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Committee on the Internal Market and Consumer Protection

2013/0221(COD)

11.10.2013

# \*\*\*I DRAFT REPORT

on the proposal for a directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of pressure equipment (recast) (COM(2013)0471 - C7-0203/2013 - 2013/0221(COD))

Committee on the Internal Market and Consumer Protection

Rapporteur: Zuzana Roithová

(Recast - Rule 87 of the Rules of Procedure)

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# Symbols for procedures

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

# Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in *bold italics*. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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# DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of pressure equipment (recast) (COM(2013)0471 – C7-0203/2013 – 2013/0221(COD))

# (Ordinary legislative procedure - recast)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0471),
- having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0203/2013),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of ...,
- having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>1</sup>,
- having regard to the letter of ... from the Committee on Legal Affairs to the Committee on the Internal Market and Consumer Protection in accordance with Rule 87(3) of its Rules of Procedure,
- having regard to Rules 87 and 55 of its Rules of Procedure,
- having regard to the report of the Committee on the Internal Market and Consumer Protection (A7-0000/2013),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
- 1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
- 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

<sup>&</sup>lt;sup>1</sup> OJ C 77, 28.3.2002, p. 1.

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

# Proposal for a directive Recital 3

# Text proposed by the Commission

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC lays down *a* common *framework of general* principles and reference provisions intended to apply across *the* legislation *harmonising the conditions for the marketing of products* in order to provide a coherent basis for revision or recasts of that legislation. Directive 97/23/EC should therefore be adapted to that Decision.

#### Amendment

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC<sup>15</sup> lays down common principles and reference provisions intended to apply across *sectoral* legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 97/23/EC should therefore be adapted to that Decision.

Or. en

Amendment 2

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

#### Amendment

(3a) This Directive covers pressure equipment which is new to the Union market when it is placed on the market; that is to say it is either new pressure equipment made by a manufacturer established in the Union or pressure equipment, whether new or second-hand, imported from a third country.

# Proposal for a directive Recital 3 b (new)

Text proposed by the Commission

#### Amendment

(3b) This Directive should apply to all forms of supply, including distance selling.

Or. en

### Amendment 4

# Proposal for a directive Recital 15

# Text proposed by the Commission

(15) Economic operators should be responsible for the compliance of pressure equipment with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety *and the protection of users*, and to guarantee fair competition on the Union market.

#### Amendment

(15) Economic operators should be responsible for the compliance of pressure equipment with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as *the* health and safety *of persons, and the protection of domestic animals and of property*, and to guarantee fair competition on the Union market.

Or. en

# Amendment 5

# Proposal for a directive Recital 18

### Text proposed by the Commission

(18) In order to facilitate *the* communication between economic operators, *national* market surveillance authorities and consumers, Member States should encourage economic operators to *indicate* a website address in addition to

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# Amendment

(18) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to *include* a website address in

# Proposal for a directive Recital 19

### Text proposed by the Commission

(19) It is necessary to ensure that pressure equipment from third countries entering the Union market complies with the requirements of this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that pressure equipment. Provision should therefore be made for importers to make sure that the pressure equipment they place on the market complies with the requirements of this Directive and that they do not place on the market pressure equipment which does not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that marking of pressure equipment and documentation drawn up by manufacturers are available for inspection by the national authorities.

# Amendment

(19) It is necessary to ensure that pressure equipment from third countries entering the Union market complies with the requirements of this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that pressure equipment. Provision should therefore be made for importers to make sure that the pressure equipment they place on the market complies with the requirements of this Directive and that they do not place on the market pressure equipment which does not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that marking of pressure equipment and documentation drawn up by manufacturers are available for inspection by the *competent* national authorities.

Or. en

Amendment 7

# Proposal for a directive Recital 21

Text proposed by the Commission

(21) When placing pressure equipment on the market, every importer should indicate

# Amendment

(21) When placing pressure equipment on the market, every importer should indicate

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on the pressure equipment his name and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the pressure equipment does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the equipment. on the pressure equipment his name, *registered trade name or registered trade mark* and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the pressure equipment does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the equipment.

Or. en

# Amendment 8

# Proposal for a directive Recital 25

#### Text proposed by the Commission

(25) When keeping the information required under this Directive for the identification of economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with *a* pressure equipment or to whom they have supplied *a* pressure equipment.

#### Amendment

(25) When keeping the information required under this Directive for the identification of *other* economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with pressure equipment or to whom they have supplied pressure equipment.

