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)

CHAPTER 1

GENERAL PROVISIONS

Article 1

Scope

1 This Directive shall apply to the following, hereinafter referred to as 'products':

- a equipment and protective systems intended for use in potentially explosive atmospheres;
- b safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;
- c components intended to be incorporated into equipment and protective systems referred to in point (a).

2 This Directive shall not apply to:

- a medical devices intended for use in a medical environment;
- b equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;
- c equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas;
- d personal protective equipment covered by Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment[(1)];
- e seagoing vessels and mobile offshore units together with equipment on board such vessels or units;
- f means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded from the scope of this Directive;
- g the equipment covered by point (b) of Article 346(1) of the Treaty on the Functioning of the European Union.

Article 2

Definitions

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

(1) ‘equipment’ means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition;

(2) ‘protective systems’ means devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems;

(3) ‘components’ means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;

(4) ‘explosive atmosphere’ means a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture;

(5) ‘potentially explosive atmosphere’ means an atmosphere which could become explosive due to local and operational conditions;

(6) ‘equipment-group I’ means equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust, comprising equipment categories M 1 and M 2 as set out in Annex I;

(7) ‘equipment-group II’ means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 as set out in Annex I;

(8) ‘equipment category’ means the classification of equipment, within each equipment-group, specified in Annex I, determining the requisite level of protection to be ensured;

(9) ‘intended use’ means the use of a product prescribed by the manufacturer by assigning the equipment to a particular equipment-group and category or by providing all the information which is required for the safe functioning of a protective system, device or component;

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

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

(12) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trade mark or uses it for his own purposes;

(13) ‘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;

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

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

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

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

(18) ‘harmonised standard’ means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

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

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

(21) ‘conformity assessment’ means the process demonstrating whether the essential health and safety requirements of this Directive relating to a product have been fulfilled;

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

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

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

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

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

Article 3

Making available on the market and putting into service

1 Member States shall take all appropriate measures to ensure that products may be made available on the market and put into service only if, when properly installed and maintained and used in accordance with their intended use, they comply with this Directive.

2 This Directive shall not affect Member States’ entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using relevant products provided that this does not mean that such products are modified in a way not specified in this Directive.

3 At trade fairs, exhibitions and demonstrations, Member States shall not prevent the showing of products which do not comply with this Directive, provided that a visible sign clearly indicates that such products do not comply with this Directive and that they are not for sale until they have been brought into conformity by the manufacturer. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

Article 4

Essential health and safety requirements

Products shall meet the essential health and safety requirements set out in Annex II which apply to them, account being taken of their intended use.

Article 5

Free movement

Member States shall not prohibit, restrict or impede the making available on the market and putting into service in their territory of products which comply with this Directive.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6

Obligations of manufacturers

1 When placing their products on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential health and safety requirements set out in Annex II.

2 Manufacturers shall draw up the technical documentation referred to in Annexes III to IX and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of a product, other than a component, with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

Where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure, manufacturers shall draw up a written attestation of conformity as referred to in Article 13(3).

Manufacturers shall ensure that each product is accompanied by a copy of the EU declaration of conformity or of the attestation of conformity, as appropriate. However, where a large number of products are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy.

3 Manufacturers shall keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market.

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

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

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

6 Manufacturers shall ensure that products, other than components, which they have placed on the market bear the specific marking of explosion protection and, where applicable, the other markings and information referred to in point 1.0.5 of Annex II.

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

8 Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

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

10 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product with this Directive, 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 products which they have placed on the market.

Article 7

Authorised representatives

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

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

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 or, where applicable, the attestation of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the product 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 product;

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

Article 8

Obligations of importers

1 Importers shall place only compliant products on the market.

2 Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking, where applicable, is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5), (6) and (7).

Where an importer considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Annex II, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3 Importers shall indicate on the product their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II.

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

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

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

8 Importers shall, for 10 years after the product has been placed on the market, keep a copy of the EU declaration of conformity or, where applicable, of the attestation 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 in paper or electronic form necessary to demonstrate the conformity of a product 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 products which they have placed on the market.

