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)

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)];

(ii) Regulation (EU) No 167/2013 of the European Parliament and of the Council[(4)];

(iii) Regulation (EU) No 168/2013 of the European Parliament and of the Council[(5)];

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[(6)];

(ii) Directive 2014/33/EU of the European Parliament and of the Council[(7)];

(iii) Directive 2014/35/EU of the European Parliament and of the Council[(8)];

(iv) Council Directive 93/42/EEC[(9)];

(v) Directive 2009/142/EC of the European Parliament and of the Council[(10)];

(vi) Directive 2014/34/EU of the European Parliament and of the Council[(11)];

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;

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 super-heated 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.

[[X1]7 By way of derogation from paragraphs 1 to 6 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 to 6 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.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 189 of 27 June 2014).

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.

[[X1]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 19 July 2016.**]**

3 Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under this Directive.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 189 of 27 June 2014).

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.

(**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).

(**4**) 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).

(**5**) 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).

(**6**) 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).

(**7**) 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).

(**8**) 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).

(**9**) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(**10**) 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).

(**11**) 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).