

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (Text with EEA relevance)

## CHAPTER 1

### SCOPE AND DEFINITIONS

#### *Article 1*

##### **Scope**

- 1 This Directive sets out detailed rules concerning transportable pressure equipment to enhance safety and ensure free movement of such equipment within the Union.
- 2 This Directive shall apply to:
  - a new transportable pressure equipment as defined in Article 2(1), which does not bear the conformity markings provided for in Directives 84/525/EEC, 84/526/EEC, 84/527/EEC or 1999/36/EC, for the purpose of making it available on the market;
  - b transportable pressure equipment as defined in Article 2(1), bearing the conformity markings provided for in this Directive or in Directives 84/525/EEC, 84/526/EEC, 84/527/EEC or 1999/36/EC, for the purposes of its periodic inspections, intermediate inspections, exceptional checks and use;
  - c transportable pressure equipment as defined in Article 2(1), which does not bear the conformity markings provided for in Directive 1999/36/EC, for the purposes of reassessment of conformity.
- 3 This Directive shall not apply to transportable pressure equipment which was placed on the market before the date of implementation of Directive 1999/36/EC and which has not been subject to a reassessment of conformity.
- 4 This Directive shall not apply to transportable pressure equipment used exclusively for the transport of dangerous goods between Member States and third countries, carried out in accordance with Article 4 of Directive 2008/68/EC.

#### *Article 2*

##### **Definitions**

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

- (1) ‘transportable pressure equipment’ means:
  - (a) all pressure receptacles, their valves and other accessories when appropriate, as covered in Chapter 6.2 of the Annexes to Directive 2008/68/EC;
  - (b) tanks, battery vehicles/wagons, multiple-element gas containers (MEGCs), their valves and other accessories when appropriate, as covered in Chapter 6.8 of the Annexes to Directive 2008/68/EC;

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when the equipment under (a) or (b) is used in accordance with those Annexes for the transport of Class 2 gases, excluding gases or articles with figures 6 and 7 in the classification code, and for the transport of the dangerous substances of other classes specified in Annex I to this Directive.

Transportable pressure equipment shall be understood as including gas cartridges (UN No 2037) and excluding aerosols (UN No 1950), open cryogenic receptacles, gas cylinders for breathing apparatus, fire extinguishers (UN No 1044), transportable pressure equipment exempted according to 1.1.3.2 of the Annexes to Directive 2008/68/EC and transportable pressure equipment exempted from the rules for construction and testing of packaging according to special provisions in 3.3 of the Annexes to Directive 2008/68/EC;

- (2) ‘Annexes to Directive 2008/68/EC’ means Section I.1 of Annex I, Section II.1 of Annex II, and Section III.1 of Annex III to Directive 2008/68/EC;
- (3) ‘placing on the market’ means the first making available of transportable pressure equipment on the Union market;
- (4) ‘making available on the market’ means any supply of transportable pressure equipment for distribution or use on the Union market in the course of a commercial or public service activity, whether in return for payment or free of charge;
- (5) ‘use’ means filling, temporary storage linked to carriage, emptying and refilling of transportable pressure equipment;
- (6) ‘withdrawal’ means any measure aimed at preventing transportable pressure equipment from being made available on the market or from being used;
- (7) ‘recall’ means any measure aimed at achieving the return of transportable pressure equipment that has already been made available to the end user;
- (8) ‘manufacturer’ means any natural or legal person who manufactures transportable pressure equipment, or parts thereof, or who has such equipment designed or manufactured and markets it under his name or trademark;
- (9) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from the manufacturer to act on his behalf in relation to specified tasks;
- (10) ‘importer’ means any natural or legal person established within the Union, who places transportable pressure equipment or parts thereof from a third country on the Union market;
- (11) ‘distributor’ means any natural or legal person established within the Union, other than the manufacturer or the importer, who makes transportable pressure equipment or parts thereof available on the market;
- (12) ‘owner’ means any natural or legal person established within the Union who owns transportable pressure equipment;
- (13) ‘operator’ means any natural or legal person established in the Union using transportable pressure equipment;
- (14) ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, the owner or the operator acting in the course of a commercial or public service activity, whether in return for payment or free of charge;

