

COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 18.9.2009 COM(2009) 482 final

2009/0131 (COD)

Proposal for a

## DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ....

on transportable pressure equipment

## EXPLANATORY MEMORANDUM

#### 1. CONTEXT OF THE PROPOSAL

The transport of pressure equipment, e. g. tanks, receptacles, drums and cylinders, constitutes an important area of the transport of dangerous goods.

On 29 April 1999 the Council adopted a Directive on transportable pressure equipment (1999/36/EC, OJ L138 of 1/6/1999). This Directive ensures a high level of transport safety for transportable pressure equipment whilst allowing their free movement and use on the European transport market through common norms for their design, construction and subsequent checks.

For the technical requirements, the existing Directive 1999/36/EC refers to Directives 94/55/EC and 96/49/EC, which have been repealed by Directive 2008/68/EC with effect of 1 July 2009. Directive 2008/68/EC incorporates into Community legislation the requirements contained in international agreements on transport of dangerous goods by road (ADR: *European Agreement concerning the International Carriage of Dangerous Goods by Road*), rail (RID: *Regulations concerning the International Carriage of Dangerous Goods by Rail*) and inland waterways (ADN: *European Agreement concerning the International Carriage of Dangerous Goods by Rail*).

As a result of these recent legislative developments, which in turn reflect technical developments over the last 10 years, the European Union rules have become complicated and highly difficult to understand. In addition, on a number of technical issues the interplay between European and international rules will lead to certain contradictions which would make their application even more difficult. It is therefore necessary to simplify the rules wherever possible by eliminating the contradictions and streamlining the rules. As a by-product this will lead to a considerable reduction of the volume of the legislation which benefits users as well as national authorities which are called upon to ensure their full application.

The second key objective of the proposal concerns the use of the equipment itself for transport operations in the internal market. Whereas the existing Directive 1999/36/EC already ensures the equipment's free movement and use, recent developments in Community legislation relating to the marketing of products on the single European market, i.e. the "*New Legislative Framework*" Regulation No 765/2008/EC and Decision No 768/2008/EC, should be taken into account. The "*New Legislative Framework*" sets a general framework which should, wherever possible, be applied across all industrial sectors. Its principles are appropriate for the market of transportable pressure equipment and are therefore incorporated in this proposal. Such incorporation, whilst not introducing fundamental changes, would contribute towards a key objective of the "*New Legislative Framework*" of harmonising market rules in as many industrial sectors as possible as well as simplify the use of such rules by industry.

In view of these facts it is necessary to revise Directive 1999/36/EC.

## 2. CONSULTATION OF INTERESTED PARTIES

This proposal is the result of intensive consultations with the Member States and other interested parties. There is a general consensus that a revision of Directive 1999/36/EC is warranted.

The proposal focuses on a highly specified sector using transportable pressure equipment for gases and a small number of other substances. Furthermore, issues relating directly to safety, namely technical design, construction and testing provisions, are not addressed by the proposal itself, but by international agreements. Therefore the general public consultation on the proposal was not extended to these aspects.

## 3. LEGAL ELEMENTS OF THE PROPOSAL

The proposed Directive is to be adopted by codecision by the European Parliament and the Council. It would replace an existing Council Directive. The legal base of the proposal is Article 71of the Treaty.

## Subsidiarity principle

Besides guaranteeing a high level of safety in transport of dangerous goods, the proposed Directive also sets out rules for maintaining the already existing internal market for the equipment needed in the transport operations by relying on general European principles specified in the so-called "*New Legislative Framework*" rules Regulation No 765/2008/EC and Decision No 768/2008/EC. Such an objective cannot be achieved by national measures only.

## Proportionality principle

As there is an existing Directive, the legislative bodies of the European Union have already deemed such a measure necessary and proportional. This judgement appears well founded, since transportable pressure equipment is inherently dangerous, but they must be used for international transport of substances that are not locally available and yet are necessary, *inter alia*, for medical, scientific and industrial uses. Thus a European legislation guaranteeing a common level of safety and allowing efficient use of transportable pressure equipment is warranted.

