



EUROPEAN COMMISSION

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2011/0350 (COD)

**NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT PACKAGE  
(Implementation of the Goods Package)**

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 simple pressure vessels**

**(Recast)**

(Text with EEA relevance)

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### **General context, reasons for and objectives of this proposal**

This proposal is presented in the framework of the **implementation of the “goods package”** adopted in 2008. It is part of a package of proposals aligning ten product directives to Decision No 768/2008/EC establishing a common framework for the marketing of products.

Union (EU) harmonisation legislation ensuring the free movement of products has contributed considerably to the completion and operation of the Single Market. It is based on a high level of protection and provides economic operators with the means to demonstrate conformity, thus ensuring free movement through trust in the products.

Directive 2009/105/EC is an example of that Union harmonisation legislation, ensuring the free movement of simple pressure vessels. It sets out essential safety requirements that simple pressure vessels must comply with in order to be made available on the EU market. Manufacturers must demonstrate that a simple pressure vessel has been designed and manufactured in compliance with the essential safety requirements and affix the CE marking.

Experience with the implementation of Union harmonisation legislation has shown – on a cross-sector scale - certain weaknesses and inconsistencies in the implementation and enforcement of this legislation, leading to

- the presence of non-compliant or dangerous products on the market and consequently a certain lack of trust in CE marking
- competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules
- unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices
- differing practices in the designation of conformity assessment bodies by national authorities
- problems with the quality of certain notified bodies

Furthermore the regulatory environment has become more and more complex, as frequently several pieces of legislation apply simultaneously to one and the same product. Inconsistencies in these pieces of legislation make it increasingly difficult for economic operators and authorities to correctly interpret and apply that legislation.

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the **“New Legislative Framework”** was adopted in 2008 as part of the **goods package**. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, **Regulation (EC) No 765/2008 on accreditation and market surveillance** and **Decision No 768/2008/EC establishing a common framework for the marketing of products**.

The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The provisions of the NLF Decision and those of the NLF Regulation are complementary and closely interlinked. The NLF Decision contains the corresponding obligations for economic operators and notified bodies allowing market surveillance authorities and authorities responsible for notified bodies to properly perform the tasks imposed on them by the NLF Regulation and to ensure an effective and consistent enforcement of EU product legislation.

However, unlike the NLF Regulation, 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.

A survey after the adoption of the goods package in 2008 showed that a majority of Union harmonisation legislation on products was due to be revised within the following 3 years, not only to address the problems observed throughout all sectors but also for sector-specific reasons. Any such revision would automatically include an alignment of the legislation concerned to the NLF Decision since Parliament, Council and Commission have committed themselves to use its provisions as much as possible in future legislation on products in order to further the utmost coherence of the regulatory framework.

For a number of other Union harmonisation directives, including simple pressure vessels Directive 2009/105/EC no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance and notified bodies are nevertheless addressed in these sectors, and for the sake of consistency of the overall regulatory environment on products, it was decided to align these directives within a package to the provisions of the NLF Decision.

### **Consistency with other policies and objectives of the Union**

This initiative is in line with the Single Market Act<sup>1</sup>, which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

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<sup>1</sup> Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

## **2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **Consultation of interested parties**

The alignment of Directive 2009/105/EC to the NLF Decision has been discussed with national experts responsible for the implementation of this Directive, the notified body group, the administrative cooperation group as well as in bilateral contacts with industry associations.

From June to October 2010 a public consultation was organised that comprised all the sectors involved in this initiative. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and the Commission services received 300 replies. The results are published at:

[http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index\\_en.htm](http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm)

In addition to the general consultation a specific SME consultation was carried out. 603 SMEs were consulted through the Enterprise Europe Network in May/June 2010. The results are available at [http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes\\_statistics\\_en.pdf](http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes_statistics_en.pdf)

The consultation process revealed widespread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation. Certain concerns were expressed on some obligations which are, however, indispensable for increasing the efficiency of market surveillance. These measures will not entail significant costs for industry, and the benefits resulting from improved market surveillance should by far outweigh the costs.

### **Collection and use of expertise**

The impact assessment for this implementation package has largely built on the impact assessment carried out for the New Legislative Framework. In addition to the expertise collected and analysed in that context, further consultation of sector-specific experts and interest groups, as well as horizontal experts active in the area of technical harmonisation, conformity assessment, accreditation and market surveillance, has taken place.

### **Impact assessment**

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.

#### **Option 1 - No changes to the current situation**

This option proposes no changes to the current directive and relies exclusively on certain improvements that can be expected from the NLF Regulation.

#### **Option 2 – Alignment to the NLF Decision by non-legislative measures**

Option 2 considers the possibility of encouraging a voluntary alignment to the provisions set out in the NLF Decision by, e.g., presenting them as best practices in guidance documents.

### **Option 3 – Alignment to NLF Decision by legislative measures**

This option consists in integrating the provisions of the NLF Decision into the existing directives.

Option 3 was found to be the preferred option because

- it will improve the competitiveness of companies and notified bodies taking their obligations seriously, as opposed to those cheating on the system;
- it will improve the functioning of the internal market by ensuring equal treatment of all economic operators, notably importers and distributors, as well as notified bodies;
- it does not entail significant costs for economic operators and notified bodies; for those who are already acting responsibly, no extra costs or only negligible costs are expected;
- it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;
- options 1 and 2 do not provide answers to the problem of inconsistencies in the regulatory framework and therefore have no positive impact on the simplification of the regulatory environment.

## **3. MAIN ELEMENTS OF THE PROPOSAL**

### **3.1. Horizontal definitions**

The proposal introduces harmonised definitions of terms which are commonly used throughout Union harmonisation legislation and should therefore be given a consistent meaning throughout that legislation.

### **3.2. Obligations of economic operators and traceability requirements**

The proposal clarifies the obligations of manufacturers and authorised representatives and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that simple pressure vessels are correctly marked and accompanied by the instructions and safety information. They must keep a copy of the Declaration of conformity and indicate their name and address on the product. Distributors must verify that the simple pressure vessel bears the CE marking, the name of the manufacturer and of the importer, if relevant, and that it is accompanied by the required documentation and instructions.

Importers and distributors must cooperate with market surveillance authorities and take appropriate actions when they have supplied non-compliant simple pressure vessels.

**Enhanced traceability obligations** are introduced for all economic operators. Simple pressure vessels have to bear the manufacturer's name and address and a number allowing to identify and link the simple pressure vessel to its technical documentation. When a simple pressure vessel is imported the importer's name and address must also be on the simple pressure vessel. Furthermore every economic operator must be able to identify towards authorities the economic operator who has supplied him with a simple pressure vessel or to whom he has supplied a simple pressure vessel.

### **3.3. Harmonised standards**

Compliance with harmonised standards provides a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation<sup>2</sup> that sets out a horizontal legal framework for European standardisation. The proposal for the Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisations, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 2009/105 which cover the same aspects have been deleted in this proposal for reasons of legal certainty.

The provision conferring presumption of conformity to harmonised standards has been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential requirements.

### **3.4. Conformity assessment and CE marking**

Directive 2009/105/EC has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their simple pressure vessels comply with the essential safety requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision. It keeps some specific elements already provided for in Directive 2009/105/EC as the welding tests.

General principles of the CE marking are set out in Article 30 of Regulation 765/2008, while the detailed provisions on the affixing of the CE marking to simple pressure vessels have been inserted in this proposal.

### **3.5. Notified Bodies**

The proposal reinforces the notification criteria for notified bodies. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements for notifying authorities are introduced, and the procedure for notification of notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. Where accreditation has not been used to evaluate the competence of a notified body, the notification must comprise the documentation demonstrating how the

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<sup>2</sup> Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council. COM(2011) 315 final

competence of that body has been evaluated. Member States will have the possibility to object to a notification.

### **3.6. Market surveillance and the safeguard clause procedure**

The proposal revises the existing safeguard clause procedure. It introduces a phase of information exchange between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant simple pressure vessel is found. A real safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or not - is only launched when another Member State objects to a measure taken against a simple pressure vessel. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

## **4. LEGAL ELEMENTS OF THE PROPOSAL**

### **Legal basis**

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

### **Subsidiarity principle**

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 2009/105/EC, namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of notified bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objective of this directive. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. In view of the increasing internationalisation of trade, the number of cross-border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

### **Proportionality**

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of

modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

### **Legislative technique used**

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Directive 2009/105/EC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>3</sup>.

The changes made to the provisions of Directive 2009/105/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, notified bodies, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope of Directive 2009/105/EC and the essential safety requirements.

## **5. BUDGETARY IMPLICATIONS**

This proposal does not have any implications for the EU budget.

## **6. ADDITIONAL INFORMATION**

### **Repeal of existing legislation**

The adoption of the proposal will lead to repeal of Directive 2009/105/EC.

### **European Economic Area**

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

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<sup>3</sup> OJ C 77, 28.3.2002.

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↓ 2009/105/EC (adapted)

2011/0350 (COD)

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**relating to ~~⊗~~ on the harmonisation of the laws of the Member States relating to making available on the market of ~~⊗~~ simple pressure vessels**

**(Recast)**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~ ~~⊗~~ on the Functioning of the European Union ~~⊗~~, and in particular Article ~~95~~ ~~⊗~~ 114 ~~⊗~~ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>4</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

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↓ 2009/105/EC recital 1 (adapted)

~~Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels<sup>5</sup> has been substantially amended several times. In the interests of clarity and rationality the said Directive should be codified.~~

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<sup>4</sup> OJ C 27, 3.2.2009, p. 41.

<sup>5</sup> ~~OJL 220, 8.8.1987, p. 48.~~

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↓ new

- (1) A number of substantive changes are to be made to Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels<sup>6</sup>. In the interests of clarity, that Directive should be recast.
- (2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>7</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (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>8</sup> 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 2009/105/EC should therefore be adapted to that Decision.

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↓ 2009/105/EC recital 2 (adapted)

- (4) Member States ~~have the responsibility of ensuring~~ ☒ should ensure ☒ the safety on their territory of persons, domestic animals and property with regard to the hazards resulting from the leakage or bursting of simple pressure vessels.

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↓ 2009/105/EC recital 3

~~In each Member State, mandatory provisions define in particular the safety level required of simple pressure vessels by specifying design and operating characteristics, conditions of installation and use and inspection procedures before and after the placing on the market. These mandatory provisions do not necessarily lead to different safety levels from one Member State to another but do, by their disparity, hinder trade within the Community.~~

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↓ 2009/105/EC recital 4

~~This Directive should therefore contain only mandatory and essential requirements. To facilitate proof of conformity with the essential requirements, it is necessary to~~

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<sup>6</sup> OJ L 264, 8.10.2009, p. 12.

<sup>7</sup> OJ L 218, 13.8.2008, p. 30.

<sup>8</sup> OJ L 218, 13.8.2008, p. 82.

~~have harmonised standards at Community level, in particular as to the design, operation and installation of simple pressure vessels, so that products complying with them may be assumed to conform to the safety requirements. These standards harmonised at Community level are drawn up by private bodies and should remain non-mandatory texts. For that purpose, the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) and the European Telecommunications Standards Institute (ETSI) are recognised as the competent bodies for the adoption of harmonised standards in accordance with the general guidelines<sup>9</sup> for cooperation between the Commission, the European Free Trade Association (EFTA) and those three bodies signed on 28 March 2003.~~

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↓ new

- (5) Economic operators should be responsible for the compliance of simple pressure vessels, 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.
- (6) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market simple pressure vessels which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.