- (15) ‘conformity assessment’ means the assessment and the procedure for the assessment of conformity set out in the Annexes to Directive 2008/68/EC;
- (16) ‘Pi marking’ means a marking which indicates that the transportable pressure equipment is in conformity with the applicable conformity assessment requirements set out in the Annexes to Directive 2008/68/EC and in this Directive;
- (17) ‘reassessment of conformity’ means the procedure undertaken, at the request of the owner or operator, for the subsequent assessment of the conformity of transportable pressure equipment manufactured and placed on the market before the date of implementation of Directive 1999/36/EC;
- (18) ‘periodic inspection’ means the periodic inspection and the procedures governing the periodic inspection as set out in the Annexes to Directive 2008/68/EC;
- (19) ‘intermediate inspection’ means the intermediate inspection and the procedures governing the intermediate inspection as set out in the Annexes to Directive 2008/68/EC;
- (20) ‘exceptional check’ means the exceptional check and the procedures governing the exceptional check set out in the Annexes to Directive 2008/68/EC;
- (21) ‘national accreditation body’ means the sole body in a Member State that performs accreditation with authority derived from the State;
- (22) ‘accreditation’ means an attestation by a national accreditation body that a notified body meets the requirements set out in the second paragraph of 1.8.6.8 of the Annexes to Directive 2008/68/EC;
- (23) ‘notifying authority’ means the authority designated by a Member State pursuant to Article 17;
- (24) ‘notified body’ means an inspection body meeting the requirements set out in the Annexes to Directive 2008/68/EC and the conditions set out in Articles 20 and 26 of this Directive and notified in accordance with Article 22 of this Directive;
- (25) ‘notification’ is the process of awarding notified body status to an inspection body and includes communication of this information to the Commission and to the Member States;
- (26) ‘market surveillance’ means the activities carried out and measures taken by public authorities to ensure that transportable pressure equipment during its life cycle complies with the requirements set out in Directive 2008/68/EC and this Directive and does not endanger health, safety or any other aspect of public interest protection.

### *Article 3*

#### **On-site requirements**

Member States may on their territory establish on-site requirements for the mid- or long-term storage or the on-site use of transportable pressure equipment. However, Member States shall not establish additional requirements for the transportable pressure equipment itself.

## CHAPTER 2

### OBLIGATIONS OF ECONOMIC OPERATORS

#### *Article 4*

##### **Obligations of manufacturers**

1 When placing their transportable pressure equipment on the market, manufacturers shall ensure that the equipment has been designed, manufactured and documented in accordance with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

2 Where the compliance of the transportable pressure equipment with the applicable requirements has been demonstrated through the conformity assessment process set out in the Annexes to Directive 2008/68/EC and in this Directive, manufacturers shall affix the Pi marking in accordance with Article 15 of this Directive.

3 Manufacturers shall keep the technical documentation specified in the Annexes to Directive 2008/68/EC. This documentation shall be kept for the period specified therein.

4 Manufacturers who consider or have reason to believe that transportable pressure equipment which they have placed on the market is not in conformity with the Annexes to Directive 2008/68/EC or with this Directive shall immediately take the corrective measures necessary to bring the transportable pressure equipment into conformity, to withdraw it or to recall it, if appropriate. Furthermore, where the transportable pressure equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the transportable pressure equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5 Manufacturers shall document all such instances of non-compliance and corrective measures.

6 Manufacturers shall, further to a reasoned request from the competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment, in a language easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by transportable pressure equipment which they have placed on the market.

7 Manufacturers shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

#### *Article 5*

##### **Authorised representatives**

1 Manufacturers may, by a written mandate, appoint an authorised representative.

The obligations set out in Article 4(1) and (2) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- a keep the technical documentation at the disposal of national surveillance authorities for at least the period as specified in the Annexes to Directive 2008/68/EC for manufacturers;
  - 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 transportable pressure equipment in a language easily understood by that authority;
  - c cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by transportable pressure equipment covered by the mandate.
- 3 The identity and address of the authorised representative shall be indicated on the certificate of conformity specified in the Annexes to Directive 2008/68/EC.
- 4 Authorised representatives shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

### *Article 6*

#### **Obligations of importers**

1 Importers shall only place on the Union market transportable pressure equipment which is in conformity with the Annexes to Directive 2008/68/EC and with this Directive.

2 Before placing transportable pressure equipment on the market, importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation and that the transportable pressure equipment bears the Pi marking and is accompanied by the certificate of conformity specified in the Annexes to Directive 2008/68/EC.

Where an importer considers or has reason to believe that the transportable pressure equipment is not in conformity with the Annexes to Directive 2008/68/EC or with this Directive, he shall not place the transportable pressure equipment on the market until it has been brought into conformity. Furthermore, where the transportable pressure equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3 Importers shall indicate their name and the address at which they can be contacted either in, or attached to, the certificate of conformity specified in the Annexes to Directive 2008/68/EC.