## Choice of instrument

The proposed measure is a Directive. Firstly, it would replace an already existing Directive. Secondly, the implementation of the measure allows Member States their own organisational choices.

## 4. **BUDGETARY IMPLICATIONS**

Given that the provisions of the existing Directive on transportable pressure equipment are already implemented, any further budgetary implications will be minor.

## 5. **SIMPLIFICATION**

The need for simplification and clarification is the main reason for the Commission to propose this revision. Neither the scope, nor the measures of the existing Directive will be changed in any substantial way. This also results in minimal budgetary and other economic impacts on administration and operators.

As for the technical provisions, a central simplification objective is to remove conflicting issues between the existing Directive on Transportable Pressure Equipment and international rules on the transport of dangerous goods, in particular since these rules have already been extended to Community legislation through Directive 2008/68/EC.

The proposal simplifies existing provisions, in particular those relating to the modules on conformity assessment procedures. This dimension will be substantially streamlined and simplified in the proposal, which makes reference to the relevant international agreements. The technical rules and administrative procedures are more consistently presented in one source, i.e. in the international agreements. The proposed Directive focuses on those issues that can be treated satisfactorily only through European legislation.

As for making the equipment required for transport operations available on the market, the Community has recently adopted rules relating to the marketing of products on the EU single market ("*New Legislative Framework*") which should, wherever possible, be applied across all industrial sectors. By incorporating these rules into the proposal for the specific sector of transportable pressure equipment the Commission will help to simplify the rules by not creating different, sector-specific rules where the general rules would serve the purpose.

#### 6. ADDITIONAL INFORMATION

#### Repeal of existing legislation

The proposal will repeal Council Directive 1999/36/EC and a number of obsolete Directives on pressure cylinders.

#### Correlation table

The Member States are required to communicate to the Commission the text of national provisions transposing the directive as well as a correlation table between those provisions and this directive.

#### European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Detailed explanation of the proposal

Article 1: Scope

The Article identifies safety and the integrity of the internal market as key objectives and sets out the equipment to which the Directive applies.

## Article 2: Definitions

The Article defines a number of terms regarding transportable pressure equipment, actors and measures guaranteeing the safety of the equipment and its use on the internal market. Furthermore, the relevant terminology from the "New Legislative Framework" is defined.

#### Article 3: On-site requirements

The Article details when additional requirements for transportable pressure equipment may be established.

#### Article 4: Obligations of manufacturers

The Article establishes the obligations of manufacturers of transportable pressure equipment in normal operation and in cases where there is a reason to believe that the equipment is not in conformity with the rules.

#### Article 5: Authorised representatives

The Article specifies the steps to appoint an authorised representative and the tasks for such a body.

#### Article 6: Obligations of importers

The Article establishes the obligations of importers of transportable pressure equipment in normal operations and in cases where there is reason to believe that the equipment is not in conformity with the rules.

#### Article 7: Obligations of distributors

The Article establishes the obligations of distributors of transportable pressure equipment in normal operations and in cases where there is reason to believe that the equipment is not in conformity with the rules.

#### Article 8: Obligations of owners

The Article establishes the obligations of owners of transportable pressure equipment. Given the inherent danger of such equipment there needs to be formal obligations for guaranteeing continuing safety as long as the transportable pressure equipment is being used.

#### Article 9: Obligations of operators

The Articles ensures that operators use only equipment that is in conformity with the rules. Where the transportable pressure equipment presents a risk the operator shall inform the owner and market surveillance authorities.

#### Article 10: Cases in which obligations of manufacturers apply to importers and distributors

The Article specifies the cases when the importers or distributors shall have the obligations of the manufacturer, namely when they place transportable pressure equipment on the market.

#### Article 11: Identification of economic operators

The Article lays down the obligations relating to identification of actors in the supply chain of transportable pressure equipment.

