Directive 2014/28/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 the making available on the market and supervision of explosives for civil uses (recast) (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1

Scope

- 1 This Directive shall apply to explosives for civil uses.
- 2 This Directive shall not apply to:
 - a explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police;
 - b pyrotechnic articles falling within the scope of Directive 2013/29/EU;
 - c ammunition, save as provided for in Articles 12, 13 and 14.

Annex I contains a non-exhaustive list of pyrotechnic articles and ammunition referred to in point (b) of this paragraph and in point 2 of Article 2 respectively identified following the United Nations recommendations on the transport of dangerous goods.

3 This Directive shall not prevent Member States from designating certain substances not covered by this Directive as explosives under national laws or regulations.

Article 2

Definitions

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

- (1) 'explosives' means the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations;
- (2) 'ammunition' means projectiles with or without propelling charges and blank ammunition used in portable firearms, other guns and artillery;
- (3) 'safety' means the prevention of accidents and, where prevention fails, the containment of their effects;
- (4) 'security' means the prevention of use contrary to law and order;
- (5) 'approval' means the decision taken to allow envisaged transfers of explosives within the Union;
- (6) 'transfer' means any physical movement of explosives within the Union except movements within one and the same site;

- (7) 'making available on the market' means any supply of an explosive for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (8) 'placing on the market' means the first making available of an explosive on the Union market;
- (9) 'manufacturer' means any natural or legal person who manufactures an explosive or has an explosive designed or manufactured, and markets that explosive under his name or trade mark or uses it for his own purposes;
- (10) '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;
- (11) 'importer' means any natural or legal person established within the Union who places an explosive from a third country on the Union market;
- (12) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an explosive available on the market;
- (13) 'economic operators' means the manufacturer, the authorised representative, the importer, the distributor and any natural or legal person who engages in the storage, use, transfer, import, export or trade of explosives;
- (14) 'dealer' means any natural or legal person whose occupation consists wholly or partly in the manufacture, trade, exchange, hiring out, repair or conversion of fire arms and ammunition;
- (15) 'technical specification' means a document that prescribes technical requirements to be fulfilled by an explosive;
- (16) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (17) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (18) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (19) 'conformity assessment' means the process demonstrating whether the essential safety requirements of this Directive relating to an explosive have been fulfilled;
- (20) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (21) 'recall' means any measure aimed at achieving the return of an explosive that has already been made available to the end-user;
- (22) 'withdrawal' means any measure aimed at preventing an explosive in the supply chain from being made available on the market;
- (23) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

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

Article 3

Free movement

Member States shall not prohibit, restrict or hinder the making available on the market of explosives which satisfy the requirements of this Directive.

Article 4

Making available on the market

Member States shall take the necessary measures to ensure that explosives may be made available on the market only if they comply with the requirements of this Directive.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 5

Obligations of manufacturers

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

2 Manufacturers shall draw up the technical documentation referred to in Annex III and have the relevant conformity assessment procedure referred to in Article 20 carried out.

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

3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the explosive 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 design or characteristics of the explosive and changes in the harmonised standards or in other technical specifications by reference to which conformity of an explosive is declared shall be adequately taken into account.

5 Manufacturers shall ensure that explosives which they have placed on the market bear a unique identification in accordance with the system for the identification and traceability of explosives set out in Article 15. For explosives excluded from that system, manufacturers shall:

a ensure that explosives which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the small size, shape or design of the explosive does not allow it, that the required information is provided on its packaging or in a document accompanying the explosive;

b indicate on the explosive 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 explosive. 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.

6 Manufacturers shall ensure that explosives which they have placed on the market are 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.

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

8 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 explosive 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 explosives which they have placed on the market.

Article 6

Authorised representatives

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

The obligations laid down in Article 5(1) and the obligation to draw up technical documentation referred to in Article 5(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 and the technical documentation at the disposal of national market surveillance authorities for 10 years after the explosive 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 an explosive;
- c cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by explosives covered by the authorised representative's mandate.

Article 7

Obligations of importers

1 Importers shall place only compliant explosives on the market.

2 Before placing an explosive on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 20 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the explosive bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 5(5).

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

3 Importers shall indicate, on the explosive, 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 explosive. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the explosive 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 an explosive is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex II.

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

7 Importers shall, for 10 years after the explosive has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

8 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 an explosive 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 explosives which they have placed on the market.

Article 8

Obligations of distributors

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

2 Before making an explosive available on the market distributors shall verify that the explosive bears the CE marking, that it is accompanied by 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 explosive is to be made available on the market, and that the

manufacturer and the importer have complied with the requirements set out in Article 5(5) and Article 7(3) respectively.

Where a distributor considers or has reason to believe that an explosive is not in conformity with the essential safety requirements set out in Annex II, he shall not make the explosive available on the market until it has been brought into conformity. Furthermore, where the explosive 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 an explosive is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex II.