4 Importers shall ensure that, while transportable pressure equipment is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in the Annexes to Directive 2008/68/EC.

5 Importers who consider or have reason to believe that transportable pressure equipment which they have placed on the market is not in conformity with the Annexes to Directive 2008/68/EC or with this Directive shall immediately take the corrective measures necessary to bring the transportable pressure equipment into conformity, to withdraw it or to recall it, if appropriate. Furthermore, where the transportable pressure equipment presents a risk, importers shall immediately inform the manufacturer and the competent national authorities of the Member States in which they made the transportable pressure equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

Importers shall document all such instances of non-compliance and corrective measures.

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6 Importers shall, for at least the period specified in the Annexes to Directive 2008/68/EC for manufacturers, keep a copy of the technical documentation at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request.

7 Importers shall, further to a reasoned request from the competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment, in a language easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by transportable pressure equipment which they have placed on the market.

8 Importers shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

#### *Article 7*

### **Obligations of distributors**

1 Distributors shall only make available on the Union market transportable pressure equipment which is in conformity with the Annexes to Directive 2008/68/EC and with this Directive. Before making transportable pressure equipment available on the market distributors shall verify that the transportable pressure equipment bears the Pi marking, and that it is accompanied by the certificate of conformity and the contact address referred to in Article 6(3) of this Directive.

Where a distributor considers or has reason to believe that transportable pressure equipment is not in conformity with the Annexes to Directive 2008/68/EC or with this Directive, he shall not make the transportable pressure equipment available on the market until it has been brought into conformity. Furthermore, where the transportable pressure equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

2 Distributors shall ensure that, while transportable pressure equipment is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in the Annexes to Directive 2008/68/EC.

3 Distributors who consider or have reason to believe that transportable pressure equipment which they have made available on the market is not in conformity with the Annexes to Directive 2008/68/EC or with this Directive shall make sure that the corrective measures necessary to bring that transportable pressure equipment into conformity, to withdraw it or to recall it, if appropriate, are taken. Furthermore, where the transportable pressure equipment presents a risk, distributors shall immediately inform the manufacturer, the importer, where relevant, and the competent national authorities of the Member States in which they made the transportable pressure equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

Distributors shall document all such instances of non-compliance and corrective measures.

4 Distributors shall, further to a reasoned request from the competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment in a language easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by transportable pressure equipment which they have made available on the market.

5 Distributors shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

#### *Article 8*

### **Obligations of owners**

1 Where an owner considers or has reason to believe that transportable pressure equipment is not in conformity with the Annexes to Directive 2008/68/EC, including the requirements for periodic inspection, and with this Directive, he shall not make it available or use it until it has been brought into conformity. Furthermore, where the transportable pressure equipment presents a risk, the owner shall inform the manufacturer or the importer or the distributor to that effect as well as the market surveillance authorities.

Owners shall document all such instances of non-compliance and corrective measures.

2 Owners shall ensure that, while transportable pressure equipment is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in the Annexes to Directive 2008/68/EC.

3 Owners shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

4 This Article shall not apply to private individuals intending to use or using transportable pressure equipment for their personal or domestic use or for their leisure or sporting activities.

#### *Article 9*

### **Obligations of operators**

1 Operators shall only use transportable pressure equipment which is in conformity with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

2 Where the transportable pressure equipment presents a risk, the operator shall inform the owner to that effect as well as the market surveillance authorities.

#### *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 subject to the obligations of the manufacturer pursuant to Article 4, where he places transportable pressure equipment on the market under his name or trademark or modifies transportable pressure equipment already placed on the market in such a way that compliance with the applicable requirements may be affected.

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### *Article 11*

#### **Identification of economic operators**

Economic operators shall, on request from the market surveillance authority, identify the following to it for a period of at least 10 years:

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

### CHAPTER 3

#### **CONFORMITY OF TRANSPORTABLE PRESSURE EQUIPMENT**

### *Article 12*

#### **Conformity of transportable pressure equipment and its assessment**

1 The transportable pressure equipment referred to in Article 1(2)(a) shall meet the relevant conformity assessment, periodic inspection, intermediate inspection and exceptional checks requirements set out in the Annexes to Directive 2008/68/EC and in Chapters 3 and 4 of this Directive.