## Article 12: Conformity of the transportable pressure equipment and its assessment

The Article defines the necessary conformity assessment requirements for new transportable pressure equipment and for transportable pressure equipment previously assessed and marked under Directive 1999/36/EC and old cylinder directives. The Article also ensures that conformity assessments, reassessments, periodic inspections and exceptional checks shall be valid in all Member States.

#### Article 13: Reassessment of conformity

The Article provides for the reassessment of conformity of old transportable pressure equipment not previously assessed under Directive 1999/36/EC to bring it under the scope of this Directive.

## Article 14: General principles of the Pi marking

The Article specifies the relevance of the Pi marking, when a Pi marking can be affixed, the responsibilities relating to the affixing of the marking and provisions to prohibit the misuse of the marking.

## Article 15: Rules and conditions for the affixing of the Pi marking

The Article lays down the rules regarding the Pi marking itself, including its shape, size and the auxiliary markings of the inspection body.

#### Article 16: Free movement of the transportable pressure equipment

The Article provides for the free movement of transportable pressure equipment in the European Union.

#### Article 17: Notifying authorities

The Article lays down the procedures and responsibilities regarding notifying authorities.

Article 18: Requirements relating to notifying authorities

The Article defines the conditions for guaranteeing the proper functioning of notifying authorities.

Article 19: Information obligation for the notifying authorities

The Article ensures the transparency of assessment, notification and monitoring of notified bodies.

Article 20: General requirements relating to notified bodies

The Article sets out requirements relating to the capabilities of the body to carry out the tasks.

Articles 21, 22, 23, 24 and 25: Procedures relating to notified bodies and notification

These Articles define the application and procedures for notifications, identification of notified bodies, subsequent changes to notifications and course of action in cases where there is doubt over the capacity of a notified body.

## Article 26: Operational obligations for notified bodies

The Article sets out operational obligations for the notified bodies including mutual recognition of those bodies.

#### Article 27: Information obligations for notified bodies

The Article sets out information obligations for the notified bodies including where there has been a refusal or withdrawal of certificates.

#### Article 28 and 29: Cooperation between notified bodies

These Articles provide for an exchange of experience and coordination among authorities responsible for notification policy, market surveillance and notified bodies.

#### Article 30, 31, 32 and 33: Safeguard procedures

These Articles lay down the procedures for dealing with safety and other risks, including formal issues, at national and Community levels.

#### Article 34: Transitional provisions

The Article provides for transitional measures through Annex II of the proposal.

#### Article 35: Adaptations

Any adaptations of the annexes for technical and scientific progress will take place through the regulatory procedure with scrutiny.

#### Article 36: Committee

The Committee set up under the Directive on the inland transport of dangerous goods (2008/68/EC) will be used for the purposes of this Directive.

#### Article 37: Repeal

The existing Directive 1999/36/EC as well as a number of obsolete directives on pressure cylinders will be repealed

#### Article 38: Recognition of equivalence

The Article provides for recognition of EEC pattern approvals issued under obsolete directives on pressure cylinders and for valves and accessories marked according to the Pressure equipment directive.

#### Article 39: Transposition

The standard approach on transposition is followed. The Member States shall implement the Directive by 30 June 2011, when the transitory period contained in the international

agreements on transport of dangerous goods ends, to avoid conflict with the existing Directive 1999/36/EC.

A delay in the application of the Directive for equipment used by some dangerous goods is provided for in order to give a reasonable period for compliance as they were not previously under the scope of Directive 1999/36/EC.

## Article 40: Entry into force

The Directive will enter into force on the twentieth day following its publication in the Official Journal.

## Article 41: Addressees

The Directive is addressed to the Member States.

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## THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71 thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the procedure in Article 251 of the Treaty<sup>4</sup>,

Whereas:

- (1) Council Directive 1999/36/EC of 29 April 1999 on transportable pressure equipment<sup>5</sup> was adopted as a first step towards enhancing transport safety for transportable pressure equipment, whilst ensuring the free movement of transportable pressure equipment in a single transport market.
- (2) In the light of developments in transport safety, it is necessary to update certain technical provisions of Directive 1999/36/EC.
- (3) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods<sup>6</sup> extended the application of the provisions of certain international agreements to cover national traffic in order to harmonise the conditions under which dangerous goods are transported by road, rail and inland waterways across the Community.
- (4) It is therefore necessary to update the provisions of Directive 1999/36/EC accordingly to avoid conflicting rules, in particular as regards conformity requirements, conformity

<sup>&</sup>lt;sup>1</sup> OJ C , , p. .