Or. en

#### Amendment 9

#### Proposal for a directive Recital 29

#### Text proposed by the Commission

(29) In view of the nature of the risks involved in the use of pressure equipment and in order to enable economic operators to demonstrate and the competent authorities to ensure that pressure equipment made available on the market

#### Amendment

(29) In view of the nature of the risks involved in the use of pressure equipment and in order to enable economic operators to demonstrate and the competent authorities to ensure that pressure equipment made available on the market

conforms to the essential safety requirements, it is necessary to provide for conformity assessment procedures . These procedures should be devised in the light of the level of danger which is inherent in the pressure equipment. Therefore, for each category of pressure equipment there should be an adequate procedure or a choice between different procedures of equivalent stringency. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. The details added to those procedures are justified by the nature of the verification required for pressure equipment.

*comply with* the essential safety requirements, it is necessary to provide for conformity assessment procedures. These procedures should be devised in the light of the level of danger which is inherent in the pressure equipment. Therefore, for each category of pressure equipment there should be an adequate procedure or a choice between different procedures of equivalent stringency. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. The details added to those procedures are justified by the nature of the verification required for pressure equipment.

Or. en

#### Amendment 10

#### Proposal for a directive Recital 33

#### Text proposed by the Commission

(33) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a 'single EU declaration of conformity'.

#### Amendment

(33) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. *In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.* 

Or. en

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#### Proposal for a directive Recital 33 a (new)

Text proposed by the Commission

#### Amendment

(33a) A check on compliance with the relevant essential safety requirements is necessary in order to provide effective protection for consumers, other users and third parties.

Or. en

Amendment 12

# Proposal for a directive Recital 54

#### Text proposed by the Commission

(54) It is necessary to provide for transitional arrangements that allow the making available on the market and *the* putting into service of pressure equipment *which complies* with Directive 97/23/EC.

#### Amendment

(54) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into service, without the need to comply with further product requirements, of pressure equipment that has already been placed on the market in accordance with Directive 97/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply pressure equipment that has been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

Or. en

Amendment 13

Proposal for a directive Recital 55

#### Text proposed by the Commission

(55) Member States should lay down rules on penalties applicable to infringements of the provisions *of national law* adopted pursuant to this Directive and ensure that *they are implemented. Those* penalties *must* be effective, proportionate and dissuasive.

#### Amendment

(55) Member States should lay down rules on penalties applicable to infringements of the *national* provisions adopted pursuant to this Directive and ensure that *these rules are enforced. The* penalties *provided for should* be effective, proportionate and dissuasive.

Or. en

### Amendment 14

# Proposal for a directive Recital 57

#### Text proposed by the Commission

(57) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive *change* as compared *with Directive 97/23/EC*. The obligation to transpose the provisions which are unchanged arises under Directive *97/23/EC*.

#### Amendment

(57) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive *amendment* as compared *to the earlier Directive*. The obligation to transpose the provisions which are unchanged arises under *the earlier* Directive.

Or. en

# Amendment 15

### Proposal for a directive Article 2 – paragraph 1 – introductory part

Text proposed by the Commission

For the purposes of this Directive the following definitions apply :

Amendment

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

# Proposal for a directive Article 2 – paragraph 1 – point 24

Text proposed by the Commission

(24) 'accreditation' means accreditation as defined in Article 2*(10)* of Regulation (EC) No 765/2008;

# Amendment

(24) 'accreditation' means accreditation as defined in *point 10 of* Article 2 of Regulation (EC) No 765/2008;

Or. en

# Amendment 17

# Proposal for a directive Article 2 – paragraph 1 – point 25

# Text proposed by the Commission

(25) 'national accreditation body' means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

# Amendment

(25) 'national accreditation body' means national accreditation body as defined in *point 11 of* Article 2 of Regulation (EC) No 765/2008;

Or. en

# Amendment 18

### Proposal for a directive Article 2 – paragraph 1 – point 28

Text proposed by the Commission

(28) 'recall' means any measure aimed at achieving the return of pressure equipment that has already been made available to the *user*;

### Amendment

(28) 'recall' means any measure aimed at achieving the return of pressure equipment that has already been made available to the *consumers or other users*;

Or. en

## Proposal for a directive Article 3 – paragraph 2

#### Text proposed by the Commission

2. This Directive shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment in question provided that this does not mean modifications to such equipment in a way not specified in this Directive.

### Amendment

2. This Directive shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment *or assemblies* in question provided that this does not mean modifications to such equipment *or assemblies* in a way not specified in this Directive.