2 The transportable pressure equipment referred to in Article 1(2)(b) shall meet the specifications of the documentation according to which the equipment was manufactured. The equipment shall be subject to periodic inspections, intermediate inspections and exceptional checks in accordance with the Annexes to Directive 2008/68/EC and with the requirements of Chapters 3 and 4 of this Directive.

3 Certificates of conformity assessment and certificates of reassessment of conformity and reports of periodic inspections, intermediate inspections and exceptional checks issued by a notified body shall be valid in all Member States.

For demountable parts of refillable transportable pressure equipment a separate conformity assessment may be carried out.

### *Article 13*

#### **Reassessment of conformity**

The reassessment of conformity of transportable pressure equipment referred to in Article 1(2)(c) manufactured and put into service before the date of implementation of Directive 1999/36/EC shall be established in accordance with the conformity reassessment procedure set out in Annex III to this Directive.

The Pi marking shall be affixed in accordance with Annex III to this Directive.



## Article 14

### General principles of the Pi marking

1 The Pi marking shall only be affixed by the manufacturer or, in cases of reassessment of conformity, as set out in Annex III. For gas cylinders previously in compliance with Directives 84/525/EEC, 84/526/EEC or 84/527/EEC the Pi mark shall be affixed by or under the surveillance of the notified body.

2 The Pi marking shall be affixed only to transportable pressure equipment which:

- meets the conformity assessment requirements in the Annexes to Directive 2008/68/EC and in this Directive; or
- meets the reassessment of conformity requirements referred to in Article 13.

It shall not be affixed to any other transportable pressure equipment.

3 By affixing or having affixed the Pi marking, the manufacturer indicates that he takes responsibility for the conformity of the transportable pressure equipment with all applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

4 For the purposes of this Directive, the Pi marking shall be the only marking which attests conformity of the transportable pressure equipment with the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

5 The affixing on transportable pressure equipment of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the Pi marking, shall be prohibited. Any other marking shall be affixed to the transportable pressure equipment in such a way that the visibility, legibility and meaning of the Pi marking are not thereby impaired.

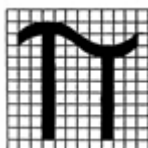
6 Demountable parts of refillable transportable pressure equipment with a direct safety function shall be Pi-marked.

7 Member States shall ensure correct implementation of the rules governing the Pi marking and shall take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

## Article 15

### Rules and conditions for the affixing of the Pi marking

1 The Pi marking shall consist of the following symbol in the following form:



2 The minimum height of the Pi marking shall be 5 mm. For transportable pressure equipment with a diameter less than or equal to 140 mm the minimum height shall be 2,5 mm.

3 The proportions given in the graduated drawing in paragraph 1 shall be respected. The grid does not form part of the marking.

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4 The Pi marking shall be affixed visibly, legibly and permanently to the transportable pressure equipment or to its data plate as well as to demountable parts of refillable transportable pressure equipment having a direct safety function.

5 The Pi marking shall be affixed before the new transportable pressure equipment or demountable parts of refillable transportable pressure equipment having a direct safety function are placed on the market.

6 The Pi marking shall be followed by the identification number of the notified body involved in the initial inspections and tests.

The identification number of the notified body shall be affixed by the body itself, or under its instructions, by the manufacturer.

7 The marking of the date of the periodic inspection or, where appropriate, the intermediate inspection shall be accompanied by the identification number of the notified body responsible for the periodic inspection.

8 With regard to gas cylinders previously in compliance with Directives 84/525/EEC, 84/526/EEC or 84/527/EEC not bearing the Pi marking, when the first periodic inspection is carried out in accordance with this Directive, the identification number of the notified body responsible shall be preceded by the Pi marking.

#### *Article 16*

### **Free movement of transportable pressure equipment**

Without prejudice to the safeguard procedures in Articles 30 and 31 of this Directive and to the market surveillance framework set out in Regulation (EC) No 765/2008<sup>(1)</sup>, no Member State shall prohibit, restrict or impede on its territory the free movement, the making available on the market and the use of transportable pressure equipment, which complies with this Directive.

## CHAPTER 4

### **NOTIFYING AUTHORITIES AND NOTIFIED BODIES**

#### *Article 17*

### **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, notification and subsequent monitoring of notified bodies.

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 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 set out in Article 18(1) to (6).

In addition the entrusted body 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 18*

### **Requirements relating to notifying authorities**

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

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

3 The notifying authority shall be organised in such a way that each decision relating to notification of the notified bodies is taken by competent persons different from those who carried out the assessment.

4 The notifying authority shall not offer or provide any activities or consultancy services on a commercial or competitive basis that notified bodies perform.

