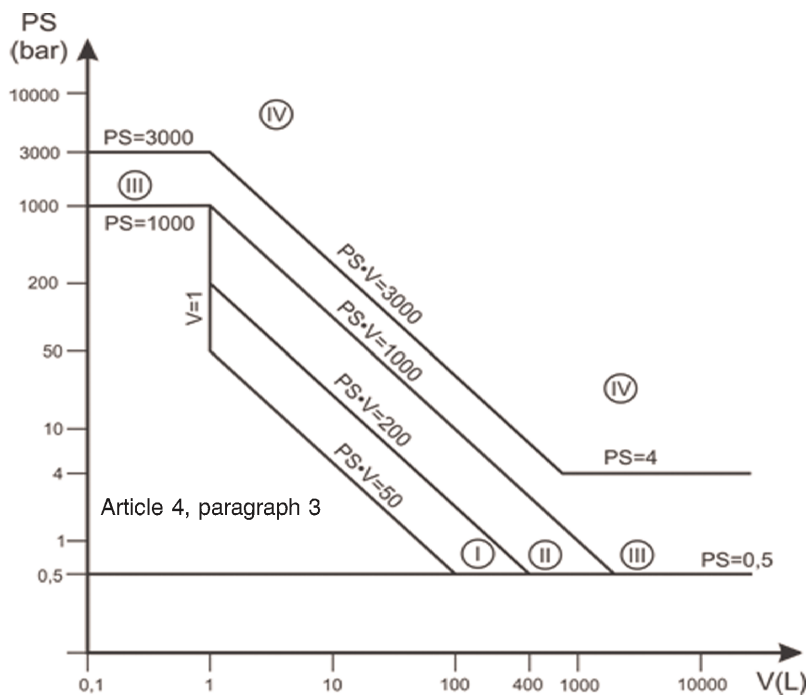


Table 2

Vessels referred to in Article 4(1)(a)(i), second indent

Exceptionally, portable extinguishers and bottles for breathing equipment shall be classified at least in category III.