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↓ 2009/105/EC recital 5 (adapted)

~~The Council has already adopted a series of Directives designed to remove technical barriers to trade in accordance with the principles established in its Resolution of 7 May 1985 on a new approach to technical harmonisation and standards<sup>10</sup>, each of those Directives provides for the affixing of the ‘CE’ marking. The Commission, in its Communication of 15 June 1989 on a global approach to certification and testing<sup>11</sup>, proposed that common rules be drawn up concerning a ‘CE’ marking with a single design. The Council, in its Resolution of 21 December 1989 on a global approach to conformity assessment<sup>12</sup>, approved as a guiding principle the adoption of a consistent approach such as this with regard to the use of the ‘CE’ marking. The two basic elements of the new approach which should be applied are the essential requirements and the conformity assessment procedures.~~

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<sup>9</sup> OJ C 91, 16.4.2003, p. 7.

<sup>10</sup> OJ C 136, 4.6.1985, p. 1.

<sup>11</sup> OJ C 267, 19.10.1989, p. 3.

<sup>12</sup> OJ C 10, 16.1.1990, p. 1.

- (7) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure for simple pressure vessels. Conformity assessment should therefore remain the obligation of the manufacturer alone.
- (8) It is necessary to ensure that simple pressure vessels from third countries entering the Union market comply with the requirements of this Directive, and in particular that the appropriate assessment procedures have been carried out by manufacturers with regard to those simple pressure vessels. Provision should therefore be made for importers to make sure that the simple pressure vessels they place on the market comply with the requirements of this Directive and that they do not place on the market simple pressure vessels which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that simple pressure vessel marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.
- (9) The distributor makes a simple pressure vessel available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the simple pressure vessel does not adversely affect the compliance of the simple pressure vessel.
- (10) When placing a simple pressure vessel on the market, every importer should indicate on the simple pressure vessel his name and the address at which he can be contacted.
- (11) Any economic operator that either places a simple pressure vessel on the market under its own name or trademark or modifies a simple pressure vessel in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (12) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the simple pressure vessel concerned.
- (13) Ensuring traceability of a simple pressure vessel throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non compliant simple pressure vessels available on the market.
- (14) This Directive should be limited to the expression of the essential safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for products which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No [.../...] of the European Parliament and of the Council of .... on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC

and 2009/23/EC of the European Parliament and of the Council<sup>13</sup> for the purpose of expressing detailed technical specifications of those requirements, in particular as to the design, operation and installation of simple pressure vessels.

- (15) Regulation (EU) No [...] [...] [on European Standardisation] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (16) In order to enable economic operators to demonstrate and the competent authorities to ensure that simple pressure vessels made available on the market comply with the essential safety requirements it is necessary to provide for conformity assessment procedures. 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.
- (17) Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of a simple pressure vessel with the requirements of this Directive and of other relevant Union harmonisation legislation.
- (18) The CE marking, indicating the conformity of a simple pressure vessel, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008/EC. Rules governing the affixing of the CE marking should be laid down in this Directive.

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↓ 2009/105/EC recital 6 (adapted)

- (19) A check on compliance with the relevant ~~technical~~  essential safety  requirements is necessary in order to provide effective protection for users and third parties. ~~The existing inspection procedures differ from one Member State to another. In order to avoid multiple inspections, which are in effect barriers to the free movement of vessels, arrangements should be made for the mutual recognition of inspection procedures by the Member States. In order to facilitate the mutual recognition of inspection procedures, Community procedures should be established as well as the criteria for appointing the bodies responsible for carrying out tests, surveillance and verification.~~

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↓ 2009/105/EC recital 7

~~The presence on a simple pressure vessel of the ‘CE’ marking should raise a presumption that it satisfies the provisions of this Directive and should therefore make it unnecessary, upon the importation and putting into service of the vessel, to repeat the inspections already carried out. Nevertheless simple pressure vessels might~~

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<sup>13</sup> OJ L [...], [...], p. [...].

~~represent a safety hazard. Provision should therefore be made for a procedure to reduce this hazard.~~

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↓ new

- (20) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (21) Experience has shown that the criteria set out in Directive 2009/105/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (22) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (23) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (24) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (25) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (26) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the simple pressure vessels to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the

monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

- (27) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (28) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (29) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (30) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to simple pressure vessels. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (31) Directive 2009/105/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against simple pressure vessels it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the aim of making it more efficient and of drawing on expertise available in the Member States.
- (32) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to simple pressure vessels presenting a risk to the health and safety of persons or to other aspects of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such simple pressure vessels.
- (33) Where Member States and the Commission agree as to the justification for a safeguard measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (34) It is necessary to provide for transitional arrangements that allow making available on the market and putting into service simple pressure vessels that have already been placed on the market in accordance with Directive 2009/105/EC.
- (35) 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 these

rules are implemented. The penalties provided for should be effective, proportionate and dissuasive.

(36) Since the objective of this Directive, namely to ensure that simple pressure vessels on the market fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(37) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with Directive 2009/105/EC. The obligation to transpose the provisions which are unchanged arises under the earlier Directives.

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↓ 2009/105/EC recital 8

(38) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in ~~Annex IV~~, Part B of Annex IV to Directive 2009/105/EC.

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↓ 2009/105/EC (adapted)  
⇒ new

HAVE ADOPTED THIS DIRECTIVE:

## **CHAPTER II**

### **~~SCOPE, DEFINITIONS, PLACING ON THE MARKET AND FREE MOVEMENT~~ ☒ GENERAL PROVISIONS ☒**

#### *Article 1*

##### ☒ **Scope** ☒

1. This Directive ☒ shall apply ☒ ~~applies~~ to simple pressure vessels ☒ (hereinafter vessels) ☒ manufactured in series ☒ with the following characteristics ☒ ☒:

(a) ~~'simple pressure vessel' or~~ ☒ the vessels are ☒ ~~'vessel' means any welded vessel~~ subjected to an internal gauge pressure greater than 0,5 bar, ~~which is~~ intended to contain air or nitrogen and ~~which is~~ ☒ are ☒ not intended to be fired ☒.

- (b) ~~The parts and assemblies~~  components  contributing to the strength of the vessel under pressure ~~shall be~~  are  made either of non-alloy quality steel or of non-alloy aluminium or non-age hardening aluminium alloys~~;~~
- (c) ~~The vessel shall be~~  is  made of either  of the following :
- (i) a cylindrical part of circular cross-section closed by ~~inwardly~~  outwardly  dished and/or flat ends which revolve around the same axis as the cylindrical part; ~~or~~
  - (ii) two dished ends revolving around the same axis~~;~~
- (d) ~~The maximum working pressure of the vessel shall~~  does  not exceed 30 bar and the product of that pressure and the capacity of the vessel (PS x V) ~~shall~~  does  not exceed 10000 bar.~~L<sub>2</sub>;~~
- (e) ~~The minimum working temperature must be~~  is  no lower than – 50 °C and the maximum working temperature ~~must~~  is  not ~~be~~ higher than 300 °C for steel and 100 °C for aluminium or aluminium alloy vessels~~;~~

↓ 2009/105/EC

~~(b) a ‘harmonised standard’ means a technical specification (European standard or harmonisation document) adopted by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) or the European Telecommunications Standards Institute (ETSI) or by two or three of those bodies upon a remit from the Commission in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services<sup>14</sup> and the general guidelines for cooperation between the Commission, the European Free Trade Association (EFTA) and those three bodies signed on 28 March 2003.~~

↓ 2009/105/EC (adapted)

2. ~~The following vessels shall be excluded from the scope of~~  This Directive  shall not apply to the following vessels  :

↓ 2009/105/EC

- (a) vessels specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
- (b) vessels specifically intended for installation in or the propulsion of ships and aircraft;

<sup>14</sup> ~~OJL 204, 21.7.1998, p. 37~~

(c) fire extinguishers.

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↓ 2009/105/EC (adapted)

Article 2 [Article R1 of Decision No 768/2008/EC]

### ⊗ Definitions ⊗

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

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↓ new

(1) ‘making available on the market’ means any supply of a vessel for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(2) ‘placing on the market’ means the first making available of a vessel on the Union market;

(3) ‘manufacturer’ means any natural or legal person who manufactures a vessel or has a vessel designed or manufactured, and markets that vessel under his name or trademark;

(4) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(5) ‘importer’ means any natural or legal person established within the Union who places a vessel from a third country on the Union market;

(6) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a vessel available on the market;

(7) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(8) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a vessel;

(9) ‘harmonised standard’ means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No [.../] [on European Standardisation];

(10) ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

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

(12) ‘conformity assessment’ means the process demonstrating whether the requirements of this Directive relating to a vessel have been fulfilled;

(13) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(14) ‘recall’ means any measure aimed at achieving the return of a vessel that has already been made available to the user;

(15) ‘withdrawal’ means any measure aimed at preventing a vessel in the supply chain from being made available on the market;

(16) ‘CE marking’ means a marking by which the manufacturer indicates that the vessel is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(17) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.

↓ 2009/105/EC (adapted)  
⇒ new

### Article ~~22~~

#### ⊗ Making available on the market and putting into service ⊗

1. Member States shall take all necessary steps to ensure that the vessels may be ~~placed~~ ⇒ made available ⇐ on the market and put into service only if they do not compromise the safety of persons, domestic animals or property when properly installed and maintained and used for the purposes for which they are intended.

2. The provisions of this Directive shall not affect the right of Member States to specify ~~— with due observance of the Treaty —~~ the requirements they deem necessary in order to ensure that workers are protected when using vessels, provided it does not mean that those vessels are modified in a way unspecified in this Directive.

### Article ~~34~~

#### ⊗ Essential requirements ⊗

1. Vessels ~~in respect~~ of which the product of PS x V exceeds 50 bar.L ~~must~~ ⊗ shall ⊗ satisfy the essential safety requirements set out in Annex I.

2. Vessels ~~in respect~~ of which the product of PS x V is 50 bar.L or less ~~must~~ ⊗ shall ⊗ be manufactured in accordance with sound engineering practice in one of the Member States ~~and bear markings as laid down in point 1 of Annex III, with the exception of the ‘CE’ marking referred to in Article 16.~~

## Article 45

### ⊗ Free movement ⊗

Member States shall not impede the ~~placing~~ ⇒ making available ⇐ on the market and the putting into service ~~in~~ ⊗ on ⊗ their territory of vessels which satisfy the requirements of this Directive.

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↓ new

## CHAPTER 2

### OBLIGATIONS OF ECONOMIC OPERATORS

Article 6 [Article R2 of Decision No 768/2008/EC]

#### Obligations of manufacturers

1. When placing on the market the vessels of which the product of PS x V exceeds 50 bar.L, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.

When placing on the market vessels of which the product of PS x V is 50 bar.L or less, manufacturers shall ensure that they have been designed and manufactured in accordance with the sound engineering practice in one of the Member States.

2. For vessels of which the product of PS x V exceeds 50 bar.L, manufacturers shall draw up the technical documentation referred to in points 2 and 3 of Annex III and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of a vessel of which the product of PS x V exceeds 50 bar.L with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the inscriptions provided for in point 1 of Annex III.

Manufacturers shall ensure that vessels of which the product of PS x V is 50 bar.L or less, bear the inscriptions laid down in point 1 of Annex III.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the vessel has been placed on the market.