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

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

#### *Article 19*

### **Information obligation of notifying authorities**

Member States shall inform the Commission of their national procedures for the assessment, notification and monitoring of notified bodies, and of any changes to that information.

The Commission shall make that information publicly available.

#### *Article 20*

### **Requirements relating to notified bodies**

1 For the purposes of notification, a notified body shall meet the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

2 A competent authority, within the meaning of the Annexes to Directive 2008/68/EC may be a notified body provided it meets the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive and that it does not also act as the notifying authority.

3 The notified body shall be established under national law and shall have legal personality.

4 The notified body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body

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coordination group established pursuant to Article 29 and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### *Article 21*

##### **Application for notification**

- 1 An inspection body shall submit an application for notification to the notifying authority of the Member State in which it is established.
- 2 The application shall be accompanied by a description of:
  - a the activities relating to conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity;
  - b the procedures relating to point (a);
  - c the transportable pressure equipment for which the body claims to be competent;
  - d an accreditation certificate issued by a national accreditation body within the meaning of Regulation (EC) No 765/2008, attesting that the inspection body fulfils the requirements set out in Article 20 of this Directive.

#### *Article 22*

##### **Notification procedure**

- 1 Notifying authorities shall notify only those bodies which have satisfied the requirements set out in Article 20.
- 2 They shall notify the Commission and the other Member States using the electronic tool developed and managed by the Commission.
- 3 The notification shall include the information required in Article 21(2).
- 4 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification.

Only such a body shall be considered a notified body for the purposes of this Directive.
- 5 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.
- 6 In-house inspection services of the applicant as defined in the Annexes to Directive 2008/68/EC shall not be notified.

#### *Article 23*

##### **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 allocated to them and the activities for which they have been notified.

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

#### *Article 24*

### **Changes to notifications**

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements set out in Article 20, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification, as appropriate, 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 withdrawal, restriction or suspension of notification or where the notified body has ceased its activity, the notifying Member State shall take the appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities on request.

#### *Article 25*

### **Challenge to the competence of notified bodies**

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

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

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

4 Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification, if necessary.

#### *Article 26*

### **Operational obligations of notified bodies**

1 Notified bodies shall carry out conformity assessments, periodic inspections, intermediate inspections and exceptional checks in accordance with the terms of their notification and the procedures set out in the Annexes to Directive 2008/68/EC.

2 Notified bodies shall carry out reassessments of conformity in accordance with Annex III.

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3 Notified bodies notified by one Member State shall be authorised to work in all Member States. The notifying authority which carried out the initial assessment and notification retains the responsibility for monitoring the ongoing activities of the notified body.

#### *Article 27*

### **Information obligation of notified bodies**

- 1 Notified bodies 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 and conditions for notification;
  - c any request for information on activities performed which they have received from market surveillance authorities;
  - d on request, activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
- 2 Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment, periodic inspection, intermediate inspections and exceptional checks activities covering the same transportable pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### *Article 28*

### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible under this Directive for:

- (a) notification policy;
- (b) market surveillance.

#### *Article 29*

### **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

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

## CHAPTER 5

**SAFEGUARD PROCEDURES***Article 30***Procedure for dealing with transportable pressure equipment presenting a risk at national level**

1 Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008 or where they have sufficient reason to believe that transportable pressure equipment covered by this Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the transportable pressure equipment concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities, including granting access to their premises and providing samples as appropriate.

Where, in the course of that evaluation, the market surveillance authorities find that the transportable pressure equipment does not comply with the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the transportable pressure equipment into compliance with those requirements, to withdraw the transportable pressure equipment 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 corrective action 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 transportable pressure equipment that it has made available on the Union market.

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 transportable pressure equipment being made available on their national market, to withdraw the equipment from that market or to recall it.

They shall inform the Commission and the other Member States, without delay, of those measures.

5 The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant transportable pressure equipment, the origin of the equipment, the nature of the alleged non-compliance 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:

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- a failure of the transportable pressure equipment to meet requirements relating to the health or safety of persons or to other aspects of public interest protection set out in the Annexes to Directive 2008/68/EC and in this Directive, or
- b shortcomings in the standards or technical codes referred to in the Annexes to Directive 2008/68/EC or in other provisions of that Directive.

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

7 Where, within two months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

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

### *Article 31*

#### **Union safeguard procedure**

1 Where, on completion of the procedure set out in Article 30(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 a legally binding Union act, 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 decide 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 to the relevant economic operator or operators.

2 If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant transportable pressure equipment is withdrawn from their markets, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw it.