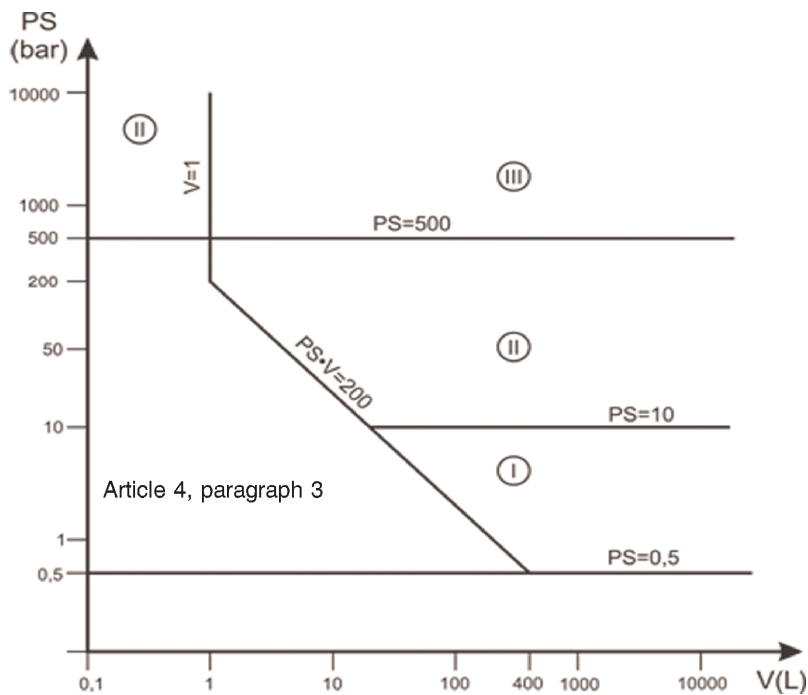


Table 3

Vessels referred to in Article 4(1)(a)(ii), first indent

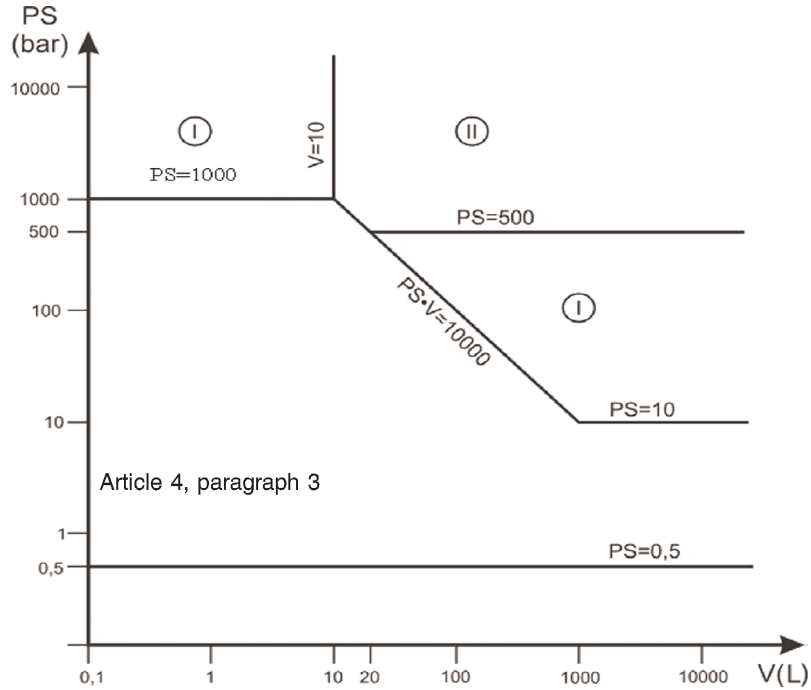


Table 4

Vessels referred to in Article 4(1)(a)(ii), second indent

Exceptionally, assemblies intended for generating warm water as referred to in the second subparagraph of Article 4(2), shall be subject either to an EU-type examination (Module B — design type) with respect to their conformity with the essential requirements referred to in points 2.10, 2.11, 3.4, 5(a) and 5(d) of Annex I, or to full quality assurance (Module H).

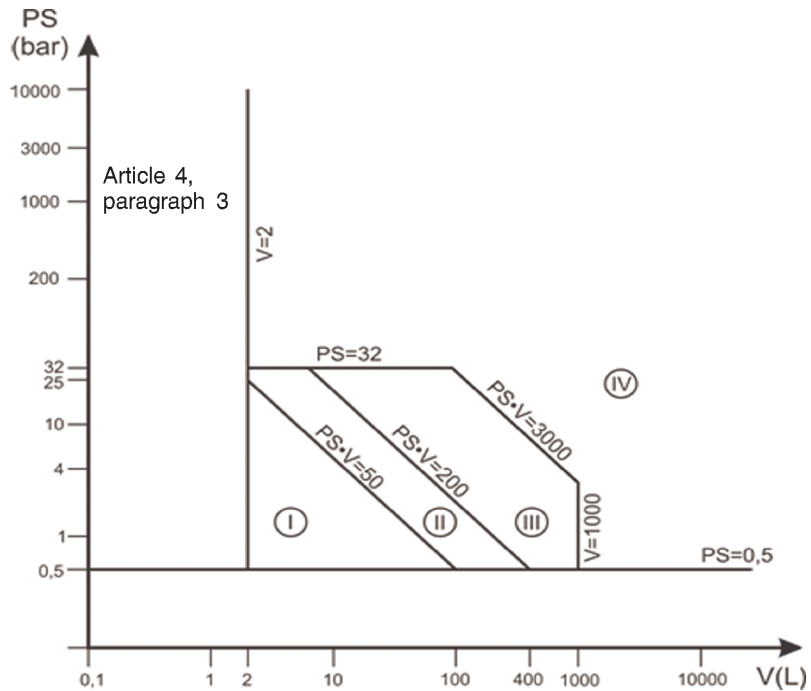


Table 5

Pressure equipment referred to in Article 4(1)(b)

Exceptionally, the design of pressure-cookers shall be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

