

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast) (Text with EEA relevance)

DIRECTIVE 2014/68/EU OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

of 15 May 2014

on the harmonisation of the laws of the Member States relating
to the making available on the market of pressure equipment

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 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⁽¹⁾,

Acting in accordance with the ordinary legislative procedure⁽²⁾,

Whereas:

- (1) Directive 97/23/EC of the European Parliament and of the Council⁽³⁾ has been substantially amended⁽⁴⁾. Since further amendments are to be made, that Directive should be recast in the interests of clarity.
- (2) Regulation (EC) No 765/2008 of the European Parliament and of the Council⁽⁵⁾ 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⁽⁶⁾ lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 97/23/EC should therefore be adapted to that Decision.
- (4) This Directive covers pressure equipment and assemblies which are new to the Union market when they are placed on the market; that is to say they are either new pressure equipment or assemblies made by a manufacturer established in the Union or pressure equipment or assemblies, whether new or second-hand, imported from a third country.
- (5) This Directive should apply to all forms of supply, including distance selling.

- (6) This Directive should apply to pressure equipment subject to a maximum allowable pressure PS greater than 0,5 bar. Pressure equipment subject to a pressure of not more than 0,5 bar does not pose a significant risk due to pressure. Therefore, there should not be any obstacle to its free movement within the Union.
- (7) This Directive should also apply to assemblies composed of several pieces of pressure equipment assembled to constitute an integrated and functional whole. Those assemblies may range from simple assemblies such as pressure cookers to complex assemblies such as water tube boilers. If the manufacturer of an assembly intends to place it on the market and put it into service as an assembly — and not in the form of its constituent non-assembled elements — that assembly should comply with this Directive. However, this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations.
- (8) This Directive should harmonise national provisions on risks due to pressure. The other risks which this equipment may present may fall within the scope of other Directives dealing with those risks.
- (9) However, some pressure equipment is covered by other Directives based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). The provisions laid down in some of those Directives deal also with the risk due to pressure. Those Directives are considered adequate to provide appropriate protection where the risk due to pressure associated with such equipment remains small. Therefore, such equipment should be excluded from the scope of this Directive.
- (10) For some pressure equipment covered by international agreements for its international transport, national transport and pressure hazards and risks are dealt with by Union Directives based on such agreements. Those Directives extend the application of those agreements to national transport, in order to ensure the free movement of dangerous goods whilst enhancing transport safety. Such equipment which is covered by Directive 2008/68/EC of the European Parliament and of the Council⁽⁷⁾ and by Directive 2010/35/EU of the European Parliament and of the Council⁽⁸⁾ should be excluded from the scope of this Directive.
- (11) Certain types of pressure equipment, although subject to a maximum allowable pressure PS greater than 0,5 bar, do not present any significant risk due to pressure, and therefore the free movement of such equipment in the Union should not be hindered if it has been legally manufactured or placed on the market in a Member State. It is not necessary in order to ensure free movement of such equipment to include it within the scope of this Directive. Consequently it should be expressly excluded from its scope.
- (12) Other pressure equipment subject to a maximum allowable pressure greater than 0,5 bar and presenting a significant risk due to pressure, but in respect of which free movement and an appropriate level of safety are guaranteed, should be excluded from the scope of this Directive. Such exclusions should, however, be regularly reviewed in order to ascertain whether it is necessary to take action at Union level.

- (13) The scope of this Directive should be based on a general definition of the term ‘pressure equipment’ so as to allow for the technical development of products.
- (14) Compliance with the essential safety requirements is necessary in order to ensure the safety of pressure equipment. Those requirements should be subdivided into general and specific requirements that need to be met by pressure equipment. In particular the specific requirements should take account of particular types of pressure equipment. Certain types of pressure equipment in categories III and IV should be subject to a final assessment comprising final inspection and proof tests.
- (15) Member States should be in a position to allow the showing at trade fairs of pressure equipment which is not yet in conformity with the requirements of this Directive. During demonstrations, appropriate safety measures should be taken in accordance with the general safety rules of the Member State concerned to ensure the safety of persons.
- (16) Directive 97/23/EC provides for a classification of pressure equipment in categories, according to the ascending level of hazard. This includes the classification of the fluid contained in the pressure equipment as dangerous or not, according to Council Directive 67/548/EEC⁽⁹⁾. On 1 June 2015 Directive 67/548/EEC is to be repealed and replaced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁽¹⁰⁾, which implements in the Union the Globally Harmonised System of Classification and Labelling of Chemicals that has been adopted at international level, within the United Nations structure. Regulation (EC) No 1272/2008 introduces new hazard classes and categories only partially corresponding to those provided for by Directive 67/548/EEC. Directive 97/23/EC should therefore be aligned to Regulation (EC) No 1272/2008 while maintaining the existing levels of protection provided for in that Directive.
- (17) Economic operators should be responsible for the compliance of pressure equipment and assemblies with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons, and the protection of domestic animals and of property, and to guarantee fair competition on the Union market.
- (18) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market pressure equipment and assemblies 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 economic operator in the supply and distribution chain.
- (19) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (20) In order to facilitate the communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (21) It is necessary to ensure that pressure equipment and assemblies from third countries entering the Union market comply with the requirements of this Directive, and in

particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that pressure equipment or those assemblies. Provision should therefore be made for importers to make sure that the pressure equipment or assembly they place on the market complies with the requirements of this Directive and that they do not place on the market pressure equipment or assemblies which do not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that marking of pressure equipment or assemblies and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

- (22) When placing pressure equipment or assemblies on the market, every importer should indicate on the pressure equipment or assembly his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the pressure equipment or assembly does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the pressure equipment or assembly.
- (23) The distributor makes pressure equipment or assemblies available on the market after they have been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the pressure equipment or assembly does not adversely affect the compliance of the pressure equipment or assembly with the requirements of this Directive.
- (24) Any economic operator that either places pressure equipment or assemblies on the market under his own name or trademark or modifies pressure equipment or assemblies 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.
- (25) 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 pressure equipment or assembly concerned.
- (26) Ensuring traceability of pressure equipment and assemblies 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 pressure equipment or assemblies available on the market.
- (27) When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with pressure equipment or an assembly or to whom they have supplied pressure equipment or an assembly.
- (28) 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 a presumption of conformity for pressure equipment or assemblies which

are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁽¹¹⁾ for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, manufacture and testing of pressure equipment or assemblies.

