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 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.