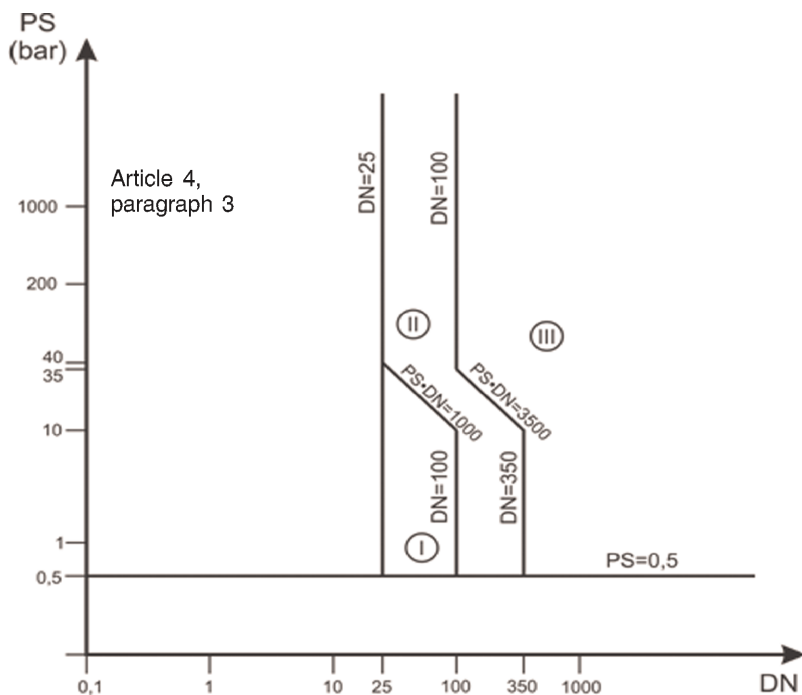


Table 6

Piping referred to in Article 4(1)(c)(i), first indent

Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of Table 6 shall be classified in category III.

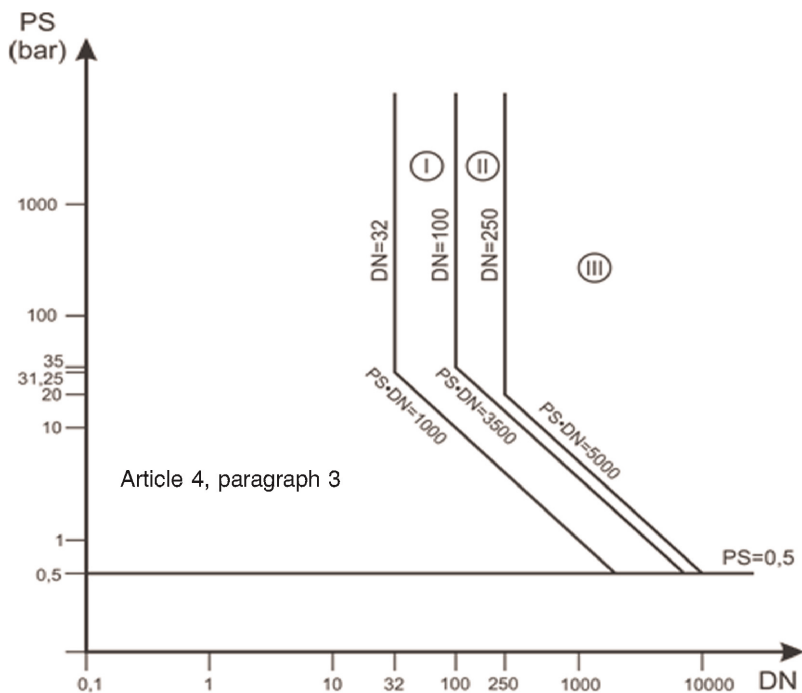


Table 7

Piping referred to in Article 4(1)(c)(i), second indent

Exceptionally, all piping containing fluids at a temperature greater than 350 °C and falling within category II on the basis of Table 7 shall be classified in category III.