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

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

5. Manufacturers shall ensure that their vessels bear a type and serial or batch identification allowing their identification.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the vessel. The address must indicate a single point at which the manufacturer can be contacted.

7. Manufacturers shall ensure that the vessel of which the product of PS x V exceeds 50 bar.L, is accompanied by the instructions and safety information referred to in point 2 of Annex III, in the official language or languages of the country Member State of destination.

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

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

#### *Article 7 [Article R3 of Decision No 768/2008/EC]*

#### **Authorised representatives**

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

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.

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

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the vessel has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a vessel;

- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by vessels covered by the authorised representative's mandate.

*Article 8 [Article R4 of Decision No 768/2008/EC]*

**Obligations of importers**

1. Importers shall place only compliant vessels on the market.

2. Before placing on the market a vessel of which the product of PS x V exceeds 50 bar.L, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 6 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the vessel bears the CE marking and the inscriptions provided for in point 1 of Annex III and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that a vessel of which the product of PS x V exceeds 50 bar.L is not in conformity with the essential safety requirements set out in Annex I, he shall not place the vessel on the market until it has been brought into conformity. Furthermore, where the vessel presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Before placing on the market a vessel of which the product of PS x V is 50 bar.L or less, importers shall ensure that it bears the inscriptions provided for in point 1 of Annex III and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the vessel or, where that is not possible, on its packaging or in a document accompanying the vessel.

4. Importers shall ensure that the vessel of which the product of PS x V exceeds 50 bar.L, is accompanied by the instructions and safety information referred to in point 2 of Annex III, in the official language or languages of the Member State of destination.

5. Importers shall ensure that, while a vessel in respect of which the product of PS x V exceeds 50 bar.L is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by a vessel, importers shall, to protect the health and safety of users, carry out sample testing of vessels made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming vessels and vessel recalls, and shall keep distributors informed of such monitoring.

7. Importers who consider or have reason to believe that a vessel which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the vessel presents a risk, importers shall immediately

inform the competent national authorities of the Member States in which they made the vessel available to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.

8. For vessels of which the product of PS x V exceeds 50 bar.L, importers shall, for 10 years after the vessel has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

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

#### *Article 9 [Article R5 of Decision No 768/2008/EC]*

### **Obligations of distributors**

1. When making a vessel available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making a vessel of which the product of PS x V exceeds 50 bar.L available on the market, distributors shall verify that the vessel bears the CE marking and the inscriptions provided for in point 1 of Annex III, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by users in the Member State in which the vessel 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).

Where a distributor considers or has reason to believe that a vessel of which the product of PS x V exceeds 50 bar.L is not in conformity with the essential safety requirements set out in Annex I, he shall not make the vessel available on the market until it has been brought into conformity. Furthermore, where the vessel presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making a vessel of which the product of PS x V is 50 bar.L or less available on the market, distributors shall verify that the vessel bears the inscriptions provided for in point 1 of Annex III and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3).

3. Distributors shall ensure that, while a vessel of which the product of PS x V exceeds 50 bar.L is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that a vessel 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 vessel into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the vessel presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they

made the vessel available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

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

*Article 10 [Article R6 of Decision No 768/2008/EC]*

#### **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places a vessel on the market under his name or trademark or modifies a vessel already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

*Article 11 [Article R7 of Decision No 768/2008/EC]*

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

Economic operators shall, on request, identify the following to the market surveillance authorities:

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

Economic operators shall be able to present the information referred to in the first subparagraph for a period of 10 years after they have been supplied with the vessel and for a period of 10 years after they have supplied the vessel.

## CHAPTER 3

### CONFORMITY OF VESSELS OF WHICH THE PRODUCT OF PS x V EXCEEDS 50 bar.L

↓ 2009/105/EC (adapted)

Article ~~5~~12 [Article R8 of Decision No 768/2008/EC]

#### ⊗ Presumption of conformity ⊗

↓ new

Vessels of which the product of PS x V exceeds 50 bar.L and which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements covered by those standards or parts thereof, set out in Annex I.

[Where a harmonised standard satisfies the requirements which it covers and which are set out in Annex I or Article 21, the Commission shall publish the references of those standards in the *Official Journal of the European Union*.]

↓ 2009/105/EC

~~Member States shall presume that vessels bearing the CE marking comply with all the provisions of this Directive.~~

~~Conformity of vessels with the national standards which transpose the harmonised standards, the reference numbers of which have been published in the *Official Journal of the European Union*, shall result in a presumption of conformity to the essential safety requirements set out in Annex I.~~

~~Member States shall publish the reference numbers of such national standards.~~

~~2. Member States shall presume that vessels for which the standards referred to in the second subparagraph of paragraph 1 do not exist or in respect of which the manufacturer has not applied or has only partially applied such standards, comply with the essential safety requirements set out in Annex I, where, after receipt of an EC type examination certificate, their conformity with the approved model has been certified by the affixation of the 'CE' marking.~~

~~3. Where vessels are subject to other Directives covering other aspects and which also provide for the affixing of the ‘CE’ marking, the latter shall indicate that the vessels in question are also presumed to conform to the provisions of those other Directives.~~

~~However, where one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the ‘CE’ marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Union*, shall be given in the documents, notices or instructions required by the Directives and accompanying such vessels.~~

↓ 2009/105/EC (adapted)

⇒ new

## ~~CHAPTER II~~

### ~~Certification~~

#### ~~Section 1 Article 13~~

~~Certification~~ ☒ **Conformity assessment** ☒ procedures

#### ~~Article 8~~

1. Prior to production of ☒ their manufacture ☒ pressure vessels of which the product of PS x V exceeds 50 bar.L, ~~manufactured in accordance with the harmonised standards~~ ⇒ shall be subject to the EU-type examination (Module B) ⇐ referred to in ~~Article 5(1)~~, the manufacturer, or his authorised representative established within the Community, shall at his own choice either point 1 of Annex II, ☒ as follows ☒ :

↓ new

(a) for vessels manufactured in accordance with the harmonised standards referred to in Article 12, at the choice of the manufacturer, in either of the following two manners:

↓ 2009/105/EC

~~(a) inform an approved inspection body as referred to in Article 9, which, after examining the design and manufacturing schedule referred to in point 3 of Annex II, shall draw up a certificate of adequacy attesting that the schedule is satisfactory~~

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↓ new

- i) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence without examination of a specimen (Module B - design type);
- 

↓ 2009/105/EC  
⇒ new

- ~~(bii)~~ ⇒ examination of ~~submit~~ a prototype vessel ⇒ representative of the production envisaged of the complete vessel ~~for the EC type examination referred to in Article 10~~ ⇒ Module B – production type) ⇐ .
- 

↓ 2009/105/EC (adapted)

- ~~2(b)~~ ~~Prior to production of pressure~~ ☒ for ☒ vessels of which the product of PS x V exceeds 50 bar. ~~It~~ not manufactured, or manufactured only partly, in accordance with the harmonised standards referred to in Article ~~5(1)12~~, the manufacturer, ~~or his authorised representative established within the Community~~, shall submit ☒ for examination ☒ a prototype vessel ~~for the EC type examination referred to in Article 10~~ ☒ representative of the production envisaged of the complete vessel (Module B – production type) ☒ .

~~32. Vessels manufactured in accordance with the harmonised standards referred to in Article 5(1) or with the approved prototype shall, prior to their being placed~~ ☒ placing ☒ on the market, ☒ vessels shall ☒ be subject ☒ to the following procedures ☒ :

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↓ 2009/105/EC  
⇒ new

- (a) ~~to the EC verification referred to in Article 11~~ where the product of PS x V exceeds 3000 bar. ~~It~~ ⇒ , to Module C1 (conformity to type based on internal production control plus supervised product testing) set out in point 2 of Annex II ⇐;
- 

↓ 2009/105/EC (adapted)  
⇒ new

- (b) ~~at the choice of the manufacturer~~, where the product of PS x V does not exceed 3000 bar. ~~It~~ but exceeds ~~50~~ ⇒ 200 ⇐ bar. ~~It~~, ☒ at the choice of the manufacturer, to ☒ either ☒ of the following modules ☒ :

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↓ 2009/105/EC  
⇒ new

(i) ~~to the EC declaration~~ ⇒ Module C1 ~~of~~ (conformity ⇒ to type based on internal production control plus supervised product testing) ⇐ referred to in ~~Article 12~~ point 2 of Annex II; ~~or~~

(ii) ~~to the EC verification~~ ⇒ Module C2 (conformity to type based on internal production control plus supervised product checks at random intervals ⇐ referred to in ~~Article 11~~ point 3 Annex II.

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↓ new

(c) where the product of PS x V does not exceed 200 bar.L but exceeds 50 bar.L, at the choice of the manufacturer, to either of the following modules:

(i) Module C1 (conformity to type based on internal production control plus supervised product testing) referred to in point 2 of Annex II;

(ii) Module C (conformity to type based on internal production control) referred to in point 4 of Annex II.

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↓ 2009/105/EC (adapted)

43. The records and correspondence relating to the certification procedures referred to in paragraphs 1 and 2 ~~and 3~~ shall be drafted in an official language of the Member State in which the ~~approved inspection~~ ☒ notified ☒ body is established or in a language accepted by that body.

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↓ new

*Article 14 [Article R10 of Decision No 768/2008/EC]*

### **EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex III of Decision No 768/2008/EC, shall contain the elements specified in the relevant modules set out in Annex II of this Directive and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the vessel is placed or made available.

3. Where the vessel 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.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the vessel.

*Article 15 [Article R11 of Decision No 768/2008/EC]*

### **General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

*Article 16 [Article R12 of Decision No 768/2008/EC]*

### **Rules and conditions for affixing the CE marking and other markings**

1. The CE marking and the inscriptions referred to in point 1 of Annex III shall be affixed visibly, legibly and indelibly to the vessel or to its data plate.

2. The CE marking shall be affixed before the vessel is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body involved in the production control phase.

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

4. The CE marking and the identification number referred to in paragraph 3 may be followed by a pictogram or any other mark indicating a special risk or use.