Or. en

Amendment 20

# Proposal for a directive Article 5 – paragraph 2

Text proposed by the Commission

2. Member States may require, to the extent that it is needed for safe and correct use of pressure equipment, the information referred to in points 3.3 and 3.4 of Annex I to be provided in *the official* language(s) of the Union which may be determined by the Member State in which the equipment reaches the user.

#### Amendment

2. Member States may require, to the extent that it is needed for safe and correct use of pressure equipment, the information referred to in points 3.3 and 3.4 of Annex I to be provided in *a* language *easily understood by consumers, other users and market surveillance authorities*.

Amendment

Or. en

### Amendment 21

### Proposal for a directive Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. For pressure equipment referred to in

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# 2. For pressure equipment referred to in

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Article 4(1) and (2), manufacturers shall draw up the technical documentation referred to in Annex II and *carry out the* conformity assessment procedure referred to in Article 14 *or have it* carried out. Article 4(1) and (2), manufacturers shall draw up the technical documentation referred to in Annex II and *have the relevant* conformity assessment procedure referred to in Article 14 carried out.

Or. en

# Amendment 22

# Proposal for a directive Article 6 – paragraph 4 – subparagraph 1

#### Text proposed by the Commission

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in pressure equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of pressure equipment is declared shall be adequately taken into account.

#### Amendment

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity *with this Directive*. Changes in pressure equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of pressure equipment is declared shall be adequately taken into account.

Or. en

#### Amendment 23

#### Proposal for a directive Article 6 – paragraph 4 – subparagraph 2

#### Text proposed by the Commission

When deemed appropriate with regard to the risks presented by pressure equipment, manufacturers shall, to protect the health and safety of consumers and other users, carry out sample testing of pressure equipment made available on the market, investigate, and, if necessary, keep a register of complaints of non-conforming pressure equipment and recalls of such equipment, and shall keep distributors

#### Amendment

When deemed appropriate with regard to the risks presented by pressure equipment, manufacturers shall, to protect the health and safety of consumers and other users, *upon a duly justified request of the competent authorities,* carry out sample testing of pressure equipment made available on the market, investigate, and, if necessary, keep a register of complaints of non-conforming pressure equipment and

informed of any such monitoring.

recalls of such equipment, and shall keep distributors informed of any such monitoring.

Or. en

# Amendment 24

#### Proposal for a directive Article 6 – paragraph 5

#### Text proposed by the Commission

5. Manufacturers shall ensure that *their* pressure equipment bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment does not allow it, that the required information is provided on the packaging or in a document accompanying the equipment.

#### Amendment

5. Manufacturers shall ensure that *the* pressure equipment *which they have placed on the market* bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment does not allow it, that the required information is provided on the packaging or in a document accompanying the equipment.

Or. en

### Amendment 25

# Proposal for a directive Article 6 – paragraph 6

#### Text proposed by the Commission

6. Manufacturers shall indicate their name, registered trade name or registered trade mark, *the postal address, and, if available, the website* address at which they can be contacted *on the pressure equipment* or, where that is not possible, on their packaging or in a document accompanying the equipment. The address *must* indicate a single point at which the manufacturer can be contacted.

#### Amendment

6. Manufacturers shall indicate *on the pressure equipment* their name, registered trade name or registered trade mark *and the postal* address at which they can be contacted or, where that is not possible, on their packaging or in a document accompanying the equipment. The address *shall* indicate a single point at which the manufacturer can be contacted. *The contact details shall be in a language easily understood by consumers, other users and market surveillance authorities.* 

# Proposal for a directive Article 7 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The obligations laid down in Article 6(1)and the *drawing up of* technical documentation shall not form part of the authorised representative's mandate.

#### Amendment

The obligations laid down in Article 6(1) and the *obligation to draw up* technical documentation *referred to in Article 6(2)* shall not form part of the authorised representative's mandate.

Or. en

### Amendment 27

# Proposal for a directive Article 9 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Before making pressure equipment referred to in Article 4(1) and (2) available on the market distributors shall verify that the pressure equipment bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6)and Article 8(3).

#### Amendment

2. Before making pressure equipment referred to in Article 4(1) and (2) available on the market distributors shall verify that the pressure equipment bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6)and Article 8(3) *respectively*.

# Proposal for a directive Article 9 – paragraph 2 – subparagraph 3

#### Text proposed by the Commission

Before making pressure equipment referred to in Article 4(3) available on the market distributors shall verify that the pressure equipment is accompanied by adequate instructions for use, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3).