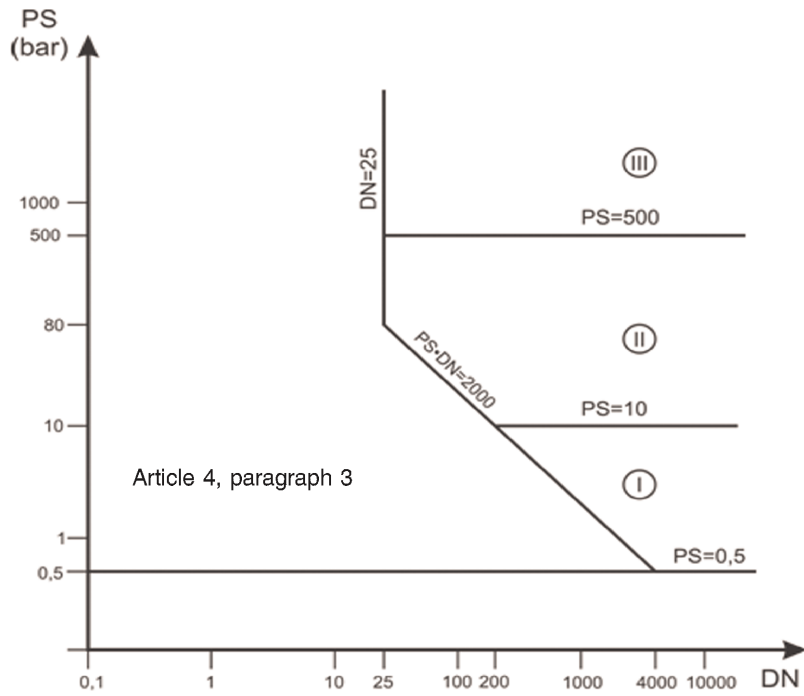


Table 8

Piping referred to in Article 4(1)(c)(ii), first indent

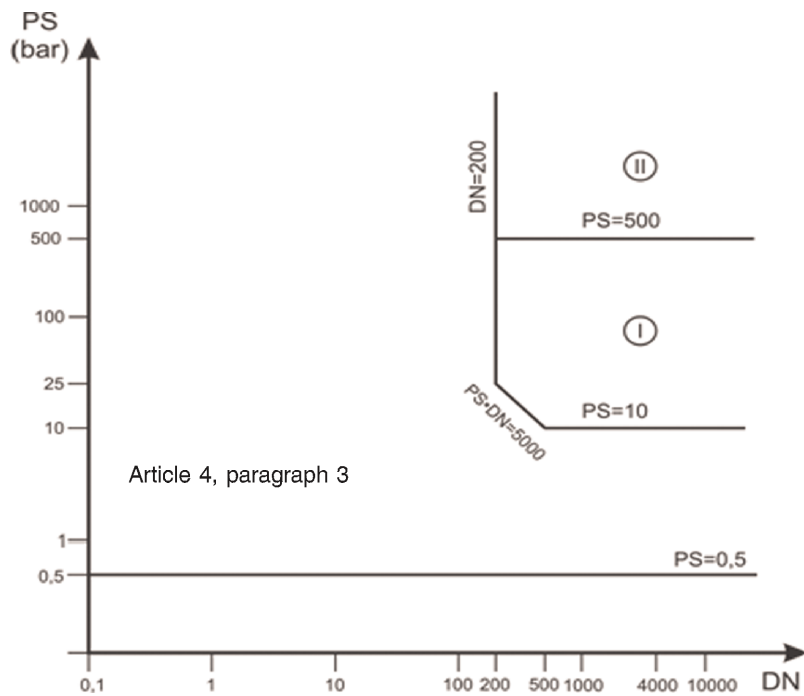


Table 9

Piping referred to in Article 4(1)(c)(ii), second indent

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ANNEX III

CONFORMITY ASSESSMENT PROCEDURES

The obligations arising from the provisions on pressure equipment in this Annex also apply to assemblies.

1. MODULE A: (INTERNAL PRODUCTION CONTROL)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive.

2. Technical documentation

The manufacturer shall establish the technical documentation.

The technical documentation shall make it possible to assess the conformity of the pressure equipment to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,
- a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and a description of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in point 2 and with the requirements of this Directive.

4. CE marking and EU declaration of conformity

- 4.1. The manufacturer shall affix the CE marking to each individual pressure equipment that satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for the pressure equipment model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

2. **MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS**

1. Internal production control plus supervised pressure equipment checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive.

2. **Technical documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
- a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to it.

4. **Final assessment and pressure equipment checks**

The manufacturer shall perform a final assessment of the pressure equipment, monitored by means of unexpected visits by a notified body chosen by the manufacturer.

The notified body shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the pressure equipment, taking into account, inter alia, the technological complexity of the pressure equipment and the quantity of production.

During its unexpected visits, the notified body shall:

- establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Annex I.

- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment.

Should one or more of the items of pressure equipment or assembly not conform, the notified body shall take appropriate measures.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. **CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking to each individual pressure equipment that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for the pressure equipment model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. **Authorised representative**

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. **MODULE B: EU-TYPE EXAMINATION**

3.1. ***EU-Type examination – production type***

1. EU-type examination — production type is the part of a conformity assessment procedure in which a notified body examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of this Directive.
2. EU-type examination — production type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete pressure equipment.
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,

- the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:
 - a general description of the pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - results of design calculations made, examinations carried out, etc.,
 - test reports,
 - information concerning the tests provided for in manufacture,
 - information concerning the qualifications or approvals required under points 3.1.2 and 3.1.3 of Annex I,
- the specimens representative of the production envisaged.

The specimen may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.

The notified body may request further specimens if needed for carrying out the test programme;

- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer applying other relevant technical specifications, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

- 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pressure equipment and the manufacturing procedures.

In particular, the notified body shall:

- assess the materials where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with point 3.1.2 of Annex I,

— verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with points 3.1.2 or 3.1.3 of Annex I.