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↓ 2009/105/EC

### ~~Article 6~~

~~Where a Member State or the Commission considers that the harmonised standards referred to in Article 5(1) do not entirely meet the essential safety requirements set out in Annex I, the Commission or the Member State concerned shall bring the matter before the standing committee set up under Article 5 of Directive 98/34/EC, hereinafter referred to as 'the committee', giving the reasons therefor.~~

~~The committee shall deliver an opinion without delay.~~

~~In the light of the committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 5(1).~~

#### ~~Article 7~~

~~1. Where a Member State finds that vessels bearing the 'CE' marking and used in accordance with their intended purpose might compromise the safety of persons, domestic animals or property, it shall take all appropriate measures to withdraw those products from the market or to prohibit or restrict their being placed on the market.~~

~~The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether non-conformity is due to:~~

~~(a) failure to meet the essential safety requirements set out in Annex I, where the vessel does not meet the harmonised standards referred to in Article 5(1);~~

~~(b) incorrect application of the harmonised standards referred to in Article 5(1);~~

~~(c) shortcomings in the harmonised standards referred to in Article 5(1).~~

~~2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified, it shall immediately so inform the Member State that took the action and the other Member States.~~

~~Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission, after consulting the parties concerned, shall bring the matter before the committee within two months if the Member State which has taken the measures intends to maintain them and shall set in motion the procedure referred to in Article 6.~~

~~3. Where a vessel which does not comply bears the 'CE' marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall inform the Commission and the other Member States thereof.~~

~~4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of the procedure referred to in paragraphs 1, 2 and 3.~~

## ~~CHAPTER II~~

### ~~CERTIFICATION~~

#### ~~SECTION 1~~

##### ~~CERTIFICATION PROCEDURES~~

###### ~~Article 9~~

~~1. Member States shall notify the Commission and the other Member States of the approved inspection bodies which they have appointed to carry out the procedures referred to in Article 8(1), (2) and (3) together with the specific tasks which those bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.~~

~~The Commission shall publish in the *Official Journal of the European Union* a list of the notified bodies with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.~~

~~2. For the purposes of approval of the bodies referred to in paragraph 1, Member States shall meet the minimum criteria set out in Annex III.~~

~~3. A Member State which has approved an inspection body shall withdraw approval if it finds that the body no longer meets the minimum criteria set out in Annex III.~~

~~It shall immediately inform the Commission and the other Member States accordingly.~~

#### ~~SECTION 2~~

##### ~~EC TYPE EXAMINATION~~

###### ~~Article 10~~

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↓ 2009/105/EC (adapted)

~~1. EC type examination is the procedure whereby an approved inspection body ascertains and certifies that a prototype vessel satisfies the provisions of this Directive which apply to it.~~

~~2. The application for EC type examination shall be lodged by the manufacturer or by his authorised representative with a single approved inspection body in respect of a prototype vessel or of a prototype representing a family of vessels. That authorised representative must be established in the Community.~~

The application shall include:

~~(a) the name and address of the manufacturer or of his authorised representative and the place of manufacture of the vessels;~~

↓ 2009/105/EC

~~(b) the design and manufacturing schedule referred to in point 3 of Annex II.~~

~~It shall be accompanied by a vessel which is representative of the production envisaged.~~

~~3. The approved inspection body shall carry out the EC type examination in the manner referred to in the second and third subparagraphs.~~

~~It shall examine not only the design and manufacturing schedule in order to check its conformity, but also the vessel submitted.~~

~~When examining the vessel, the body shall:~~

~~(a) verify that the vessel has been manufactured in conformity with the design and manufacturing schedule and may safely be used under its intended working conditions;~~

~~(b) perform appropriate examinations and tests to check that the vessel complies with the essential requirements applicable to it.~~

~~4. If the prototype complies with the provisions applicable to it the approved inspection body shall draw up an EC type examination certificate which shall be forwarded to the applicant. That certificate shall state the conclusions of the examination, indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved prototype.~~

~~The Commission, the other approved inspection bodies and the other Member States may obtain a copy of the certificate and, on a reasoned request, a copy of the design and manufacturing schedule and the reports on the examinations and tests carried out.~~

~~5. An approved inspection body which refuses to issue an EC type examination certificate shall so inform the other approved inspection bodies.~~

~~An approved inspection body which withdraws an EC type examination certificate shall so inform the Member State which approved it. The latter shall inform the other Member States and the Commission thereof, giving the reasons for the decision.~~

## **SECTION 3**

### **EC VERIFICATION**

#### *Article 11*

1. EC verification is the procedure whereby a manufacturer or his authorised representative established within the Community ensures and declares that the vessels which have been checked in accordance with paragraph 3 are in conformity with the type described in the EC type examination certificate or with the design and manufacturing schedule referred to in point 3 of Annex II having received a certificate of adequacy.

2. The manufacturer shall take all necessary measures for the manufacturing process to ensure that the vessels conform to the type described in the EC type examination certificate or to the design and manufacturing schedule referred to in point 3 of Annex II. The manufacturer or his authorised representative established within the Community shall affix the 'CE' marking to each vessel and draw up a declaration of conformity.

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↓ 2009/105/EC (adapted)

3. The approved inspection body shall carry out the appropriate examinations and tests in order to check the conformity of the vessels with the requirements of this Directive by examination and testing of vessels in accordance with the second to tenth subparagraphs.

The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

Those batches shall be accompanied by the EC type examination certificate referred to in Article 10 or, where the vessels are not manufactured in accordance with an approved prototype, by the design and manufacturing schedule referred to in point 3 of Annex II. In the latter case the approved inspection body shall, prior to EC verification, examine the schedule in order to certify its conformity.

When a batch is examined, the approved inspection body shall ensure that the vessels have been manufactured and checked in accordance with the design and manufacturing schedule, and shall perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure  $P_h$  equal to 1,5 times the vessel's design pressure in order to check its soundness. The pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

Moreover, the approved inspection body shall carry out tests on test pieces taken from a representative production test piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality. The tests shall be carried out on longitudinal welds. However, where differing weld techniques are used for longitudinal and circular welds, the tests shall be repeated on the circular welds.

~~For the vessels referred to in point 2.1.2 of Annex I, these tests on test pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in point 2.1.2 of Annex I.~~

~~In the case of accepted batches, the approved inspection body shall affix its identification number, or cause that number to be affixed, to each vessel and shall draw up a written certificate of conformity relating to the tests carried out. All vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.~~

~~If a batch is rejected, the approved inspection body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches, the approved inspection body may suspend the statistical verification.~~

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↓ 2009/105/EC

~~The manufacturer may, under the responsibility of the approved inspection body, affix the latter's identification number during the manufacturing process.~~

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↓ 2009/105/EC (adapted)

~~The manufacturer or his authorised representative must be able to supply on request the approved inspection body's certificates of conformity referred to in the seventh subparagraph.~~

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↓ 2009/105/EC

## ~~SECTION 4~~

### ~~EC DECLARATION OF CONFORMITY~~

#### ~~Article 12~~

~~1. A manufacturer fulfilling the obligations arising under Article 13 shall affix the 'CE' marking provided for in Article 16 to vessels which he declares to be in conformity with:~~

~~(a) the design and manufacturing schedule referred to in point 3 of Annex II in respect of which a certificate of adequacy has been drawn up; or~~

~~(b) an approved prototype.~~

~~2. By the EC declaration of conformity procedure the manufacturer becomes subject to EC surveillance, in cases where the product of PS x V exceeds 200 bar.L.~~

~~The purpose of EC surveillance is to ensure, as required by the second paragraph of Article 14, that the manufacturer duly fulfils the obligations arising under Article 13(2). Surveillance shall be performed by the approved inspection body which issued the EC type-examination certificate referred to in the first subparagraph of Article 10(4) where the vessels have been manufactured in accordance with an approved prototype or, if this is not the case, by the approved body to which the design and manufacturing schedule was sent in accordance with Article 8(1)(a).~~

### ~~Article 13~~

↓ 2009/105/EC (adapted)

~~1. Where a manufacturer makes use of the procedure referred to in Article 12, he shall, before commencing manufacture, send the approved inspection body which issued the EC type-examination certificate or the certificate of adequacy a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the pressure vessels to the standards referred to in Article 5(1) or the approved prototype.~~

~~2. The document referred to in paragraph 1 shall include:~~

~~— (a) a description of the means of manufacture and checking appropriate to the construction of the vessels;~~

~~— (b) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;~~

~~— (c) an undertaking to carry out the examinations and tests in accordance with the inspection document referred to in point (b) and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure;~~

~~— those examinations and tests shall be carried out under the responsibility of qualified staff who are sufficiently independent from production personnel, and shall be the subject of a report;~~

~~— (d) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.~~

~~3. When the product of  $PS \times V$  exceeds 200 bar.L, manufacturers shall authorise access to the said places of manufacture and storage by the body responsible for EC surveillance, for inspection purposes, and shall allow that body to select sample vessels and shall provide it with all necessary information, and in particular:~~

~~— (a) the design and manufacturing schedule;~~

~~— (b) the inspection report;~~

~~— (e) the EC type examination certificate or certificate of adequacy, where appropriate;~~

~~— (d) a report on the examinations and tests carried out.~~

#### ~~Article 14~~

~~The approved inspection body which issued the EC type examination certificate or certificate of adequacy shall, before the date on which any manufacture begins, examine both the document referred to in Article 13(1) and the design and manufacturing schedule referred to in point 3 of Annex II, in order to certify its conformity, where vessels are not manufactured in accordance with an approved prototype.~~

↓ 2009/105/EC

~~In addition, where the product of PS x V exceeds 200 bar.L, that body shall during manufacture:~~

↓ 2009/105/EC (adapted)

~~— (a) ensure that the manufacturer actually checks series produced vessels in accordance with Article 13(2)(e);~~

~~— (b) take random samples at the places of manufacture or at the place of storage of vessels for inspection purposes.~~

~~The approved inspection body shall supply the Member State which approved it and, on request, the other approved inspection bodies, the other Member States and the Commission, with a copy of the inspection report.~~

↓ new

## CHAPTER 4

### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

*Article 17 [Article R13 of Decision No 768/2008/EC]*

#### Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

*Article 18 [Article R14 of Decision No 768/2008/EC]*

**Notifying authorities**

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 23.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 19(1) to (6). In addition it shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

*Article 19 [Article R15 of Decision No 768/2008/EC]*

**Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

*Article 20 [Article R16 of Decision No 768/2008/EC]*

**Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 21 [Article R17 of Decision No 768/2008/EC]*

**Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

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

3. A conformity assessment body shall be a third-party body independent of the organisation or the vessel it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of vessels which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the vessels which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed vessels that are necessary for the operations of the conformity assessment body or the use of such vessels for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite

technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 13(1), (2) and (3) and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of vessels in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

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.

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

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

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

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.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 13(1), (2) and (3) of this Directive or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their 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 apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

*Article 22 [Article R18 of Decision No 768/2008/EC]*

### **Presumption of conformity**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 21 in so far as the applicable harmonised standards cover those requirements.

*Article 23 [Article R20 of Decision No 768/2008/EC]*

### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 21 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 13(1), (2) and (3).

*Article 24 [Article R22 of Decision No 768/2008/EC]*

**Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the vessel or vessels 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 21.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 21.

*Article 25 [Article R23 of Decision No 768/2008/EC]*

**Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 21.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and vessel or vessels concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 24(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 21.

5. 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 where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

*Article 26 [Article R13 of Decision No 768/2008/EC]*

**Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

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

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

*Article 27 [Article R25 of Decision No 768/2008/EC]*

**Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 21, 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 restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

*Article 28 [Article R26 of Decision No 768/2008/EC]*

**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 29 [Article R27 of Decision No 768/2008/EC]*

**Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Article 13(1), (2) and (3).

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the vessel technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the vessel with the provisions of this Directive.

3. Where a notified body finds that the 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.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a vessel no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

*Article 30*

**Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of notified bodies is available.

*Article 31 [Article R28 of Decision No 768/2008/EC]*

**Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

- (b) any circumstances affecting the scope of and conditions for notification;
- (c) any request for information 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 activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

*Article 32 [Article R13 of Decision No 768/2008/EC]*

#### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

*Article 33 [Article R30 of Decision No 768/2008/EC]*

#### **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 or groups of notified bodies.

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

### **CHAPTER 5**

## **UNION MARKET SURVEILLANCE, CONTROL OF VESSELS ENTERING THE UNION MARKET AND SAFEGUARD PROCEDURES**

*Article 34*

#### **Union market surveillance, control of vessels entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to vessels.

**Procedure for dealing with vessels 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 a vessel covered by this Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the vessel concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the vessel does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the vessel into compliance with those requirements, to withdraw the vessel from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that noncompliance 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 vessels concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the vessel's being made available on their national market, to withdraw the vessel from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the noncompliant vessel, the origin of the vessel, the nature of the noncompliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the vessel to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this Directive;

(b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure 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 vessel 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 vessel concerned, without delay.