#### Amendment

Before making pressure equipment referred to in Article 4(3) available on the market distributors shall verify that the pressure equipment is accompanied by adequate instructions for use, in a language which can be easily understood by consumers and other users in the Member State in which the pressure equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) *respectively*.

Or. en

#### **Amendment 29**

# Proposal for a directive Article 9 – paragraph 4

### Text proposed by the Commission

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

### Amendment

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

#### Proposal for a directive Article 14 – paragraph 4

Text proposed by the Commission

4. Records and correspondence relating to conformity assessment shall be drawn up in *the official* language(s) of the Union which may be determined by the Member State where the body responsible for carrying out these procedures is established, or in a language accepted by that body.

#### Amendment

8. Records and correspondence relating to conformity assessment shall be drawn up in *a* language *easily understood by consumers, other users and market surveillance authorities*.

Or. en

Amendment 31

# Proposal for a directive Article 17 – paragraph 3

### Text proposed by the Commission

3. Where pressure equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including *the* publication references.

### Amendment

3. Where pressure equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the *Union* acts concerned including *their* publication references.

Or. en

Amendment 32

Proposal for a directive Article 19 – paragraph 5 a (new) Text proposed by the Commission

# Amendment

5a. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Or. en

Amendment 33

# Proposal for a directive Article 24 – paragraph 2

Text proposed by the Commission

2. A conformity assessment body shall be established under national law and have legal personality.

# Amendment

2. A conformity assessment body shall be established under national law *of a Member State* and have legal personality.

Or. en

# Amendment 34

# Proposal for a directive Article 24 – paragraph 6 – subparagraph 3

# Text proposed by the Commission

*It* shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

Amendment

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

#### Proposal for a directive Article 24 – paragraph 7 – introductory part

Text proposed by the Commission

7. The personnel responsible for carrying out conformity assessment *activities* shall have the following:

### Amendment

7. The personnel responsible for carrying out conformity assessment *tasks* shall have the following:

Or. en

# Amendment 36

# Proposal for a directive Article 24 – paragraph 8 – subparagraph 1

# Text proposed by the Commission

8. The impartiality of the conformity assessment bodies, their top level management and of the *assessment personnel* shall be guaranteed.

# Amendment

8. The impartiality of the conformity assessment bodies, their top level management and of the *personnel responsible for carrying out the conformity assessment tasks* shall be guaranteed.

Or. en

### Amendment 37

# Proposal for a directive Article 24 – paragraph 8 – subparagraph 2

Text proposed by the Commission

The remuneration of the top level management and *assessment personnel* of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

### Amendment

The remuneration of the top level management and *personnel responsible for carrying out the conformity assessment tasks* of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

# Proposal for a directive Article 24 – paragraph 11

#### Text proposed by the Commission

11. Conformity assessment bodies shall participate in, or ensure that their *assessment personnel* are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

### Amendment

11. Conformity assessment bodies shall participate in, or ensure that their *personnel responsible for carrying out the conformity assessment tasks* are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Or. en

Amendment 39

Proposal for a directive Article 26 – title

Text proposed by the Commission

Presumption of conformity

#### Amendment

Amendment

2. *The* application *for notification* shall be

accompanied by a description of the

conformity assessment activities, the

Presumption of conformity *of notified bodies* 

Or. en

### Amendment 40

# Proposal for a directive Article 28 – paragraph 2

Text proposed by the Commission

2. *That* application shall be accompanied by a description of the conformity assessment activities, the conformity

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assessment module or modules and the pressure equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24 or 25. conformity assessment module or modules and the pressure equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24 or 25.

Or. en

#### Amendment 41

### Proposal for a directive Article 30 – paragraph 2 – subparagraph 1

#### Text proposed by the Commission

2. The Commission shall make publicly available the list of the *notified* bodies under this Directive, including the identification numbers that have been *allocated* to them and the activities for which they have been notified.

#### Amendment

2. The Commission shall make publicly available the list of the bodies *notified* under this Directive, including the identification numbers that have been *assigned* to them and the activities for which they have been notified.

Or. en

#### Amendment 42

# Proposal for a directive Article 30 – paragraph 2 – subparagraph 2

Text proposed by the Commission

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

# Amendment

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

Or. en

#### Amendment 43

Proposal for a directive Article 33 – paragraph 2

#### Text proposed by the Commission

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.

#### Amendment

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 *notified* body concerned.