- 4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards.
- 4.3. carry out appropriate examinations and necessary tests to check whether when the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly.
- 4.4. carry out appropriate examinations and necessary tests to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive.
- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authority, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate – production type to the manufacturer. Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pressure equipment with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate – production type and shall inform the applicant accordingly, giving detailed reasons for its refusal. Provision shall be made for an appeals procedure.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate – production type of all modifications to the approved type that may affect the conformity of the pressure equipment with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU- type examination certificate – production type.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates – production type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates – production type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates – production type and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate – production type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate – production type, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

3.2. *EU-Type examination – design type*

1. EU-type examination – design type is the part of a conformity assessment procedure in which a notified body examines the technical design of the pressure equipment and verifies and attests that the technical design of the pressure equipment meets the requirements of this Directive.
2. The EU-type examination – design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen.

The experimental design method provided for in point 2.2.4 of Annex I shall not be used in the context of this module.

3. The manufacturer shall lodge an application for EU-type examination — design type with a single notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment with the applicable requirements of the Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall contain, wherever applicable, at least the following elements:
 - a general description of the pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,

- a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc.,
- information regarding the qualifications or approvals required under points 3.1.2 and 3.1.3 of Annex I,
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. This supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

The application may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.

4. The notified body shall:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product.

In particular, the notified body shall:

- assess the materials where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials,
 - approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with point 3.1.2 of Annex I.
- 4.2. carry out appropriate examinations to check whether where the manufacturer has chosen to apply the solutions in the relevant harmonised standards these have been applied correctly.
- 4.3. carry out appropriate examinations to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the design meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate — design type to the manufacturer. Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved design.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pressure equipment with the examined design to be evaluated and to allow for in-service control.

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate — design type and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate — design type of all modifications to the approved design that may affect the conformity of the pressure equipment with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate — design type.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates — design type and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates — design type and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates — design type and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate — design type, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate — design type, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

4. MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS

1. Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pressure equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to it.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. Final assessment and pressure equipment checks

A notified body, chosen by the manufacturer, shall carry out checks or have them carried out at random intervals determined by the body, in order to verify the quality of the final assessment and of the internal checks on the pressure equipment, taking into account, inter alia, the technological complexity of the pressure equipment and the quantity of production.

The notified body shall establish that the manufacturer actually performs final assessment in accordance with point 3.2 of Annex I.

An adequate sample of the final pressure equipment, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or equivalent tests applying other technical specifications, shall be carried out to check the conformity of the pressure equipment with the relevant requirements of this Directive.

The notified body shall assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of final assessment on the pressure equipment samples.

Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual pressure equipment or assembly that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for a pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

5. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment or assembly concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information on the pressure equipment type envisaged,
- the documentation concerning the quality system,
- the technical documentation of the approved type and a copy of the EU-type examination certificate.

- 3.2. The quality system shall ensure that the pressure equipment is in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc., and
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an inspection visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
 - the quality system documentation,
 - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
- 4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
 - the category of the pressure equipment,
 - the results of previous surveillance visits,
 - the need to follow up corrective actions,
 - special conditions linked to the approval of the system, where applicable,
 - significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out product tests or have them carried out in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:

- the documentation referred to point 3.1,
- the change referred to in point 3.5, as approved,
- the decisions and reports of the notified body referred to in points 3.3, 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

6. MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,
- a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

4. **Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

5. **Quality system**

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information on the pressure equipment type envisaged,
- the documentation concerning the quality system,
- the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with point 3.1.2 of Annex I, etc.,
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in point 5.2.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the pressure equipment technology concerned, and the knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

- 6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
- the quality system documentation,
 - the technical documentation referred to in point 2,
 - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
- 6.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
- the category of the pressure equipment,
 - the results of previous surveillance visits,
 - the need to follow up corrective action(s),
 - special conditions linked to the approval of the system, where applicable,
 - significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. **CE marking and EU declaration of conformity**

- 7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual pressure equipment that satisfies the applicable requirements of this Directive.
- 7.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
- the documentation referred to in point 5.1,
 - the change referred to in point 5.5,
 - the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall periodically, or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, or withdrawn, and upon request, of quality system approvals which it has issued.

10. **Authorised representative**

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

7. MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE

1. Conformity to type based on pressure equipment quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information on the pressure equipment type envisaged,
- the documentation concerning the quality system,
- the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
- the examinations and tests that will be carried out after manufacture,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I,
- the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant pressure equipment field and pressure equipment technology concerned and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
 - the quality system documentation,
 - the technical documentation,
 - the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.
- 4.4. In addition the notified body may pay unexpected visits to the manufacturer.