- (29) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (30) Manufacturing of pressure equipment calls for the utilisation of safe materials. In the absence of harmonised standards the characteristics of the materials intended for repeated use should be established. Those characteristics should be established by European approvals for materials, such approvals being issued by one of the notified bodies specifically designated for that task. The materials conforming to the European approvals should benefit from a presumption of conformity with the essential safety requirements of this Directive.
- (31) In view of the nature of the risks involved in the use of pressure equipment and assemblies and in order to enable economic operators to demonstrate and the competent authorities to ensure that pressure equipment or assemblies made available on the market comply with the essential safety requirements, it is necessary to provide for conformity assessment procedures. Those procedures should be devised in the light of the level of hazard which is inherent in the pressure equipment or assembly. Therefore, for each category of pressure equipment there should be an adequate procedure or a choice between different procedures of equivalent stringency. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. The details added to those procedures are justified by the nature of the verification required for pressure equipment.
- (32) Member States should be in a position to authorise user inspectorates to carry out certain tasks for conformity assessment in the framework of this Directive. For that purpose this Directive should set out criteria for the authorisation of user inspectorates by Member States.
- (33) Under certain procedures for conformity assessment it should be possible for each item to be inspected and tested by a notified body or a user inspectorate as part of the final assessment of the pressure equipment or assembly. In other cases provision should be made to ensure that the final assessment may be monitored by a notified body by means of unexpected visits.
- (34) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of the pressure equipment or assembly with the requirements of this Directive and of other relevant Union harmonisation legislation.

- (35) To ensure effective access to information for market surveillance purposes, in cases where pressure equipment or an assembly is covered by several pieces of Union harmonisation legislation, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (36) A check on compliance with the essential safety requirements is necessary in order to provide effective protection for consumers, other users and third parties.
- (37) Pressure equipment and assemblies should, as a general rule, bear the CE marking. The CE marking, indicating the conformity of pressure equipment or assemblies, 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. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (38) For pressure equipment defined in this Directive which presents only a minor pressure risk and for which certification procedures are therefore not justified, the CE marking should not be affixed.
- (39) Certain 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.
- (40) Experience has shown that the criteria set out in Directive 97/23/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 those bodies throughout the Union. It is, however, essential that all conformity assessment 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.
- (41) 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.
- (42) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of conformity assessment bodies.
- (43) 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.
- (44) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, 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 that 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.

- (45) 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 pressure equipment or assembly 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.
- (46) 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.
- (47) Since conformity assessment 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.
- (48) In the interests of competitiveness, it is crucial that conformity assessment 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 conformity assessment bodies.
- (49) Member States should take all appropriate measures to ensure that pressure equipment and assemblies may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Pressure equipment or assemblies should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (50) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred to the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽¹²⁾.
- (51) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

- (52) The examination procedure should be used for the adoption of implementing acts with respect to European approvals for materials presenting shortcomings and whose references were already published in the *Official Journal of the European Union*, given that such decisions could have consequences on the presumption of conformity with the applicable essential requirements.
- (53) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant pressure equipment or assemblies which present a risk to the health or safety of persons, to domestic animals or to property, imperative grounds of urgency so require.
- (54) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (55) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (56) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant pressure equipment or assemblies are justified or not.
- (57) In order to take into account emerging very serious safety reasons, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to classification of pressure equipment or assemblies. The reclassification should be based on appropriate evidence and justification in each case. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (58) The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (59) Directive 97/23/EC provides for a transitional arrangement enabling pressure equipment and assemblies which comply with the national regulations in force on the date of application of Directive 97/23/EC to be put into service. For reasons of legal certainty, it is necessary to include that transitional arrangement also in this Directive.
- (60) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and the putting into service, without the need to comply with further product requirements, of pressure equipment and assemblies that have already been placed on the market in accordance with Directive 97/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply pressure equipment and assemblies that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

- (61) 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 those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (62) Since the objective of this Directive, namely to ensure that pressure equipment or assemblies on the market fulfil the requirements providing a high level of protection of health and safety of persons and protection of domestic animals or property while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, 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.
- (63) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (64) This Directive should be without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the date of application of the Directive set out in Annex V, Part B,

HAVE ADOPTED THIS DIRECTIVE:

- (1) [OJ C 67, 6.3.2014, p. 101](#).
- (2) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 13 May 2014.
- (3) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment ([OJ L 181, 9.7.1997, p. 1](#)).
- (4) See Annex V, Part A.
- (5) 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 ([OJ L 218, 13.8.2008, p. 30](#)).
- (6) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82](#)).
- (7) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods ([OJ L 260, 30.9.2008, p. 13](#)).
- (8) Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC ([OJ L 165, 30.6.2010, p. 1](#)).
- (9) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([OJ 196, 16.8.1967, p. 1](#)).
- (10) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([OJ L 353, 31.12.2008, p. 1](#)).
- (11) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, 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, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([OJ L 316, 14.11.2012, p. 12](#)).
- (12) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).