Or. en

#### Amendment 44

# Proposal for a directive Article 34 – paragraph 3

#### Text proposed by the Commission

3. Where a *conformity assessment* body finds that essential safety requirements set out in Annex I or corresponding harmonised standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a *conformity* certificate.

#### Amendment

3. Where a *notified* body finds that essential safety requirements set out in Annex I or corresponding harmonised standards *or other technical specifications* have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.

Or. en

#### Amendment 45

### Proposal for a directive Article 36 – paragraph 1 – point b

Text proposed by the Commission

(b) any circumstances affecting the scope of *and* conditions for notification;

Amendment

(b) any circumstances affecting the scope of *or* conditions for notification;

# Proposal for a directive Article 40 – title

Text proposed by the Commission

Amendments of Annexes

Amendment

**Delegated** power

Or. en

# Amendment 47

# Proposal for a directive Article 40 – introductory part

Text proposed by the Commission

The Commission shall be empowered to adopt delegated acts in accordance with Article 41 *concerning the reclassification of* pressure equipment *when it has any of the following considerations*: Amendment

*In order to take into account technical developments in pressure equipment technology,* the Commission shall be empowered to adopt delegated acts in accordance with Article 41 *reclassifying* pressure equipment *so as to*:

Or. en

# Amendment 48

Proposal for a directive Article 40 – point a

Text proposed by the Commission

(a) an item or family of pressure equipment referred to in Article 4(3) *should be* subject to the requirements of Article 4(1);

### Amendment

(a) *make* an item or family of pressure equipment referred to in Article 4(3) subject to the requirements of Article 4(1);

Or. en

# Amendment 49

Proposal for a directive Article 40 – point b

#### Text proposed by the Commission

(b) an assembly or family of assemblies referred to in Article 4(3) *should be* subject to the requirements of Article 4(2);

# Amendment

(b) *make* an assembly or family of assemblies referred to in Article 4(3) subject to the requirements of Article 4(2); *or* 

Or. en

#### Amendment 50

# Proposal for a directive Article 40 – point c

Text proposed by the Commission

(c) an item or family of pressure equipment *should be classified*, by way of derogation from the requirements of Annex II, in another category.

#### Amendment

(c) *classify* an item or family of pressure equipment, by way of derogation from the requirements of Annex II, in another category.

Or. en

# Amendment 51

### Proposal for a directive Article 44 – paragraph 1 – subparagraph 1

### Text proposed by the Commission

1. Member States shall adopt and publish by 1 March 2015 *at the latest*, the laws, regulations and administrative provisions necessary to comply with *Articles* 2(15) to (31), 6, 7, 8, 9, 10, 11, 12, 17, 18, 19(3) *to* (5), 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 42, 43 and Annexes III and IV. They shall forthwith communicate *to the Commission* the text of those measures.

### Amendment

1. Member States shall adopt and publish, by 1 March 2015, the laws, regulations and administrative provisions necessary to comply with *Article* 2(15) to (31), *Articles* 6 to 12, 17 and 18, *Article* 19(3), (4) and (5), *Articles* 20 to 38, 42 and 43 and Annexes III and IV. They shall forthwith communicate the text of those measures to the Commission.

Proposal for a directive Annex IV – heading

Text proposed by the Commission

# EU DECLARATION OF CONFORMITY

# Amendment

EU DECLARATION OF CONFORMITY (No XXXX)<sup>1</sup>

<sup>1</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

Or. en

# Amendment 53

Proposal for a directive Annex IV – point 1

Text proposed by the Commission

Amendment

1. No ... (unique identification of the pressure equipment):

deleted

# ANNEX: OPINION OF THE CONSULTATIVE WORKING PARTY OF THE LEGAL SERVICES OF THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE COMMISSION



CONSULTATIVE WORKING PARTY OF THE LEGAL SERVICES

Brussels,

# **OPINION**

# FOR THE ATTENTION OF THE EUROPEAN PARLIAMENT THE COUNCIL THE COMMISSION

Proposal for a directive of the European Parliament and of the Council on Harmonisation of the laws of the MS relating to making available on the market of pressure equipment (recast)

# **EXPLANATORY STATEMENT**

# Background

This report brings modifications to a proposal of the European Commission (EC) recasting Directive 97/23/EC of the European Parliament (EP) and of the Coucil (CEU) on the approximation of the laws of the Member States (MS) concerning pressure equipment.

The EC presented this recast in June 2013 in the framework of the implementation of the New Legislative Framework (NLF) adopted in 2008 as "the goods package" covering the complementary instruments, Decision 768/2008 on a common framework for the marketing of products, and repealing CEU Decision 93/465/EEC and Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

The existing Directive 97/23/EC sets out essential safety requirements that pressure equipment and assemblies must comply with in order to be made available on the EU market.