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:

- the category of the pressure equipment,
- the results of previous surveillance visits,
- the need to follow up corrective actions,

- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organisation, policy or techniques.

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. **CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pressure equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
 - the documentation referred to in point 3.1,
 - the change referred to in point 3.5, as approved,
 - the decisions and reports from the notified body which are referred to in points 3.3, 3.5, 4.3 and 4.4.
7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

8. **MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING**

1. Quality assurance of final pressure equipment inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of this Directive that apply to it.

2. **Technical documentation**

The manufacturer shall establish the technical documentation. The technical documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the pressure equipment,

- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
- a list of the harmonised standards, the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

4. **Manufacturing**

The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment as specified in point 5 and shall be subject to surveillance as specified in point 6.

5. **Quality system**

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information on the pressure equipment type envisaged,
- the documentation concerning the quality system, and
- the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.

Under the quality system, each item of pressure equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 12, or equivalent tests, and particularly final assessment as referred to in point 3.2 of Annex I, shall be carried out in order to ensure its conformity with the requirements of this Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

- the procedures used for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
- the examinations and tests that will be carried out after manufacture,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with point 3.1.2 of Annex I,
- the means of monitoring the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is required.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documentation referred to in point 2,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
- 6.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:
- the category of the equipment,
 - the results of previous surveillance visits,
 - the need to follow up corrective action(s),
 - special conditions linked to the approval of the system, where applicable,
 - significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. **CE marking and EU declaration of conformity**

- 7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual item of pressure equipment that satisfies the applicable requirements of this Directive.
- 7.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
- the documentation referred to in point 5.1,
 - the change referred to in point 5.5, as approved,
 - the decisions and reports of the notified body referred to in points 5.3, 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn and shall periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

10. **Authorised representative**

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

9. MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION

1. Conformity to type based on pressure equipment verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned, which has been subject to the provisions of point 3, is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive which apply to it.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements of this Directive which apply to them.

3. **Verification**

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests in order to check the conformity of the pressure equipment with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the pressure equipment with the appropriate requirements shall be carried out by examination and testing of every product as specified in point 4.

4. **Verification of conformity by examination and testing of every item of pressure equipment**

- 4.1. All pressure equipment shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the EU-type examination certificate and with the appropriate requirements of this Directive. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

In particular, the notified body shall:

- verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with points 3.1.2 and 3.1.3 of Annex I,
- verify the certificate issued by the materials manufacturer in accordance with point 4.3 of Annex I,
- carry out or have carried out the final inspection and proof test referred to in point 3.2 of Annex I and examine the safety devices, if applicable.

- 4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number or have it affixed under its responsibility to each approved item of pressure equipment.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment has been placed on the market.

5. **CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual item of pressure equipment that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities, for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the pressure equipment.

6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the pressure equipment during the manufacturing process.

7. **Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.

10. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

2. **Technical documentation**

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4.

The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pressure equipment.

The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,
- a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards, have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports,
- appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the personnel concerned in accordance with points 3.1.2 and 3.1.3 of Annex I.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pressure equipment has been placed on the market.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment with the applicable requirements of this Directive.

4. **Verification**

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standard(s) and/or equivalent tests, to check the conformity of the pressure equipment with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.

In particular the notified body shall:

- examine the technical documentation with respect to the design and the manufacturing procedures,
- assess the materials used where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,
- approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with point 3.1.2 of Annex I,
- verify the qualifications or approvals required under points 3.1.2 and 3.1.3 of Annex I,
- carry out the final inspection referred to in point 3.2.1 of Annex I, perform or have performed the proof test referred to in point 3.2.2 of Annex I, and examine the safety devices, if applicable.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved pressure equipment, or have it affixed under its responsibility. The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.

5. **CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each item of pressure equipment that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. **Authorised representative**

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

11. MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfies the requirements of this Directive that apply to it.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture, final product inspection and testing of the pressure equipment as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - results of design calculations made, examinations carried out, etc.,
 - test reports,
- the documentation concerning the quality system, and
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the pressure equipment will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment, pertaining to the product type covered, particularly with regard to materials in accordance with point 4 of Annex I,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
- the examinations and tests to be carried out before, during, and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.,
- the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as assessor in the pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
 - the quality system documentation,
 - the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
 - the quality records provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer.