#### *Article 36 [Article R32 of Decision No 768/2008/EC]*

#### **Union safeguard procedure**

1. Where, on completion of the procedure set out in Article 35(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall 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 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 vessel is withdrawn from their market, 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 vessel is attributed to shortcomings in the harmonised standards referred to in Article 35(5)(b) of this Directive, the Commission shall apply the procedure provided for in Article 8 of Regulation (EU) No [...] [on European Standardisation].

#### *Article 37 [Article R33 of Decision No 768/2008/EC]*

#### **Compliant vessels which present a risk to health and safety**

1. Where, having performed an evaluation under Article 35(1), a Member State finds that although a vessel is in compliance with 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 vessel concerned, when

placed on the market, no longer presents that risk, to withdraw the vessel 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 vessels concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the vessel concerned, the origin and the supply chain of the vessel, 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 the relevant economic operator or operators.

*Article 38 [Article R34 of Decision No 768/2008/EC]*

**Formal non-compliance**

1. Without prejudice to Article 35, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking and/or the inscriptions referred to in point 1 of Annex III have been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Directive;
- (b) the CE marking and/or the inscriptions provided for in point 1 of Annex III have not been affixed;
- (c) the EU declaration of conformity has not been drawn up;
- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) the technical documentation is either not available or not complete.

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 vessel being made available on the market or ensure that it is recalled or withdrawn from the market.

## ~~CHAPTER III~~

### ~~'CE' MARKING AND INSCRIPTIONS~~

#### ~~Article 15~~

~~Without prejudice to Article 7:~~

~~(a) where a Member State establishes that the 'CE' marking has been affixed unduly, the manufacturer or his authorised representative established within the Community shall be obliged to make the product conform with the provisions concerning the 'CE' marking and to end the infringement under the conditions imposed by that Member State;~~

~~(b) where the non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 7.~~

#### ~~Article 16~~

~~1. The 'CE' marking and the inscriptions provided for in point 1 of Annex II, shall be affixed in a visible, legible and indelible form to the vessel or to a data plate attached to the vessel in such a way that it cannot be removed.~~

~~The 'CE' marking shall consist of the initials 'CE' in the form shown in the specimen in point 1.1 of Annex II. The 'CE' marking shall be followed by the identification number referred to in Article 9(1) of the approved inspection body responsible for 'CE' verifications or 'CE' surveillance.~~

~~2. The affixing on the vessels of markings which are likely to deceive third parties as to the meaning and form of the 'CE' marking shall be prohibited. Any other marking may be affixed to the vessels or the data plate provided that the visibility and legibility of the 'CE' marking are not thereby reduced.~~

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↓ 2009/105/EC (adapted)

## CHAPTER ~~IV~~6

### ⊗ *TRANSITIONAL AND* ⊗ *FINAL PROVISIONS*

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↓ 2009/105/EC

#### ~~Article 17~~

~~Any decision taken pursuant to this Directive which results in restrictions on the placing on the market or the putting into service of a vessel shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the judicial remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.~~

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↓ new

#### Article 39

##### **Penalties**

Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those provisions to the Commission by [the date set out in the second subparagraph of Article 41(1)] at the latest and shall notify it without delay of any subsequent amendment affecting them.

#### Article 40

##### **Transitional provisions**

Member States shall not impede the making available on the market and/or the putting into service of vessels covered by Directive 2009/105/EC which are in conformity with that Directive and which were placed on the market before [the date set out in the second subparagraph of Article 41(1)].

Certificates of conformity issued under Directive 2009/105/EC shall be valid under this Directive until [the date set out in the second subparagraph of Article 41(1)] unless they expire before that date.

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Article ~~18~~41

### Transposition

1. Member States shall adopt and publish by [insert date – 2 years after adoption] at the latest, the laws, regulations and administrative provisions necessary to comply with Articles 2, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 and Annex II. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [day after date set out in first subparagraph].

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. They shall also include a statement that references in existing laws, regulations and administrative provisions to the directive repealed by this Directive shall be construed as references to this directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

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↓ 2009/105/EC

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.

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↓ 2009/105/EC (adapted)

Article ~~19~~42

### ⊗ Repeal ⊗

Directive ~~87/404/EEC~~ 2009/105/EC, as amended by the Directives listed in Annex IV, Part A, is repealed ⊗ with effect from [day after the date set out in the second subparagraph of Article 41(1)] ⊗, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in ~~Annex IV~~, Part B of Annex IV to Directive 2009/105/EC.

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↓ 2009/105/EC

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

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↓ 2009/105/EC (adapted)

*Article ~~20~~43*

⊗ **Entry into force** ⊗

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↓ 2009/105/EC

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

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↓

Articles 1, 3, 4, 5 and Annexes I and III shall apply from [the date set out in the second subparagraph of Article 41(1)].

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↓ 2009/105/EC (adapted)

*Article ~~24~~44*

⊗ **Addressees** ⊗

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↓ 2009/105/EC

This Directive is addressed to the Member States.

Done at [...],

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

---

↓ 2009/105/EC

**ANNEX I**

**ESSENTIAL SAFETY REQUIREMENTS**

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↓ 2009/105/EC (adapted)

~~(referred to in Article 3(1))~~

**1. MATERIALS**

Materials ~~must~~ ☒ shall ☒ be selected according to the intended use of the vessels and in accordance with points 1.1 to 1.4.

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↓ 2009/105/EC

*1.1. Pressurised parts*

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↓ 2009/105/EC (adapted)

The materials ~~referred to in Article 4~~ used for manufacturing the pressurised parts of the vessels ~~must~~ ☒ shall ☒ be:

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↓ 2009/105/EC

- (a) capable of being welded;
  - (b) ductile and tough, so that a rupture at minimum working temperature does not give rise to either fragmentation or brittle-type fracture;
  - (c) not adversely affected by ageing.
- 

↓ 2009/105/EC (adapted)

For steel vessels, the materials ~~must~~ ☒ shall ☒ in addition meet the requirements set out in point 1.1.1 and, for aluminium or aluminium alloy vessels, those set out in point 1.1.2.

They ~~must~~ ☒ shall ☒ be accompanied by an inspection slip as described in point 1.3. of Annex II, drawn up by the ~~producer~~ ☒ manufacturer ☒ of the materials.

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↓ 2009/105/EC

1.1.1. *Steel vessels*

Non-alloy quality steels shall meet the following requirements:

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↓ 2009/105/EC (adapted)

- (a) they ~~must~~  shall  be non-effervescent and supplied after normalisation treatment, or in an equivalent state;
- (b) the content per product of carbon ~~must~~  shall  be less than 0,25 % and that of sulphur and phosphorus ~~must~~  shall  each be less than 0,05 %;
- (c) they ~~must~~  shall  have the following mechanical properties per product:
- (i) the maximum tensile strength  $R_{m,max}$  ~~must~~  shall  be less than  $580 \text{ N/mm}^2$ ;
- (ii) the elongation after ~~rupture~~ ~~must~~  fracture shall  be:
- 

↓ 2009/105/EC

if test pieces are taken parallel to the direction of rolling:

thickness $\geq 3$ mm:	A	$\geq 22$ %,
thickness $< 3$ mm:	$A_{80 \text{ mm}}$	$\geq 17$ %,

if test pieces are taken perpendicular to the direction of rolling:

thickness $\geq 3$ mm:	A	$\geq 20$ %,
thickness $< 3$ mm:	$A_{80 \text{ mm}}$	$\geq 15$ %,

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↓ 2009/105/EC (adapted)

- (iii) the average ~~failure~~  bending rupture  energy  $KCV$  for three longitudinal test pieces at minimum working temperature ~~must~~  shall  not be less than  $35 \text{ J/cm}^2$ . Not more than one of the three figures may be less than  $35 \text{ J/cm}^2$ , with a minimum of  $25 \text{ J/cm}^2$ .

In the case of steels used in the manufacture of vessels the minimum working temperature of which is lower than  $-10 \text{ }^\circ\text{C}$  and the wall thickness of which exceeds 5 mm, this property ~~must~~  shall  be checked.

### 1.1.2. Aluminium vessels

Non-alloy aluminium ~~must~~ ☒ shall ☒ have an aluminium content of at least 99,5 % and the alloys referred to in Article ~~1(3)(a)~~ 1(1)(b) ~~must~~ ☒ shall ☒ display adequate resistance to intercrystalline corrosion at maximum working temperature.

Moreover, these materials ~~must~~ ☒ shall ☒ satisfy the following requirements:

- (a) they ~~must~~ ☒ shall ☒ be supplied in an annealed state; ~~and~~
- (b) they ~~must~~ ☒ shall ☒ have the following mechanical characteristics per product:
  - the maximum tensile strength  $R_{m,max}$  ~~must~~ ☒ shall ☒ be no more than  $350 \text{ N/mm}^2$ ;
  - the elongation after ~~rupture~~ ~~must~~ ☒ fracture shall ☒ be:

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↓ 2009/105/EC

- $A \geq 16 \%$  if the test piece is taken parallel to the direction of rolling;
- $A \geq 14 \%$  if the test piece is taken perpendicular to the direction of rolling.

### 1.2. Welding materials

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↓ 2009/105/EC (adapted)

The welding materials used to manufacture the welds on or of the ~~simple pressure~~ vessel ~~must~~ ☒ shall ☒ be appropriate to and compatible with the materials to be welded.

### 1.3. Accessories contributing to the strength of the vessel

These accessories (for example bolts and nuts) ~~must~~ ☒ shall ☒ be made of a material specified in point 1.1 or of other kinds of steel, aluminium or an appropriate aluminium alloy compatible with materials used for the manufacture of pressurised parts.

The latter materials ~~must~~ ☒ shall ☒ at minimum working temperature have an appropriate elongation after ~~rupture~~ ☒ fracture ☒ and ~~toughness~~ ☒ bending rupture energy ☒.

### 1.4. Non-pressurised parts

All unpressurised parts of welded vessels ~~must~~ ☒ shall ☒ be of materials which are compatible with that of the components to which they are welded.

## 2. VESSEL DESIGN

- (a) The manufacturer ~~must~~ ☒ shall ☒, when designing the vessel, define the use to which it will be put, and select:

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↓ 2009/105/EC

~~(a)~~(i) the minimum working temperature  $T_{\min}$ ;

~~(b)~~(ii) the maximum working temperature  $T_{\max}$ ;

~~(c)~~(iii) the maximum working pressure PS.

---

↓ 2009/105/EC (adapted)

However, should a minimum working temperature exceeding  $-10\text{ }^{\circ}\text{C}$  be selected, the qualities required of the materials ~~must~~  shall  be satisfied at  $-10\text{ }^{\circ}\text{C}$ .

(b) The manufacturer ~~must~~  shall  also take account of the following provisions:

(i) it ~~must~~  shall  be possible to inspect the inside of vessels;

(ii) it ~~must~~  shall  be possible to drain the vessels;

(iii) the mechanical qualities ~~must~~  shall  be maintained throughout the period of use of the vessel for the intended purpose;

(iv) the vessels ~~must~~  shall , bearing in mind their prescribed use, be adequately protected against corrosion;

~~and~~  (c) The manufacturer shall take account of  the fact that under the conditions of use envisaged:

(i) the vessels ~~must~~  shall  not be subjected to stresses likely to impair their safety in use;

(ii) internal pressure ~~must~~  shall  not permanently exceed the maximum working pressure PS. However, it may momentarily do so by up to 10 %.