The NLF was adopted to remedy shortcomings in existing Union harmonisation legislation in order to complete the Single Market, with fair competition and safe products. Inconsistent implementation and enforcement in the MSs of the existing Union harmonisation, together with complex regulation, has made it increasingly difficult for both economic operators and authorities to correctly interpret and apply legislation, which lead to unequal market conditions and also unsafe products placed on the market. "The goods package" gives the overall framework to streamline product legislation, in order to make it more uniform and comprehensible for both economic operators and market surveillance authorities.

However, the provisions of the NLF Decision are not directly applicable. To ensure that all economic sectors subject to Union harmonisation legislation benefit from the improvements of the NLF, the provisions of the NLF Decision need to be integrated into the existing product legislation.

This Directive has been separated from the Alignment package presented in November 2011 because, unlike the other 9 Directive, this recast also contains an alignment with another EU legislative act, namely Regulation (EC) No 1272/2008 (CLP Regulation) of the EP and of the CEU of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

The changes made to the provisions of this Directive concern definitions, obligations of economic operators (i.e. declaration of conformity (DoC)), the presumption of conformity provided by harmonised standards, the CE marking, the conformity assessment bodies, market surveillance, the safeguard clause procedure, the classification of pressure equipment, comitology and delegated acts.

The intention of the proposal was restricted to a pure alignment with the horizontal provisions in Decision 768/2008/EC and CLP Regulation as well as the new terminology within the Lisbon Treaty, including new rules on comitology.

# Procedure

The alignment to the NLF Decision and the CLP Regulation requires a number of substantive amendments to the provisions of this Directive. The technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001.

Pursuant to Rule 87 of the Rules of Procedure of the EP, the Committee responsible for legal affairs will examine the proposal, based on the reports from the Consultative Working Party (legal services of the EP, the CEU and the EC), and decide if it entails substantive changes other than those identified as such in the proposal or those identified by the CWP.

# **Rapporteur's Position**

Your Rapporteur considers this alignment as a continuation of the alignment package and then one new step towards the completion of the EU single market.

The NLF introduces a simplified regulatory environment for products and allows more consistent implementation of technical norms, which will help improving the functioning of the single market, by ensuring equal treatment of non-compliant products and of economic operators, as well as an equal assessment of notified bodies throughout the EU market.

It is your Rapporteur's opinion, that an alignment with the NLF will increase the confidence of both producers and consumers, by clarifying obligations for economic operators and provide MSs authorities with more effective tools to carry out market surveillance controls, all leading to a reduction of non-compliant and unsafe products on the market.

Your Rapporteur also welcomes the alignment with the CLP Regulation, which implements within the Union the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) that has been adopted at the international level, within the structure of the United Nations.

Your Rapporteur supports the EC's general intention of a pure alignment and has therefore limited her amendments to the EC proposal to changes reflecting the agreement obtained between the CEU and the EP on the nine other Directives and which had been omitted in the proposal. It concerns:

• The **further alignment** of the Directive to the NLF and the **legal certainty**: As agreed in the Alignment package, your Rapporteur considers important to re-insert a number of changes to the proposed Directive in order to reach a higher level of consistency with the terms used by the Decision No 768/2008/E and eliminate the possible inconsistencies in the text which could otherwise create legal uncertainty. It is also important to insert the clarification related to the legal situation for products which have been legally placed on the market in compliance with the current Directive before the new Directive applies, but which are still in stock. The non-retroactive nature of EU legislation should be emphasized and it should be clarified that these products can still be made available on the market after the date of application of the new Directive.

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- The cutting down of **red tape**: Your Rapporteur supports the simplification and modernisation of procedures provided in the NLF, but wants to underline at the same time that a need for flexibility is necessary regarding some obligations created by the new framework, as recognised in the final agreement on the Alignment package. Therefore, the exception to the rule on 'one single DoC' has been re-inserted. It aims at solving cases where providing a single document creates specific problems due to its complexity or extent. Here it should be possible to provide all relevant DoCs separately. In addition, it should be optional for the manufacturer to assign a number to the DoC.
- The clarification of the legal framework applicable to **distance selling** and the protection of the **CE marking**: Your Rapporteur has re-inserted an amendment to make sure that the Directive applies to all types of selling, including distance selling. Finally, your Rapporteur stressed the need for appropriate actions to be taken by the MSs against improper use of CE marking.