<sup>&</sup>lt;sup>2</sup> OJ C , , p. .

<sup>&</sup>lt;sup>3</sup> OJ C , , p. .

<sup>&</sup>lt;sup>4</sup> OJ C , , p. .

<sup>&</sup>lt;sup>5</sup> OJ L 138, 1.6.1999, p. 20.

<sup>&</sup>lt;sup>6</sup> OJ L 260, 30.9.2008, p. 13.

assessment and conformity assessment procedures in relation to transportable pressure equipment.

- (5) In order to enhance safety with regard to transportable pressure equipment approved for the inland transport of dangerous goods and to ensure the free movement, including placing on the market, making available on the market and use of such transportable pressure equipment within the Community, it is necessary to lay down detailed rules concerning the obligations of the various operators and the requirements to be fulfilled by the equipment concerned.
- (6) Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products<sup>7</sup> constitutes a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products. This framework should apply where appropriate for the transportable pressure equipment sector in line with the objective of harmonising rules on the free movement of products.
- (7) In order not to hinder transport operations between Member States and third countries, this Directive should not apply to transportable pressure equipment exclusively used for the transport of dangerous goods between the territory of the Community and that of third countries.
- (8) The obligations of the different economic operators, including owners and operators of transportable pressure equipment, should be clearly defined in the interests of transport safety and the free movement of transportable pressure equipment.
- (9) Economic operators should be responsible for the compliance of transportable pressure equipment with the safety and market access rules in relation to their respective roles in the supply chain.
- (10) Compliance of new transportable pressure equipment with the technical requirements of the Annexes to Directive 2008/68/EC and this Directive should be shown by means of a conformity assessment to provide evidence that the transportable pressure equipment is safe.
- (11) Periodic inspections and exceptional checks of transportable pressure equipment should be carried out in accordance with the Annexes to Directive 2008/68/EC and with this Directive to ensure continued compliance with their safety requirements.
- (12) Transportable pressure equipment should bear a mark indicating its compliance with Directive 2008/68/EC and this Directive to ensure its free movement and use.
- (13) Existing transportable pressure equipment not previously assessed for conformity with Directive 1999/36/EC should be reassessed and marked according to the provisions of this Directive in order to demonstrate its compliance with safety requirements and ensure free movement and use.

OJ L 218, 13.8.2008, p. 82.

- (14) It is necessary to set requirements for authorities responsible for the assessment, notification and monitoring of notified bodies in order to ensure a consistent level of quality in the performance of notified bodies.
- (15) The conformity assessment procedures provided for in the Annexes to Directive 2008/68 and in this Directive require the intervention of inspection bodies setting out detailed operational requirements to ensure a uniform level of performance throughout the Community. These inspection bodies should then be notified by the Member States to the Commission.
- (16) The notifying authority should retain responsibility for monitoring the notified body regardless of where the notified body performs its activities in order to ensure clear responsibility for ongoing monitoring.
- (17) It is necessary to lay down common rules for the mutual recognition of notified bodies which ensure compliance with Directive 2008/68/EC and this Directive. Those common rules will have the effect of eliminating unnecessary costs and administrative procedures related to the approval of the equipment and of eliminating technical barriers to trade;
- (18) Member States should be able to take measures to limit or prohibit the placing on the market and use of equipment in cases where it presents a risk to safety in certain specified circumstances.
- (19) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>8</sup>.
- (20) In particular the Commission should be empowered to adapt the Annexes to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (21) Council Directive 76/767/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to common provisions for pressure vessels and methods for inspecting them<sup>9</sup>, Council Directive 84/525/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, steel gas cylinders<sup>10</sup>, Council Directive 84/526/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders<sup>11</sup>, Council Directive 84/527/EEC of 17 September 1984 on the approximation of the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders<sup>11</sup>, Council Directive 84/527/EEC of 17 September 1984 on the approximation of the laws of the laws of the Nember States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders<sup>11</sup>, Council Directive 84/527/EEC of 17 September 1984 on the approximation of the laws of the laws of the Nember States relating to seamless relating to welded unalloyed steel gas cylinders<sup>12</sup> and Directive 1999/36/EC have become obsolete and should therefore be repealed,