~~Circular~~  (d) Circumferential  and longitudinal seams ~~must~~  shall  be made using full penetration welds or welds of equivalent effectiveness. Convex ends other than hemispherical ones ~~must~~  shall  have a cylindrical edge.

### 2.1. Wall thickness

If the product of  $PS \times V$  is not more than 3000 bar.L, the manufacturer ~~must~~  shall  select one of the methods described in points 2.1.1 and 2.1.2 for determining vessel wall thickness; if the product of  $PS \times V$  is more than 3000 bar.L, or if the maximum working temperature exceeds  $100\text{ }^{\circ}\text{C}$ , such thickness ~~must~~  shall  be determined by the method described in point 2.1.1.

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↓ 2009/105/EC

The actual wall thickness of the cylindrical section and ends shall, however, be not less than 2 mm in the case of steel vessels and not less than 3 mm in the case of aluminium or aluminium alloy vessels.

#### 2.1.1. Calculation method

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↓ 2009/105/EC (adapted)  
⇒ new

The minimum thickness of pressurised parts ~~must~~ ☒ shall ☒ be calculated having regard to the intensity of the stresses and to the following provisions:

- (a) the calculation pressure to be taken into account ~~must~~ ☒ shall ☒ not be less than the maximum working pressure PS selected;
- (b) the permissible general membrane stress ~~must~~ ☒ shall ☒ not exceed the lower of the values  $0,6 R_{eT}$  or  $0,3 R_m$ . The manufacturer ~~must~~ ☒ shall ☒ use the  $R_{eT}$  and  $R_m$  minimum values guaranteed by the material manufacturer in order to determine the permissible stress.

However, where the cylindrical portion of the vessel has one or more longitudinal welds made using a non-automatic welding process, the thickness calculated as referred to in the first paragraph ~~must~~ ☒ shall ☒ be multiplied by the coefficient 1,15.

#### 2.1.2. Experimental method

Wall thickness ~~must~~ ☒ shall ☒ be so determined as to enable the vessels to resist at ambient temperature a pressure equal to at least five times the maximum working pressure, with a permanent circumferential deformation factor of no more than 1 %.

### 3. MANUFACTURING PROCESSES

Vessels shall be constructed and subjected to production checks in accordance with ~~the design and manufacturing record referred to in~~ points ⇒ 2, ⇐ 3 ⇒ or 4 ⇐ of Annex II.

#### 3.1. Preparation of the component parts

Preparation of the component parts (for example forming and chamfering) ~~must~~ ☒ shall ☒ not give rise to surface defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the vessels.

#### 3.2. Welds on pressurised parts

The characteristics of welds and adjacent zones ~~must~~ ☒ shall ☒ be similar to those of the welded materials and ~~must~~ ☒ shall ☒ be free of any surface or internal defects detrimental to the safety of the vessels.

Welds ~~must~~ ☒ shall ☒ be performed by qualified welders or operators possessing the appropriate level of competence, in accordance with approved welding processes. Such approval and qualification tests ~~must~~ ☒ shall ☒ be carried out by ~~approved inspection~~ ☒ notified ☒ bodies.

The manufacturer ~~must~~ ☒ shall ☒ also, during manufacture, ensure consistent weld quality by conducting appropriate tests using adequate procedures. These tests ~~must~~ ☒ shall ☒ be the subject of a report.

#### **4. PUTTING INTO SERVICE OF THE VESSELS**

Vessels ~~must~~ ☒ shall ☒ be accompanied by the instructions drawn up by the manufacturer, as referred to in point 2 of Annex III.

## ANNEX II

### ☒ CONFORMITY ASSESSMENT PROCEDURES ☒

#### ☒ 1. EU-TYPE EXAMINATION MODULE B ☒

☒ 1.1. EU-type examination is the part of a conformity assessment procedure in which notified body examines the technical design of a vessel and verifies and attests that the technical design of the vessel meets the requirements of this Directive that apply to it. ☒

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↓ new

1.2. EU-type examination may be carried out in either of the following manners:

- examination of a prototype vessel, representative of the production envisaged, of the complete vessel (production type);
  - assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a prototype vessel (design type).
- 

↓ 2009/105/EC (adapted)

☒ 1.3. The application for EU-type examination shall be lodged by the manufacturer or by his authorised representative with a single notified body in respect of a prototype vessel or of a prototype representing a family of vessels. ☒

☒ The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice. ☒

☒ The application shall include: ☒

☒ (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well; ☒

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↓ new

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the vessel's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the vessel. The technical documentation shall contain, wherever applicable, at least the following elements:

- (i) a general description of the vessel;
- (ii) conceptual design and manufacturing drawings of the type and schemes of components, etc.;
- (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
- (iv) a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (v) results of design calculations made, examinations carried out, etc.;
- (vi) test reports;
- (vii) the prototype vessels representative of the production envisaged. The notified body may request further prototype vessels if needed for carrying out the test programme;
- (viii) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

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↓ 2009/105/EC (adapted)

- ⊗ (ix) the instructions; ⊗
- ⊗ (x) a document describing: ⊗
  - ⊗ the materials selected; ⊗
  - ⊗ the welding processes selected; ⊗
  - ⊗ the checks selected; ⊗
  - ⊗ any pertinent details as to the vessel design. ⊗

⊗ When a prototype vessel is examined, the technical documentation shall also include: ⊗

- ☒ the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators; ☒
  - ☒ the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel; ☒
  - ☒ a report on the examinations and tests performed or a description of the proposed checks. ☒
- 

↓ new

1.4. The notified body shall:

For the vessel:

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the vessel.

For the prototype vessel(s):

1.4.2. verify that the prototype vessels have been manufactured in conformity with the technical documentation that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed without applying the relevant provisions of those standards;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive;

1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of the report, in full or in part, only with the agreement of the manufacturer.

1.6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured vessels with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

1.7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the vessel with the essential safety requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

1.8. Each notified body shall immediately inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the vessel has been placed on the market.

1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

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↓ 2009/105/EC (adapted)

☒ 2. CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING (MODULE C1) ☒

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↓ new

2.1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2, 2.3 and 2.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring to ensure conformity of the manufactured vessels with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

2.3. Product checks

2.3.1. For each individual vessel manufactured one or more tests on one or more specific aspects of the vessel shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the type described in the EU-type examination certificate and with the corresponding requirements of this Directive. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

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↓ 2009/105/EC (adapted)

☒ 2.3.2. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the vessels with the requirements of this Directive by examination and testing of vessels in accordance with the following paragraphs: ☒

- ☒ (a) The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced. ☒
- ☒ (b) Those batches shall be accompanied by the EU-type examination certificate. ☒
- ☒ (c) When a batch is examined, the notified body shall ensure that the vessels have been manufactured and checked in accordance with the technical documentation, and shall perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in

the batch at a pressure  $P_h$  equal to 1,5 times the vessel's design pressure in order to check its strength. The pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed. ☒

- ☒ (d) Moreover, the notified body shall carry out tests on test-pieces taken from a representative production test-piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality. The tests shall be carried out on longitudinal welds. However, where differing weld techniques are used for longitudinal and circumferential welds, the tests shall be repeated on the circumferential welds. ☒
- ☒ (e) For the vessels referred to in point 2.1.2 of Annex I, these tests on test-pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in point 2.1.2 of Annex I. ☒
- ☒ (f) In the case of accepted batches, the notified body shall affix its identification number, or cause that number to be affixed, to each vessel and shall draw up a written certificate of conformity relating to the tests carried out. All vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test. ☒
- ☒ (g) If a batch is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches, the notified body may suspend the statistical verification. ☒
- ☒ (h) The manufacturer shall be able to supply on request the notified body's certificates of conformity referred to in the seventh subparagraph (f). ☒

#### ☒ 2.4. CE marking and declaration of conformity ☒

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↓ new

2.4.1. The manufacturer shall affix the CE marking set out in this Directive to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

2.4.2. The manufacturer shall draw up a written declaration of conformity for a vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The declaration of conformity shall identify the vessel model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

#### 2.5. Authorised representative

The manufacturer's obligations set out in point 2.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### 3. CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED VESSEL CHECKS AT RANDOM INTERVALS (MODULE C2)

3.1. Conformity to type based on internal production control plus supervised vessel checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.3 and 3.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

#### 3.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive.

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↓ 2009/105/EC (adapted)

⊗ 3.2.1. Before commencing manufacture, the manufacturer shall send the notified body a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels to the EU-type examination certificate. ⊗

⊗ 3.2.2. The document shall include: ⊗

⊗ (a) a description of the means of manufacture and checking appropriate to the construction of the vessels; ⊗

⊗ (b) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed; ⊗

⊗ (c) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; ⊗

⊗ those examinations and tests shall be carried out under the responsibility of qualified staff who are sufficiently independent from production personnel, and shall be the subject of a report; ⊗

⊗ (d) the addresses of the places of manufacture and storage and the date on which manufacture is to commence. ⊗

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↓ new

#### 3.3. Vessel checks

A notified body, chosen by the manufacturer, shall carry out vessel checks or have them carried out at appropriate intervals determined by the body, in order to verify the quality of

the internal checks on the vessel, taking into account, *inter alia*, the technological complexity of the vessels and the quantity of production. An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards or equivalent tests, shall be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.

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↓ 2009/105/EC (adapted)

☒ The notified body shall also ensure that the manufacturer actually checks series-produced vessels in accordance with point 3.2 c); ☒

☒ The manufacturer shall provide the notified body with all necessary information, and in particular: ☒

☒ (a) the technical documentation; ☒

☒ (b) the inspection report; ☒

☒ (c) the EU-type examination certificate; ☒

☒ (d) a report on the examinations and tests carried out. ☒

☒ The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report. ☒

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↓ new

Where a sample does not comply with the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the vessel performs within acceptable limits, with a view to ensuring conformity of the vessel.

Where the tests are carried out by notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

### 3.4. CE marking and declaration of conformity

3.4.1. The manufacturer shall affix the CE marking set out in this Directive to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.4.2. The manufacturer shall draw up a written declaration of conformity for a vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been

placed on the market. The declaration of conformity shall identify the vessel model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the declaration shall be supplied with each vessel that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual vessels in those cases where a large number of vessels is delivered to a single user.

### 3.5. Authorised representative

The manufacturer's obligations set out in point 3.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## 4. CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (MODULE C)

4.1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.3, and ensures and declares that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

### 4.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall send the notified body which issued the EU-type examination certificate a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels to the EU-type examination certificate.

↓ 2009/105/EC (adapted)

⊗ The document shall include: ⊗

⊗ (a) a description of the means of manufacture and checking appropriate to the construction of the vessels; ⊗

⊗ (b) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed; ⊗

☒ (c) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; ☒

☒ those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report; ☒

☒ (d) the addresses of the places of manufacture and storage and the date on which manufacture is to commence. ☒

☒ The notified body which issued the EU-type examination certificate shall, before the date on which any manufacture begins, examine the document referred to in point 4.2 in order to certify its conformity with the EU-type examination certificate. ☒

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↓ new

#### 4.3. CE marking and declaration of conformity

4.3.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.3.2. The manufacturer shall draw up a written declaration of conformity for a vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The declaration of conformity shall identify the vessel model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the declaration shall be supplied with each vessel that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual vessels in those cases where a large number of vessels is delivered to a single user.