Article 9

Obligations of distributors

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

2 Before making a product available on the market distributors shall verify that the product bears the CE marking, where applicable, that it is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents and by instructions and safety information, in a language which can be easily understood by end-users in the Member State in which the product 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), (6) and (7) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Annex II, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3 Distributors shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II.

4 Distributors who consider or have reason to believe that a product 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 product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the product available on the market 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 in paper or electronic form necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.

Article 10

Cases in which obligations of manufacturers apply to importers and distributors

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

Article 11

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 product;

(b) any economic operator to whom they have supplied a product.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the product and for 10 years after they have supplied the product.

CHAPTER 3

CONFORMITY OF THE PRODUCT

Article 12

Presumption of conformity of products

1 Products 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 health and safety requirements set out in Annex II covered by those standards or parts thereof.

2 In the absence of harmonised standards, Member States shall take any steps which they deem necessary to bring to the attention of the parties concerned the existing national standards and technical specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements set out in Annex II.

Article 13

Conformity assessment procedures

1 The procedures to be followed for assessing the conformity of equipment and, where necessary, the devices referred to in point (b) of Article 1(1) shall be as follows:

a for equipment-groups I and II, equipment-categories M 1 and 1, the EU-type examination set out in Annex III, in conjunction with either of the following:
   — conformity to type based on quality assurance of the production process set out in Annex IV,
   — conformity to type based on product verification set out in Annex V;

b for equipment-groups I and II, equipment categories M 2 and 2:

   (i) in the case of internal combustion engines and electrical equipment in these groups and categories, the EU-type examination set out in Annex III, in conjunction with either of the following:
      — conformity to type based on internal production control plus supervised product testing set out in Annex VI,
      — conformity to type based on product quality assurance set out in Annex VII;

   (ii) in the case of other equipment in these groups and categories, internal production control set out in Annex VIII and the communication of the technical documentation provided for in Annex VIII, point 2, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

c for equipment-group II, equipment category 3, internal production control set out in Annex VIII;

d for equipment-groups I and II, in addition to the procedures referred to in points (a), (b) and (c) of this paragraph, conformity based on unit verification set out in Annex IX may also be followed.

2 The procedure referred to in point (a) or (d) of paragraph 1 shall be used for conformity assessment of protective systems.

3 The procedures referred to in paragraph 1 shall be applied in respect of components with the exception of the affixing of the CE marking and the drawing up of the EU declaration of conformity. A written attestation of conformity shall be issued by the manufacturer, declaring the conformity of the components with the applicable provisions of this Directive and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential health and safety requirements set out in Annex II applicable to finished equipment or protective systems.

4 With regard to the safety aspects referred to in point 1.2.7 of Annex II, in addition to the conformity assessment procedures referred to in paragraphs 1 and 2, the procedure referred to in Annex VIII may also be followed.

5 By derogation from paragraphs 1, 2 and 4, the competent authorities may, on a duly justified request, authorise the placing on the market and putting into service on the territory of the Member State concerned of the products other than components in respect of which the procedures referred to in paragraphs 1, 2 and 4 have not been applied and the use of which is in the interests of protection.

6 Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 to 4 shall be drawn up in a language, determined by the Member State concerned.

Article 14

EU declaration of conformity

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

2 The EU declaration of conformity shall have the model structure set out in Annex X, shall contain the elements specified in the relevant conformity assessment procedures set out in Annexes III to IX and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the product is placed or made available on the market.

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

4 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in this Directive.

Article 15

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

Rules and conditions for affixing the CE marking and other markings

1 The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

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

3 The CE marking shall be followed by the identification number of the notified body, where that body is 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, where applicable, the identification number of the notified body shall be followed by the specific marking of explosion protection  , the symbols of the equipment-group and category and, where applicable, the other markings and information referred to in point 1.0.5 of Annex II.

5 The CE marking and the markings, symbols and information referred to in paragraph 4, and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use.