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors shall be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action(s),
- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organisation, policy or techniques.

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual item of pressure equipment that satisfies the applicable requirements of this Directive.

- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
- the technical documentation referred to in point 3.1,
 - the documentation concerning the quality system referred to in point 3.1,
 - the change referred to point 3.4, as approved,
 - the decisions and reports of the notified body referred to in points 3.3, 3.4, 4.3 and 4.4.
7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

12. **MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION**

1. Conformity based on full quality assurance plus design examination and special surveillance of the final assessment is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the pressure equipment concerned satisfy the requirements of the Directive that apply to it.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the pressure equipment shall have been examined in accordance with point 4.

3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

- the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - results of design calculations made, examinations carried out, etc.,
 - test reports,
- the documentation concerning the quality system,
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment pertaining to the pressure equipment type covered, particularly with regard to materials in accordance with point 4 of Annex I,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.,
- the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.6. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

4. Design examination

- 4.1. The manufacturer shall lodge an application for examination of the design of each item of pressure equipment not covered by a previous design examination with the notified body referred to in point 3.1.

- 4.2. The application shall make it possible to understand the design, manufacture and operation of the pressure equipment, and to assess the conformity with the requirements of this Directive that apply to it. It shall include:

- the name and address of the manufacturer,

- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The documentation shall make it possible to assess the conformity of the pressure equipment with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the pressure equipment. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
 - a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive, where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - results of design calculations made, examinations carried out, etc., and
 - test reports,
- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the requirements of this Directive that apply to the pressure equipment it shall issue an EU design examination certificate to the manufacturer. The certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval — from the notified body that issued the EU design examination certificate — in the form of an addition to the original EU design examination certificate.

- 4.5. Each notified body shall inform its notifying authorities of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EU design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

- 4.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market.

5. Surveillance under the responsibility of the notified body

- 5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.

- 5.4. In addition, the notified body may pay unexpected visits to the manufacturer.

The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action(s),

- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organisation, policy or techniques.

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5.5. Special surveillance of the final assessment

Final assessment as referred to in section 3.2 of Annex I is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body shall conduct examinations on the pressure equipment.

It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. CE marking and EU declaration of conformity

- 6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual item of pressure equipment that satisfies the applicable requirements of this Directive.
- 6.2. The manufacturer shall draw up a written EU declaration of conformity for each pressure equipment model and keep it at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. The EU declaration of conformity shall identify the pressure equipment model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

7. The manufacturer shall, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities:
 - the documentation concerning the quality system referred to in point 3.1,
 - the change referred to in point 3.5, as approved,
 - the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX) ⁽¹⁾

1. Pressure equipment or assembly (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of pressure equipment or assembly allowing traceability; it may, where necessary for the identification of the pressure equipment or assembly, include an image):
 - description of the pressure equipment or assembly,
 - conformity assessment procedure followed,
 - in the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed,
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. Where appropriate, the name, address and number of the notified body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU-type examination certificate – design type, EU design examination certificate or certificate of conformity.
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

(where appropriate, particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative)

⁽¹⁾ It is optional for the manufacturer to assign a number to the declaration of conformity.

ANNEX V

PART A**Repealed Directive with list of the successive amendments thereto**

(referred to in Article 50)

Directive 97/23/EC of the European Parliament and of the Council

(OJ L 181, 9.7.1997, p. 1).

Regulation (EC) No 1882/2003 of the European Parliament and of the Council Only point 13 of Annex I

(OJ L 284, 31.10.2003, p. 1).

Regulation (EU) No 1025/2012 of the European Parliament and of the Council Only point (f) of Article 26(1)

(OJ L 316, 14.11.2012, p. 12).

PART B**Time-limit for transposition into national law and date of application**

(referred to in Article 49)

Directive	Time-limit for transposition	Date of application
97/23/EC	29 May 1999	29 November 1999 ⁽¹⁾

⁽¹⁾ In accordance with Article 20(3) of Directive 97/23/EC, Member States shall permit the putting into service of pressure equipment and assemblies which comply with the regulations in force in their territory at the date of application of the Directive beyond that date.