<sup>&</sup>lt;sup>8</sup> OJ L184, 17.7.1999, p. 23.

<sup>&</sup>lt;sup>9</sup> OJ L 262, 27.9.1976, p. 153.

<sup>&</sup>lt;sup>10</sup> OJ L 300, 19.11.1984, p. 1.

<sup>&</sup>lt;sup>11</sup> OJ L 300, 19.11.1984, p. 20. <sup>12</sup> OJ L 300, 10, 11, 1084, p. 48

<sup>&</sup>lt;sup>12</sup> OJ L 300, 19.11.1984, p. 48

#### HAVE ADOPTED THIS DIRECTIVE:

# 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 Community.
- 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 99/36/EC, for the purpose of making them 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 99/36/EC, for the purposes of their periodic 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 99/36/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 defined 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 defined in chapter 6.8 of the Annexes to Directive 2008/68/EC,

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;

- 2. "Annexes to Directive 2008/68" means Annex I, Section I.1, Annex II, Section II.1, and Annex III, Section III.1 to Directive 2008/68/EC;
- 3. "placing on the market" means the first making available of transportable pressure equipment on the Community market;
- 4. "making available on the market" means any supply of transportable pressure equipment for distribution or use on the Community 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 Community 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 Community, who places transportable pressure equipment or parts thereof from a third country on the Community market;
- 11. "distributor" means any natural or legal person established within the Community, 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 Community which owns transportable pressure equipment;
- 13. "operator" means any natural or legal person established in the Community using transportable pressure equipment;
- 14. "economic operators" means the manufacturer, the authorised representative, the importer, the distributor, the owner or the operator acting in the course of a commercial 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, 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. "exceptional check" means the exceptional check and the procedures governing the exceptional check set out in the Annexes to Directive 2008/68/EC;
- 20. "national accreditation body" means the sole body in a Member State that performs accreditation with authority derived from the State;
- 21. "accreditation" means an attestation by a national accreditation body that a notified body meets the requirements set out in the second paragraph of 1.8.6.4 of the Annexes to Directive 2008/68/EC;
- 22. "notifying authority" means the authority designated by a Member State pursuant to Article 17;
- 23. "notified body" means an inspection body meeting the requirements set out in Annexes to Directive 2008/68/EC and the conditions set out in Articles 20 and 26 and notified in accordance with Article 22 of this Directive;
- 24. "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;
- 25. "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;

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.

#### **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.
- 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 and with this Directive shall immediately take the necessary corrective measures 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-compliances 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, on 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 Annexes to Directive 2008/68/EC and with 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 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 20 years from the date of manufacture of the transportable pressure equipment;
- (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 their 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 Annexes to Directive 2008/68/EC and with this Directive.

## Article 6

#### Obligations of importers

- 1. Importers shall only place on the Community 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-compliances and corrective measures.

- 6. Importers shall, for at least 20 years from the date of the manufacture of the transportable pressure equipment, 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 Annexes to Directive 2008/68/EC and with this Directive.

## Article 7

## Obligations of distributors

1. Distributors shall only make available on the Community 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, that it is accompanied by the certificate of conformity and the contact address referred to in Article 6(3).

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 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-compliances 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 Annexes to Directive 2008/68/EC and with 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 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-compliances 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 Annexes to Directive 2008/68/EC and with this Directive.

## 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 under 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.

## Article 11

#### Identification of economic operators

Economic operators shall, on request from the market surveillance authority, identify the following to it for the period specified in the Annexes to Directive 2008/68/EC

- (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 the 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 and exceptional checks requirements set out in the Annexes to Directive 2008/68/EC and 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 and exceptional checks and 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 and exceptional checks issued by a notified body shall be valid in all Member States.