#### 4.4. Authorised representative

The manufacturer's obligations set out in point 4.3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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↓ 2009/105/EC (adapted)

### ANNEX III

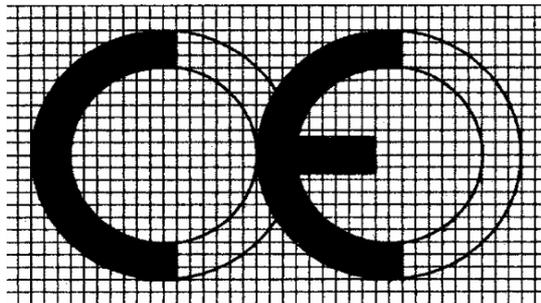
# ~~'CE' MARKING, INSCRIPTIONS, INSTRUCTIONS, DESIGN AND MANUFACTURE SCHEDULES, DEFINITIONS AND SYMBOLS~~

## 1. ~~'CE'~~ ☒ CE ☒ MARKING AND INSCRIPTIONS

↓ 2009/105/EC

### ~~1.1. 'CE' marking~~

~~The 'CE' marking shall consist of the initials 'CE' in the following form:~~



~~If the 'CE' marking is reduced or enlarged the proportions given in the graduated drawing set out in this point must be respected.~~

~~The various components of the 'CE' marking must have substantially the same vertical dimension, which may not be less than 5 mm.~~

↓ new

Vessels of which the product of PS x V exceeds 50 bar.L must bear the CE marking referred to in Articles 15 and 16.

↓ 2009/105/EC (adapted)

### ~~1.2. Inscriptions~~

☒ In addition to the CE marking and to the labelling requirements referred to in Article 6, paragraphs 5 and 6, ☒ ~~the~~ vessel or ☒ its ☒ data plate ~~must~~ ☒ shall ☒ bear at least the following information:

↓ 2009/105/EC

- (a) the maximum working pressure (PS in bar);
- (b) the maximum working temperature ( $T_{\max}$  in °C);

- (c) the minimum working temperature ( $T_{\min}$  in °C);
- (d) the capacity of the vessel (V in HL);

~~(e) the name or mark of the manufacturer;~~

~~(f) the type and serial or batch identification of the vessel;~~

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↓ 2009/105/EC (adapted)

~~(g)~~ the last two digits of the year in which the ~~‘CE’~~  CE  marking was affixed.

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↓ 2009/105/EC (adapted)

Where the data plate is used, it ~~must~~  shall  be so designed that it cannot be reused and ~~must~~  shall  include a vacant space to enable other information to be provided.

## 2. INSTRUCTIONS AND SAFETY INFORMATION

The instructions ~~must~~  shall  contain the following information:

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↓ 2009/105/EC

- (a) the particulars given in point 1 except for the vessel’s serial identification;
- (b) the intended use of the vessel;
- (c) the maintenance and installation requirements for vessel safety.

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↓ 2009/105/EC (adapted)

They must be in the official language or languages of the ~~country~~  Member State  of destination.

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↓ 2009/105/EC

## ~~3. DESIGN AND MANUFACTURING SCHEDULES~~

~~The design and manufacturing schedules must contain a description of the techniques and operations employed in order to meet the essential safety requirements set out in Annex I or the harmonised standards referred to in Article 5(1), and in particular:~~

- ~~(a) a detailed manufacturing drawing of the vessel type;~~

- ~~(b) the instructions;~~
- ~~(c) a document describing:~~
  - ~~the materials selected;~~
  - ~~the welding processes selected;~~
  - ~~the checks selected;~~
  - ~~any pertinent details as to the vessel design.~~

~~When the procedures laid down in Articles 11 to 14 are applied, the schedule must also include:~~

- ~~(a) the certificates relating to the suitable qualification of the welding operations and of the welders or operators;~~
- ~~(b) the inspection slip for the materials used in the manufacture of parts and assemblies contributing to the strength of the pressure vessel;~~
- ~~(c) a report on the examinations and tests performed or a description of the proposed checks.~~

### **43. DEFINITIONS AND SYMBOLS**

#### **43.1. Definitions**

- (a) The design pressure 'P' is the gauge pressure chosen by the manufacturer and used to determine the thickness of the vessel's pressurised parts.
- (b) The maximum working pressure 'PS' is the maximum gauge pressure which may be exerted under normal conditions of use of the vessel.
- (c) The minimum working temperature  $T_{\min}$  is the lowest stabilised temperature which the wall of the vessel may attain under normal conditions of use.
- (d) The maximum working temperature  $T_{\max}$  is the highest stabilised temperature which the wall of the vessel may attain under normal conditions of use.

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↓ 2009/105/EC (adapted)

- (e) The yield strength ' $R_{eT}$ ' is the value at the maximum working temperature  $T_{\max}$  of  any of the following  :

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↓ 2009/105/EC

- (i) the upper yield point  $R_{eH}$ , for a material with both a lower and an upper yield point:

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↓ 2009/105/EC (adapted)

- (ii) the  0,2%  proof ~~stress~~  strength   $R_{p0,2}$  ~~or~~
- (iii) the  1,0%  proof ~~stress~~  strength   $R_{p1,0}$  in the case of non-alloy aluminium.

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↓ 2009/105/EC

(f) Families of vessels:

Vessels form part of the same family if they differ from the prototype only in diameter, provided that the permissible requirements referred to in points 2.1.1 and 2.1.2 of Annex I are complied with, and/or in the length of their cylindrical portion within the following limits:

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↓ 2009/105/EC (adapted)

- (i) where a prototype has one or more shell rings in addition to the ends, variants ~~must~~  shall  have at least one shell ring;
- (ii) where a prototype has just two dished ends, variants ~~must~~  shall  have no shell rings.

Variations in length causing the apertures and/or penetrations to be modified ~~must~~  shall  be shown in the drawing for each variant.

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↓ 2009/105/EC

- (g) A batch of vessels consists at the most of 3000 vessels of the model of the same type.
- (h) There is series manufacture within the meaning of this Directive if more than one vessel of the same type is manufactured during a given period by a continuous manufacturing process, in accordance with a common design and using the same manufacturing processes.
- (i) Inspection slip: document by which the producer certifies that the products delivered meet the requirements of the order and in which he sets out the results of the routine in-plant inspection test, in particular chemical composition and mechanical characteristics performed on products made by the same production process as the supply, but not necessarily on the products delivered.

## 43.2.Symbols

↓ 2009/105/EC (adapted)		
A	elongation after <del>rupture</del> ⊗ fracture ⊗ ( $L_0 = 5,65\sqrt{S_0}$ )	%
$A_{80\text{ mm}}$	elongation after <del>rupture</del> ⊗ fracture ⊗ ( $L_0 = 80\text{ mm}$ )	%
KCV	⊗ bending ⊗ rupture energy	J/cm <sup>2</sup>
P	design pressure	Bar
PS	maximum working pressure	Bar
$P_h$	hydrostatic or pneumatic test pressure	Bar
$R_{p0,2}$	⊗ 0,2% ⊗ proof stress ⊗ strength ⊗ <del>at 0,2%</del>	N/mm <sup>2</sup>
$R_{eT}$	yield strength at maximum working temperature	N/mm <sup>2</sup>
$R_{eH}$	upper yield point	N/mm <sup>2</sup>
$R_m$	tensile strength	N/mm <sup>2</sup>
$R_{m, \text{max}}$	maximum tensile strength	N/mm <sup>2</sup>
$R_{p1,0}$	⊗ 1,0% ⊗ proof stress ⊗ strength ⊗ <del>at 1,0%</del>	N/mm <sup>2</sup>
$T_{\text{max}}$	maximum working temperature	°C
$T_{\text{min}}$	minimum working temperature	°C
V	capacity of the vessel	$\frac{L}{L}$

↓ 2009/105/EC

### ANNEX III

#### ~~MINIMUM CRITERIA TO BE MET BY MEMBER STATES FOR THE APPROVAL OF INSPECTION BODIES~~

~~(referred to in Article 9(2))~~

~~1. The approved inspection body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of vessels which they inspect, nor the authorised representative of any of those parties. They shall not become~~

~~directly involved in the design, construction, marketing or maintenance of the vessels, nor represent the parties engaged in those activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the approved inspection body.~~

~~2. The approved inspection body and its staff must carry out the verification tests with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.~~

~~3. The approved inspection body must have at its disposal the necessary staff and the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it must also have access to the equipment required for special verification.~~

~~4. The staff responsible for inspection must have:~~

~~(a) sound technical and professional training;~~

~~(b) satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests;~~

~~(c) the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.~~

~~5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.~~

~~6. The approved inspection body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.~~

~~7. The staff of the approved inspection body is bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.~~

↓ 2009/105/EC (adapted)

## ANNEX IV

### PART A

<del>Repealed Directive with list of its successive amendments</del>	
<del>(referred to in Article 19)</del>	
<del>Council Directive 87/404/EEC</del>	

<del>(OJ L 220, 8.8.1987, p. 48)</del>	
<del>Council Directive 90/488/EEC</del>	
<del>(OJ L 270, 2.10.1990, p. 25)</del>	
<del>Council Directive 93/68/EEC</del>	<del>Article 1, point 1, and Article 2 only</del>
<del>(OJ L 220, 30.8.1993, p. 1)</del>	

**PART B**

<del>List of time limits for transposition into national law and application</del>		
<del>(referred to in Article 19)</del>		
<del>Directive</del>	<del>Time limit for transposition</del>	<del>Date of application</del>
<del>87/404/EEC</del>	<del>31 December 1989</del>	<del>1 July 1990<sup>15</sup></del>
<del>90/488/EEC</del>	<del>1 July 1991</del>	<del>—</del>
<del>93/68/EEC</del>	<del>30 June 1994</del>	<del>1 January 1995<sup>16</sup></del>

↓ 2009/105/EC (adapted)

**ANNEX IV**

<i>CORRELATION TABLE</i>	
Directive <del>87/404/EEC</del> ☒ 2009/105/EC ☒	This Directive
<del>Recital 5, fifth sentence</del>	<del>Article 1(3), point (b)</del>
<del>Article 1(1)</del>	<del>Article 1(1)</del>
<del>Article 1(2), first subparagraph</del>	<del>Article 1(3), point (a), first subparagraph</del>
<del>Article 1(2), second subparagraph, first indent</del>	<del>Article 1(3), point (a), second</del>

<sup>15</sup> ~~In accordance with the third subparagraph of Article 18(2), Member States shall, for the period up to 1 July 1992, permit the placing on the market and/or in service of vessels conforming to the rules in force in their territories before 1 July 1990.~~