Products that are designed for a particular explosive atmosphere shall be marked accordingly.

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

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 17

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

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 is to 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. 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

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

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

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 the national law of a Member State and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the product 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 products 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 products which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products 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 Annexes III to VII and Annex IX 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 products 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.

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

7 The personnel responsible for carrying out conformity assessment tasks 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 health and safety requirements set out in Annex II, of the applicable harmonised standards, 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 personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

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

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 Annexes III to VII and Annex IX 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 personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 22

Presumption of conformity of notified bodies

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

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 Annexes III to VII and Annex IX.

Article 24

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 The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products 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

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 the product or products 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 notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 26

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 assigned to them and the activities for which they have been notified.

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

Article 27

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

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 notified 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 adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

Article 29

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III to VII and Annex IX.

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 product 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 product with the requirements of this Directive.

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

4 Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product 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 the notified bodies is available.

Article 31

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 or 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

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

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

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

CHAPTER 5

UNION MARKET SURVEILLANCE, CONTROL OF PRODUCTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 34

Union market surveillance and control of products entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to products covered by Article 1 of this Directive.

Article 35

Procedure for dealing with products presenting a risk at national level

1 Where the market surveillance authorities of one Member State have sufficient reason to believe that a product presents a risk to the health or safety of persons or to domestic animals or property, they shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product 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 actions to bring the product into compliance with those requirements, to withdraw the product 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 of this paragraph.

2 Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products 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 products being made available on their national market, to withdraw the product 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 the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

a failure of the product to meet requirements relating to the health or safety of persons or to the protection of domestic animals or property; or

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 under this Article 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 product concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7 Where, within three months of receipt of the information referred to in the second subparagraph of 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, such as withdrawal of the product from the market, are taken in respect of the product concerned without delay.

Article 36

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 adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.

2 If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant product is withdrawn from their market,

and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3 Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 37

Compliant products which present a risk

1 Where, having carried out an evaluation under Article 35(1), a Member State finds that although a product is in compliance with this Directive, it presents a risk to the health or safety of persons or to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product 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 products 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 product concerned, the origin and the supply chain of the product, 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 by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 39(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons or to the protection of domestic animals or property, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 39(4).

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

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 has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Directive;

b the CE marking, where required, has not been affixed;

c the specific marking of explosion protection  , the symbols of the equipment-group and category and, where applicable, the other markings and information have been affixed in violation of point 1.0.5 of Annex II or have not been affixed;

d the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 16 or has not been affixed;

e the EU declaration of conformity or the attestation of conformity, as appropriate, does not accompany the product;

f the EU declaration of conformity or, where required, the attestation of conformity has not been drawn up correctly;

g technical documentation is either not available or not complete;

h the information referred to in Article 6(7) or 8(3) is absent, false or incomplete;

i any other administrative requirement provided for in Article 6 or 8 is not fulfilled.

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

CHAPTER 6

COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS

Article 39

Committee procedure

1 The Commission shall be assisted by the Committee on equipment and protective systems intended for use in potentially explosive atmospheres. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4 Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5 The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter 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.

Article 40

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

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

Article 41

Transitional provisions

1 Member States shall not impede the making available on the market or the putting into service of products covered by Directive 94/9/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

2 Certificates issued under Directive 94/9/EC shall be valid under this Directive.

Article 42

Transposition

1 Member States shall adopt and publish by 19 April 2016 the laws, regulations and administrative provisions necessary to comply with Article 1, points 2 and 8 to 26 of Article 2, Article 3, Articles 5 to 41 and Annexes III to X. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, 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.

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.

Article 43

Repeal

Directive 94/9/EC, as amended by the Regulations listed in Annex XI, Part A, is repealed with effect from 20 April 2016, 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.

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 XII.

Article 44

Entry into force and application

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

Points 1 and 3 to 7 of Article 2, Article 4 and Annexes I, II, XI and XII shall apply from 20 April 2016.

Article 45

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

(**1**) OJ L 399, 30.12.1989, p. 18.