Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) (Text with EEA relevance)

DIRECTIVE 2014/34/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 February 2014

on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (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 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres[(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 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[(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 of 9 July 2008 on a common framework for the marketing of products[(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 94/9/EC should be adapted to that Decision.

(4) This Directive covers products which are new to the Union market when they are placed on the market; that is to say they are either new products made by a manufacturer

established in the Union or products, whether new or second-hand, imported from a third country.

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

(6) It is the duty of Member States to protect, on their territory, the health and safety of persons, especially workers, and, where appropriate, domestic animals and property, especially against the hazards resulting from the use of equipment and systems providing protection against potentially explosive atmospheres.

(7) Directive 94/9/EC has made positive steps towards effective protection against explosion hazards for both mining and surface equipment. Those two groups of equipment are used in a large number of commercial and industrial sectors and possess considerable economic significance.

(8) Compliance with the health and safety requirements is essential in order to ensure the safety of equipment and protective systems. Those requirements should be subdivided into general and additional requirements which need to be met by equipment and protective systems. In particular, the additional requirements should take account of existing or potential hazards. Equipment and protective systems should, therefore, meet at least one of those requirements where this is necessary for their proper functioning or is to apply to their intended use. The notion of intended use is of prime importance for the explosion-proofing of equipment and protective systems. It is essential that manufacturers supply full information. Specific, clear marking of equipment and protective systems, stating their use in a potentially explosive atmosphere, should also be necessary.

(9) Compliance with the essential health and safety requirements laid down in this Directive should be imperative in order to ensure the safety of equipment and protective systems. For the implementation of those requirements, both the technology obtained at the time of manufacture and overriding technical and economic requirements should be taken into account.

(10) Economic operators should be responsible for the compliance of products with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety of persons, especially workers, and, where appropriate, protection of domestic animals and property, and to guarantee fair competition on the Union market.

(11) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products 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.

(12) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(13) 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.

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

(15) When placing a product on the market, every importer should indicate on the product 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 product does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the product.

(16) The distributor makes a product 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 product does not adversely affect the compliance of the product.

(17) Any economic operator that either places a product on the market under his own name or trade mark or modifies a product in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(18) 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 product concerned.

(19) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant products available on the market. 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 a product or to whom they have supplied a product.

(20) This Directive should be limited to the expression of the essential health and safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for products 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 of 25 October

2012 on European Standardisation[7] for the purpose of expressing detailed technical specifications of those requirements.

(21) 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.

(22) In order to enable economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the essential health and 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.

(23) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a product with the requirements of this Directive and of other relevant Union harmonisation legislation.

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

(25) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

(26) 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.

(27) Experience has shown that the criteria set out in Directive 94/9/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.

(28) 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

(29) In order to ensure a consistent level of quality in the performance of conformity assessment, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(30) 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.

(31) 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.

(32) 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 products 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.

(33) 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.

(34) 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.

(35) 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.

(36) Member States should take all appropriate measures to ensure that products covered by this Directive 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. Products covered by this Directive should be considered as non-compliant with the essential health and 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.

(37) 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 products covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(38) Directive 94/9/EC already provides for a safeguard procedure which is necessary to allow the possibility for contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(39) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to products presenting a risk to the health or safety of persons, especially workers, or to domestic animals or property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.

(40) Where the Member States and the Commission agree as to the justification of a 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.

(41) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with 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[8].

(42) 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.

(43) The examination procedure should be used for the adoption of implementing acts with respect to compliant products which present a risk to the health or safety of persons or to other aspects of public interest protection.

(44) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant products which present a risk to the health or safety of persons or to domestic animals or property, imperative grounds of urgency so require.

(45) 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.

(46) 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.

(47) 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 products are justified or not.

(48) 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.

(49) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into service, without the need to comply with further product requirements, of products that have already been placed on the market in accordance with Directive 94/9/EC before the date for application of national measures transposing this Directive. Distributors should therefore be able to supply products 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.

(50) Since the objective of this Directive, namely to ensure that products on the market fulfil the requirements providing for a high level of protection of health and safety of persons, especially workers, and, where appropriate, protection of domestic animals and 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.

(51) 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.

(52) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directive set out in Annex XI, Part B,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 181, 21.6.2012, p. 105.

(**2**) Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

(**3**) OJ L 100, 19.4.1994, p. 1.

(**4**) See Annex XI, Part A.

(**5**) OJ L 218, 13.8.2008, p. 30.

(**6**) OJ L 218, 13.8.2008, p. 82.

(**7**) OJ L 316, 14.11.2012, p. 12.

(**8**) OJ L 55, 28.2.2011, p. 13.