<sup>16</sup> ~~In accordance with Article 14(2), until 1 January 1997 Member States shall allow the placing on the market and the bringing into service of products which comply with the marking arrangements in force before 1 January 1995.~~

	subparagraph
<del>Article 1(2), second subparagraph, second indent, first and second sub-indents</del>	<del>Article 1(3), point (a), third subparagraph, points (i) and (ii)</del>
<del>Article 1(2), second subparagraph, third indent</del>	<del>Article 1(3), point (a), fourth subparagraph</del>
<del>Article 1(2), second subparagraph, fourth indent</del>	<del>Article 1(3), point (a), fifth subparagraph</del>
<del>Article 1(3), first, second and third indents</del>	<del>Article 1(2), points (a), (b) and (c)</del>
<del>Articles 2, 3 and 4</del>	<del>Articles 2, 3 and 4</del>
<del>Article 5(1)</del>	<del>Article 5(1)</del>
<del>Article 5(2)</del>	<del>Article 5(2)</del>
<del>Article 5(3), points (a) and (b)</del>	<del>Article 5(3), first and second subparagraphs</del>
<del>Article 6</del>	<del>Article 6</del>
<del>Article 7(1)</del>	<del>Article 7(1)</del>
<del>Article 7(2), first and second sentences</del>	<del>Article 7(2), first subparagraph</del>
<del>Article 7(2), third sentence</del>	<del>Article 7(2), second subparagraph</del>
<del>Article 7(3)</del>	<del>Article 7(3)</del>
<del>Article 7(4)</del>	<del>Article 7(4)</del>
<del>Article 8(1), introductory wording and point (a), introductory wording</del>	<del>Article 8(1), introductory wording</del>
<del>Article 8(1), point (a), first and second indents</del>	<del>Article 8(1), points (a) and (b)</del>
<del>Article 8(1), point (b)</del>	<del>Article 8(2)</del>
<del>Article 8(2), point (a)</del>	<del>Article 8(3), point (a)</del>
<del>Article 8(2), point (b), first and second indents</del>	<del>Article 8(3), points (b)(i) and (ii)</del>
<del>Article 8(3)</del>	<del>Article 8(4)</del>
<del>Article 9</del>	<del>Article 9</del>
<del>Article 10(1)</del>	<del>Article 10(1)</del>
<del>Article 10(2), first subparagraph</del>	<del>Article 10(2), first subparagraph</del>

<del>Article 10(2), second subparagraph, first and second indents</del>	<del>Article 10(2), second subparagraph, points (a) and (b)</del>
<del>Article 10(2), third subparagraph</del>	<del>Article 10(2), third subparagraph</del>
<del>Article 10(3), first subparagraph</del>	<del>Article 10(3), first subparagraph</del>
<del>Article 10(3), second subparagraph</del>	<del>Article 10(3), second subparagraph</del>
<del>Article 10(3), third subparagraph, points (a) and (b)</del>	<del>Article 10(3), third subparagraph, points (a) and (b)</del>
<del>Article 10(4)</del>	<del>Article 10(4)</del>
<del>Article 10(5), first sentence</del>	<del>Article 10(5), first subparagraph</del>
<del>Article 10(5), second and third sentences</del>	<del>Article 10(5), second subparagraph</del>
<del>Article 11(1) and (2)</del>	<del>Article 11(1) and (2)</del>
<del>Article 11(3), introductory wording</del>	<del>Article 11(3), first subparagraph</del>
<del>Article 11(3), point 3.1</del>	<del>Article 11(3), second subparagraph</del>
<del>Article 11(3), point 3.2</del>	<del>Article 11(3), third subparagraph</del>
<del>Article 11(3), point 3.3, first subparagraph</del>	<del>Article 11(3), fourth subparagraph</del>
<del>Article 11(3), point 3.3, second subparagraph</del>	<del>Article 11(3), fifth subparagraph</del>
<del>Article 11(3), point 3.3, third subparagraph</del>	<del>Article 11(3), sixth subparagraph</del>
<del>Article 11(3), point 3.4, first subparagraph</del>	<del>Article 11(3), seventh subparagraph</del>
<del>Article 11(3), point 3.4, second subparagraph</del>	<del>Article 11(3), eighth subparagraph</del>
<del>Article 11(3), point 3.4, third subparagraph</del>	<del>Article 11(3), ninth subparagraph</del>
<del>Article 11(3), point 3.5</del>	<del>Article 11(3), tenth subparagraph</del>
<del>Article 12(1), first subparagraph, first and second indents</del>	<del>Article 12(1), points (a) and (b)</del>
<del>Article 12(1), second subparagraph</del>	<del>Article 12(2), first subparagraph</del>
<del>Article 12(2)</del>	<del>Article 12(2), second subparagraph</del>
<del>Article 13(1), first subparagraph</del>	<del>Article 13(1)</del>
<del>Article 13(1), second subparagraph</del>	<del>Article 13(2)</del>
<del>Article 13(2), indents 1 to 4</del>	<del>Article 13(3), points (a) to (d)</del>

<del>Article 14(1)</del>	<del>Article 14, first paragraph</del>
<del>Article 14(2), first subparagraph, first and second indents</del>	<del>Article 14, second paragraph, points (a) and (b)</del>
<del>Article 14(2), second subparagraph</del>	<del>Article 14, third paragraph</del>
<del>Articles 15, 16 and 17</del>	<del>Articles 15, 16 and 17</del>
<del>Article 18(1)</del>	<del>—</del>
<del>Article 18(2)</del>	<del>Article 18</del>
<del>—</del>	<del>Article 19</del>
<del>—</del>	<del>Article 20</del>
<del>Article 19</del>	<del>Article 21</del>
<del>Annex I, point 1</del>	<del>Annex I, point 1.</del>
<del>Annex I, point 1.1, first paragraph, first, second and third indents</del>	<del>Annex I, point 1.1, first paragraph, points (a), (b) and (c)</del>
<del>Annex I, point 1.1, second and third paragraphs</del>	<del>Annex I, point 1.1, second and third paragraphs</del>
<del>Annex I, points 1.1.1 and 1.1.2</del>	<del>Annex I, points 1.1.1 and 1.1.2</del>
<del>Annex I, points 1.2, 1.3 and 1.4</del>	<del>Annex I, points 1.2, 1.3 and 1.4</del>
<del>Annex I, point 2, first paragraph, first, second and third indents</del>	<del>Annex I, point 2, first paragraph, points (a), (b) and (c)</del>
<del>Annex I, point 2, second, third and fourth paragraphs</del>	<del>Annex I, point 2, second, third and fourth paragraphs</del>
<del>Annex I, points 2.1, 3 and 4</del>	<del>Annex I, points 2.1, 3 and 4</del>
<del>Annex II, point 1</del>	<del>Annex II, point 1</del>
<del>Annex II, point 1.a, first, second and third indents</del>	<del>Annex II, point 1.1, first, second and third paragraphs</del>
<del>Annex II, point 1.b, first paragraph, indents 1 to 7</del>	<del>Annex II, point 1.2, first paragraph, points (a) to (g)</del>
<del>Annex II, point 1.b, second paragraph</del>	<del>Annex II, point 1.2, second paragraph</del>
<del>Annex II, point 2, first paragraph, first, second and third indents</del>	<del>Annex II, point 2, first paragraph, points (a), (b) and (c)</del>

<del>Annex II, point 2, second paragraph</del>	<del>Annex II, point 2, second paragraph</del>
<del>Annex II, point 3, first paragraph</del>	<del>Annex II, point 3, first paragraph</del>
<del>Annex II, point 3, second paragraph, points (i), (ii) and (iii)</del>	<del>Annex II, point 3, second paragraph, points (a), (b) and (c)</del>
<del>Annex II, point 4</del>	<del>Annex II, point 4</del>
<del>Annex III, points 1, 2 and 3</del>	<del>Annex III, points 1, 2 and 3</del>
<del>Annex III, point 4, first, second and third indents</del>	<del>Annex III, point 4, points (a), (b) and (c)</del>
<del>Annex III, points 5, 6 and 7</del>	<del>Annex III, points 5, 6 and 7</del>
<del>—</del>	<del>Annex IV</del>
<del>—</del>	<del>Annex V</del>
☒ Article 1(1) ☒	☒ Article 1(1), introductory wording ☒
☒ Article 1(2) ☒	☒ Article 1(2) ☒
☒ Article 1(3) (a) ☒	☒ Article 1(1), points (a) to (e) ☒
☒ Article 1(3) (b) ☒	☒ — ☒
☒ Article 2 ☒	☒ Article 3 ☒
☒ ___ ☒	☒ Article 2 ☒
☒ Article 3 ☒	☒ Article 4 ☒
☒ Article 4 ☒	☒ Article 5 ☒
☒ ___ ☒	☒ Article 6 ☒
☒ — ☒	☒ Article 7 ☒
☒ — ☒	☒ Article 8 ☒
☒ — ☒	☒ Article 9 ☒
☒ — ☒	☒ Article 10 ☒
☒ — ☒	☒ Article 11 ☒
☒ — ☒	☒ Article 12 ☒
☒ Article 5 ☒	☒ — ☒

☒ Article 6 ☒	☒ — ☒
☒ Article 7 ☒	☒ — ☒
☒ Article 8 ☒	☒ __ ☒
☒ — ☒	☒ Article 13 ☒
☒ Article 9 ☒	☒ — ☒
☒ Article 10 ☒	☒ — ☒
☒ Article 11 (1) and (2) ☒	☒ — ☒
☒ Article 11 (3) ☒	☒ Point 2.3.2. of Annex II ☒
☒ Article 12 ☒	☒ — ☒
☒ Article 13 (1) ☒	☒ Point 3.2.1. of Annex II ☒
☒ Article 13 (2) ☒	☒ Point 3.2.2. of Annex II ☒
☒ Article 13 (3) ☒	☒ — ☒
☒ Article 14, first paragraph ☒	☒ — ☒
☒ Article 14, second paragraph, introductory wording ☒	☒ — ☒
☒ Article 14, second paragraph (a) ☒	☒ Second paragraph of point 3.3. of Annex II ☒
☒ Article 14, second paragraph (b) ☒	☒ — ☒
☒ Article 14, third paragraph ☒	☒ — ☒
☒ — ☒	☒ Article 14 ☒
☒ — ☒	☒ Article 15 ☒
☒ — ☒	☒ Article 16 ☒
☒ — ☒	☒ Article 17 ☒
☒ — ☒	☒ Article 18 ☒
☒ — ☒	☒ Article 19 ☒
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☒ — ☒	☒ Article 21 ☒

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☒ — ☒	☒ Article 23 ☒
☒ — ☒	☒ Article 24 ☒
☒ — ☒	☒ Article 25 ☒
☒ — ☒	☒ Article 26 ☒
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☒ — ☒	☒ Article 31 ☒
☒ — ☒	☒ Article 32 ☒
☒ — ☒	☒ Article 33 ☒
☒ Article 15 ☒	☒ — ☒
☒ Article 16 ☒	☒ — ☒
☒ Article 17 ☒	☒ — ☒
☒ — ☒	☒ Article 34 ☒
☒ — ☒	☒ Article 35 ☒
☒ — ☒	☒ Article 36 ☒
☒ — ☒	☒ Article 37 ☒
☒ — ☒	☒ Article 38 ☒
☒ — ☒	☒ Article 39 ☒
☒ — ☒	☒ Article 40 ☒
☒ Article 18 ☒	☒ Article 41(2) ☒
☒ — ☒	☒ Article 41(1) ☒
☒ Article 19 ☒	☒ Article 42 ☒
☒ Article 20 ☒	☒ Article 43 ☒

☒ Article 21 ☒	☒ Article 44 ☒
☒ Annex I ☒	☒ Annex I ☒
☒ — ☒	☒ Annex II ☒
☒ Annex II ☒	☒ Annex III ☒
☒ Annex III ☒	☒ — ☒
☒ Annex IV ☒	☒ — ☒
☒ Annex V ☒	☒ Annex IV ☒