ANNEX VI

CORRELATION TABLE

Directive 97/23/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 2(1) to (14)
Article 1(3)	Article 1(2)
—	Article 2(15) to (32)
Article 2	Article 3
Article 3	Article 4
Article 4(1)	Article 5(1)
Article 4(2)	Article 5(3)
—	Article 6
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
Article 5	—
Article 6	—
—	Article 12(1)
Article 7(1)	Article 45
Article 7(2)	Article 44(1)
Article 7(3)	—
Article 7(4)	Article 44(5), second subparagraph
Article 8	—
Article 9(1)	Article 13(1), introductory sentence
Article 9(2) point 1	—
—	Article 13(1)(a)
Article 9(2) point 2	Article 13(1)(b)
Article 9(3)	Article 13(2)
Article 10	Article 14

Directive 97/23/EC	This Directive
Article 11(1)	Article 15(1)
Article 11(2)	Article 15(2)
Article 11(3)	Article 15(3)
Article 11(4)	Article 12(2)
—	Article 15(4)
Article 11(5)	Article 15(5)
—	Article 15(6)
Article 12	—
Article 13	—
Article 14(1)	Article 16(1)
Article 14(2)	Article 5(2)
Article 14(3) to (8)	Article 16(2) to (7)
Article 14(9) and (10)	—
—	Article 17
—	Article 18
Article 15(1)	—
Article 15(2)	Article 19(1)
Article 15(3)	Article 19(2)
Article 15(4) and (5)	—
—	Article 19(3) to (6)
—	Article 20
—	Article 21
—	Article 22
—	Article 23
—	Article 24
—	Article 25
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—	Article 28
—	Article 29

Directive 97/23/EC	This Directive
—	Article 30
—	Article 31
—	Article 32
—	Article 33
—	Article 34
—	Article 35
—	Article 36
—	Article 37
—	Article 38
Article 16	—
Article 17	—
Article 18	—
—	Article 39
—	Article 40
—	Article 41
—	Article 42
—	Article 43
—	Article 44(2) to (4)
—	Article 44(5), first subparagraph
—	Article 46
—	Article 47
Article 19	—
Article 20(1) to (2)	—
Article 20(3)	Article 48(1)
—	Article 48(2) and (3)
—	Article 49
—	Article 50
—	Article 51
Article 21	Article 52
Annex I	Annex I

Directive 97/23/EC	This Directive
Annex II	Annex II
Annex III, introductory wording	Annex III, introductory wording
Annex III, Module A	Annex III, point 1, Module A
Annex III, Module A1	Annex III, point 2, Module A2
Annex III, Module B	Annex III, point 3.1, Module B, EU-type examination – production type
Annex III, Module B1	Annex III, point 3.2, Module B, EU-type examination – design type
Annex III, Module C1	Annex III, point 4, Module C2
Annex III, Module D	Annex III, point 5, Module D
Annex III, Module D1	Annex III, point 6, Module D1
Annex III, Module E	Annex III, point 7, Module E
Annex III, Module E1	Annex III, point 8, Module E1
Annex III, Module F	Annex III, point 9, Module F
Annex III, Module G	Annex III, point 10, Module G
Annex III, Module H	Annex III, point 11, Module H
Annex III, Module H1	Annex III, point 12, Module H1
Annex IV	—
Annex V	—
Annex VI	—
Annex VII	Annex IV
—	Annex V
—	Annex VI

STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

CORRIGENDA**Corrigendum to Regulation (EU) No 1295/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Creative Europe Programme (2014 to 2020) and repealing Decisions No 1718/2006/EC, No 1855/2006/EC and No 1041/2009/EC**

(Official Journal of the European Union L 347 of 20 December 2013)

On page 233, Article 24(6):

for: '6. By way of derogation from Article 130(2) of the Financial Regulation, and in duly justified cases, the Commission may consider costs directly linked to the implementation of the supported actions and activities as eligible even if they are incurred by the beneficiary before the submission of the grant application.'

read: '6. In accordance with Article 130(1) of the Financial Regulation, and in duly justified cases, the Commission may consider costs directly linked to the implementation of the supported actions and activities as eligible even if they are incurred by the beneficiary before the submission of the grant application.'

Corrigendum to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007

(Official Journal of the European Union L 347 of 20 December 2013)

On page 732, Article 141(2)(a)(ii):

for: '(ii) between 1 February and 31 August of the current marketing year for other quantities of beet sugar, isoglucose or inulin syrup being carried forward;'

read: '(ii) between 1 February and 31 August of the current marketing year for quantities of beet sugar or inulin syrup being carried forward;'

Corrigenda

- ★ **Corrigendum to Regulation (EU) No 1295/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Creative Europe Programme (2014 to 2020) and repealing Decisions No 1718/2006/EC, No 1855/2006/EC and No 1041/2009/EC (OJ L 347, 20.12.2013) 260**

- ★ **Corrigendum to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013) 261**

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