3 Where the national measure is considered justified and the non-compliance of the transportable pressure equipment is attributed to shortcomings in the standards as referred to in Article 30(5)(b), the Commission shall inform the relevant European standardisation body or bodies and may bring the matter before the Committee set up by Article 5 of Directive 98/34/EC<sup>(2)</sup>. That Committee may consult the relevant European standardisation body or bodies before delivering its opinion.

### *Article 32*

#### **Compliant transportable pressure equipment which presents a risk to health and safety**

1 Where having performed an evaluation pursuant to Article 30(1) a Member State finds that although transportable pressure equipment is in compliance with Directive 2008/68/EC



and this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the transportable pressure equipment concerned, when placed on the market, no longer presents that risk, to withdraw the equipment 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 transportable pressure equipment concerned that he has made available on the market or is using 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 transportable pressure equipment concerned, the origin and the supply chain of the equipment, 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 whether the measure is justified or not, and where necessary, propose appropriate measures.

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

### *Article 33*

#### **Formal non-compliance**

1 Without prejudice to Article 30, 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 that the Pi marking has been affixed in violation of Article 12, 13, 14 or 15;
- b that the Pi marking has not been affixed;
- c that the technical documentation is either not available or not complete;
- d that the requirements of the Annexes to Directive 2008/68/EC and of this Directive have not been complied with.

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 transportable pressure equipment being made available on the market or shall ensure that it is recalled or withdrawn from the market.

## CHAPTER 6

### **FINAL PROVISIONS**

#### *Article 34*

#### **Transitional provisions**

Within their territory, Member States may maintain the provisions listed in Annex II.

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Member States which maintain such provisions shall inform the Commission thereof. The Commission shall inform the other Member States.

#### *Article 35*

### **Adaptation to scientific and technical progress**

The Commission may adopt delegated acts in accordance with Article 290 TFEU as regards adaptations of the Annexes to this Directive to scientific and technical progress, in particular taking into account amendments to the Annexes to Directive 2008/68/EC.

For the delegated acts referred to in this Article, the procedures set out in Articles 36, 37 and 38 shall apply.

#### *Article 36*

### **Exercise of delegation**

1 The powers to adopt the delegated acts referred to in Article 35 shall be conferred on the Commission for an indeterminate period of time.

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

3 The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 37 and 38.

#### *Article 37*

### **Revocation of the delegation**

1 The delegation of power referred to in Article 35 may be revoked by the European Parliament or by the Council.

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

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

#### *Article 38*

### **Objections to delegated acts**

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

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

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

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

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

#### *Article 39*

### **Repeal**

Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC are repealed with effect from 1 July 2011.

References to the repealed Directive 1999/36/EC shall be construed as references to this Directive.

#### *Article 40*

### **Recognition of equivalence**

1 EEC pattern approval certificates for transportable pressure equipment issued pursuant to Directives 84/525/EEC, 84/526/EEC and 84/527/EEC and EC design-examination certificates issued pursuant to Directive 1999/36/EC shall be recognised as equivalent to the type approval certificates referred to in the Annexes to Directive 2008/68/EC and shall be subject to the provisions on time-limited recognition of type approvals set out in those Annexes.

2 Valves and accessories referred to in Article 3(3) of Directive 1999/36/EC and marked with the mark of Directive 97/23/EC<sup>(3)</sup> according to Article 3(4) of Directive 1999/36/EC may still be used.

#### *Article 41*

### **Obligations on Member States**

Member States shall take the necessary measures to ensure that the economic operators concerned comply with the provisions set out in Chapters 2 and 5. Member States shall also ensure that the necessary implementing measures are taken in respect of Articles 12 to 15.

#### *Article 42*

### **Transposition**

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2011 at the latest. They shall forthwith inform the Commission thereof.

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When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

3 Notwithstanding paragraph 1, Member States shall ensure that Article 21(2)(d) applies with effect from 1 January 2012 at the latest.

4 Member States shall ensure the laws, regulations and administrative provisions referred to in paragraph 1 apply to pressure receptacles, their valves and other accessories used for the carriage of UN No 1745, UN No 1746 and UN No 2495 from 1 July 2013 at the latest.

#### *Article 43*

#### **Entry into force**

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

#### *Article 44*

#### **Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 16 June 2010.

*For the European Parliament*

*The President*

J. BUZEK

*For the Council*

*The President*

D. LÓPEZ GARRIDO

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- (1) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218, 13.8.2008, p. 30).
- (2) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).
- (3) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1).