For demountable parts of 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.

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

## 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 and 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:
- (a) which meets the conformity assessment requirements in the Annexes to Directive 2008/68/EC and in this Directive, or

(b) which meets the reassessment of conformity requirements referred to in Article 13,

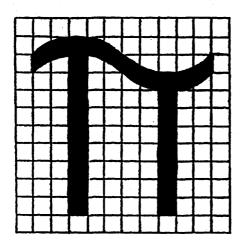
It shall not be affixed to any other transportable pressure equipment.

- 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 is not thereby impaired.
- 6. Demountable parts 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.
- 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 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 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 shall be followed 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 and 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, no Member State shall prohibit, restrict or impede on its territory the free movement, making available on the market and 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.

#### 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 for the 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.

## General 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 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 co-ordination 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 notified body status

- 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 and reassessment of conformity;
- (b) the procedures relating to a) above including periodic inspection, exceptional checks and reassessment of conformity;
- (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 full details of the conformity assessment, periodic inspection and exceptional check activities, the procedures used, the transportable pressure equipment concerned and the relevant attestation of competence.
- 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 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 Community 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 the notification

- 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.

## Challenge of the competence of notified bodies

- 1. The Commission shall investigate all cases where it doubts or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
- 2. The notifying Member State shall provide the Commission, on request, with all information 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 for notified bodies

- 1. Notified bodies shall carry out conformity assessments, periodic inspections and exceptional checks in accordance with the terms of their notification and with the conformity assessment 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.
- 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 on notified bodies

- 1. Notified bodies shall inform the notifying authority of the following:
- (a) any refusal, restriction, suspension or withdrawal of certificates;
- (b) any circumstances affecting the scope of and conditions for notification;
- (c) any request for information 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 shall provide the other bodies notified under this Directive carrying out similar conformity assessment, periodic inspection 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.

#### Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible 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 to deal 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 perform an evaluation in relation to the transportable pressure equipment covering all the requirements set out 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 the 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 transportable pressure equipment concerned that it has made available on the market throughout the Community.
- 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 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:
- (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.

## Community 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 Community 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 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 the measure.
- 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>13</sup>. That Committee may consult the relevant European standardisation body or bodies before delivering its opinion.

<sup>&</sup>lt;sup>13</sup> OJ L 204, 21.7.1998, p.37.

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

- 1. Where having performed an evaluation under 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 Community.
- 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) the Pi marking has been affixed in violation of Article 12, Article 13 or Article 14;
- (b) the Pi marking has not been affixed;
- (c) the technical documentation is either not available or not complete;
- (d) the requirements of the Annexes to Directive 2008/68/EC 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 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.

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 adapt the Annexes to this Directive to scientific and technical progress, in particular taking into account amendments to the Annexes to Directive 2008/68/EC. Those measures, designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 36(2).

## Article 36

#### Committee

- 1. The Commission shall be assisted by the Committee on the transport of dangerous goods set up under Article 9 of Directive 2008/68/EC.
- 2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

The time-limits provided for in Article 5a(3)(c), and (4)(b) and (e) of Decision 1999/468/EC shall be one month, one month and two months respectively.

## Article 37

## 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 38

## 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.
- 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>14</sup> according to Article 3(4) of Directive 1999/36/EC may still be used.

## Article 39

## 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 communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

- 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. Member States shall ensure that Article 21(2) (d) applies 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 1745, UN 1746 and UN 2495 from 1 July 2013 at the latest.

## Article 40

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

<sup>&</sup>lt;sup>14</sup> OJ L 181, 9.7.1997, p.1

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament The President For the Council The President

# ANNEX I

## LIST OF DANGEROUS GOODS OTHER THAN THOSE IN CLASS 2

UN number	Class	Dangerous substance
1051	6.1	HYDROGEN CYANIDE, STABILIZED containing less than 3% water
1052	8	HYDROGEN FLUORIDE, ANHYDROUS
1745	5.1	BROMINE PENTAFLUORIDE
		Excluding carriage in tanks
1746	5.1	BROMINE TRIFLUORIDE
		Excluding carriage in tanks
1790	8	HYDROFLUORIC ACID, SOLUTION, WITH MORE THAN 85% HYDRFLUORIC ACID
2495	5.1	IODINE PENTAFLUORIDE
		Excluding carriage in tanks

## ANNEX II

## TRANSITIONAL PROVISIONS

- 1. Member States may retain their national provisions concerning devices intended for connection with other equipment and colour codes applicable to transportable pressure equipment until such time as relevant standards for use are added to the Annexes to Directive 2008/68/EC.
- 2. Member States in which the ambient temperature is regularly lower than -20 °C may impose more stringent standards as regards the operating temperature of material intended for transportable pressure equipment for use in the national transport of dangerous goods within their territory until provisions on the appropriate reference temperatures for given climatic zones are incorporated into the Annexes to Directive 2008/68/EC.

In this case, in the Pi marking of the transportable pressure equipment, including the demountable parts having a direct safety function, the identification number of the notified body shall be followed by "-40 °C" or other relevant marking approved by the competent authority.

## ANNEX III

## PROCEDURE FOR THE REASSESSMENT OF CONFORMITY

- 1. The method for ensuring that the transportable pressure equipment referred to in Article 1 (2) (c) manufactured and put into service before the dates of implementation of Directive 1999/36/EC complies with the relevant provisions of the Annexes to Directive 2008/68/EC as applicable at the time of reassessment shall be as set out in this Annex.
- 2. The owner or his authorised representative established within the Community or the holder must make available to a notified body conforming to EN ISO/IEC 17020:2004 type A the information regarding the transportable pressure equipment which enables that body to identify the equipment precisely (origin, design rules, and for acetylene cylinders also details of the porous material). The information shall include, where appropriate, any prescribed restrictions on use, and any notes on possible damage or repairs which have been carried out.
- 3. The type A notified body shall assess whether the transportable pressure equipment affords at least the same degree of safety as the transportable pressure equipment referred to in the Annexes to Directive 2008/68/EC. The assessment shall be carried out on the basis of the information produced in accordance with point 2 and, where appropriate, of further inspections.
- 4. Where pressure receptacles were manufactured in series, Member States may authorise the assessment of conformity of individual pressure receptacles, including their valves and other accessories used for transport, to be carried out by a notified body conforming to EN ISO/IEC 17020:2004 Type B provided that conformity of the type has been assessed in accordance with paragraph 3 by a type A notified body.
- 5. If the results of the assessments in paragraphs 3 and 4 are satisfactory, the transportable pressure equipment shall be subject to the periodic inspection provided for in the Annexes to Directive 2008/68/EC and the Pi marking shall be applied by the notified body responsible for the periodic inspection in accordance with Article 14 (1) (5). The Pi marking shall be followed by the identification number of the type A notified body responsible for the reassessment of conformity and, if different, the identification number of the notified body responsible for periodic inspection.
- 6. A certificate of reassessment shall be issued.

Where the procedure in paragraph 4 is applied the type A body shall issue the certificate of reassessment containing as a minimum:

- (a) the identification of the notified body;
- (b) the name and address of the manufacturer and the holder of the original type approval for the transportable pressure equipment being reassessed when the holder is not the manufacturer;
- (c) the data identifying the transportable pressure equipment belonging to the series; and

- (d) the date of issue.
- 7. In all other cases the notified body responsible for the periodic inspection shall issue the certificate of reassessment containing as a minimum:
- (a) the identification of the notified body;
- (b) the name and address of the owner or his authorised representative established within the Community or the holder specified in paragraph 2;
- (c) the data for identification of the transportable pressure equipment to which Pi marking has been applied including at least the serial number or numbers; and
- (d) the date of issue.

By affixing or having affixed the Pi marking, the owner or operator 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 as applicable at the time of reassessment.