4 Distributors who consider or have reason to believe that an explosive 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 explosive into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the explosive presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the explosive available on the market to that effect, giving details, in particular, of the noncompliance 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 an explosive. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have made available on the market.

Article 9

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 5, where he places an explosive on the market under his name or trade mark or modifies an explosive already placed on the market in such a way that compliance with this Directive may be affected.

Article 10

Identification of economic operators

For explosives not covered by the system set out in Article 15, economic operators shall, on request, identify the following to the market surveillance authorities:

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

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 explosive and for 10 years after they have supplied the explosive.

CHAPTER 3

SECURITY PROVISIONS

Article 11

Transfers of explosives

1 Explosives may be transferred only in accordance with paragraphs 2 to 8.

2 Approval to transfer explosives shall be obtained by the consignee from the competent authority in the Member State of the consignee. The competent authority shall verify that the consignee is legally authorised to acquire explosives and that he is in possession of the necessary licences or authorisations. The economic operator responsible for the transfer shall notify the competent authorities of the transit Member State of any movement of explosives through the Member State concerned and shall obtain prior approval of the transit Member State concerned.

3 Where a Member State considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in paragraph 2, that Member State shall forward the available information on the subject to the Commission which shall inform the other Member States thereof.

4 Where the competent authority in the Member State of the consignee approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph 5. Such a document shall accompany the explosives until they arrive at their stated destination. It shall be produced at the request of the relevant competent authorities. A copy of that document shall be retained by the consignee who shall present it, upon request, for examination by the competent authority in the Member State of the consignee.

5 Where transfers of explosives must be specially supervised in order to comply with special security requirements in the territory or part of the territory of a Member State, prior to the transfer the following information shall be provided by the consignee to the competent authority in the Member State of the consignee:

- a the names and addresses of the economic operators concerned;
- b the number and quantity of the explosives being transferred;
- c a full description of the explosives in question and of the means of identification, including the United Nations identification number;
- d where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;
- e the means of transfer and the itinerary;
- f the expected dates of departure and arrival;
- g where necessary, the precise points of entry to and exit from Member States.

The information referred to in point (a) of the first subparagraph shall be sufficiently detailed in order to enable competent authorities to contact the economic operators and to obtain confirmation that the economic operators concerned are entitled to receive the consignment.

The competent authority in the Member State of the consignee shall examine the conditions under which the transfer may take place, with particular regard to the special security requirements. If the special security requirements are satisfied, approval for the transfer shall be granted. In the case of transit through the territory of other

Member States, those Member States shall likewise examine and approve the particulars concerning the transfer.

6 Where the competent authority of a Member State considers that special security requirements referred to in paragraphs 4 and 5 are unnecessary, explosives may be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph 5. The competent authority in the Member State of the consignee shall then grant an approval for a fixed period, which is liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph 4, which shall accompany the explosives until they arrive at their destination, shall refer solely to that approval.

7 Without prejudice to the normal checks which the Member State of departure is to carry out in its territory, at the request of the competent authorities concerned, the consignees and the economic operators concerned shall forward to the authorities of the Member State of departure and to those of the Member State of transit all relevant information they possess concerning the transfer of explosives.

8 No economic operator may transfer explosives unless the consignee has obtained the necessary authorisations for the transfer in accordance with paragraphs 2, 4, 5 and 6.

Article 12

Transfers of ammunition

1 Ammunition may be transferred from one Member State to another only in accordance with the procedure laid down in paragraphs 2 to 5. Those paragraphs shall also apply to transfers of ammunition under mail-order sales.

2 Where ammunition is to be transferred to another Member State the person concerned shall, before any dispatch, communicate to the Member State in which that ammunition is located:

- a the names and addresses of the person selling or transferring the ammunition, of the person purchasing or acquiring the ammunition and, where appropriate, of the owner;
- b the address to which the ammunition is to be consigned or transported;
- c the quantity of ammunition to be consigned or transported;
- d data making it possible to identify the ammunition and also an indication that the ammunition has undergone a check in accordance with the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms;
- e the means of transfer;
- f the date of departure and the estimated date of arrival.

The information referred to in points (e) and (f) of the first subparagraph need not be supplied in the case of a transfer between dealers. The Member State shall examine the conditions under which the transfer is to be carried out, in particular with regard to security. Where the Member State authorises such a transfer it shall issue a licence incorporating all the particulars referred to in the first subparagraph. That licence shall accompany the ammunition until it reaches its destination. It shall be produced whenever so required by the competent authorities of the Member States.

3 Each Member State may grant dealers the right to effect transfers of ammunition from its territory to a dealer established in another Member State without the prior authorisation referred to in paragraph 2. To that end it shall issue an authorisation valid for three years which may at any time be suspended or cancelled by reasoned decision. A document referring to

that authorisation shall accompany the ammunition until it reaches its destination. It shall be produced whenever so required by the competent authorities of the Member States.

Before effecting the transfer, the dealer shall communicate to the authorities of the Member State from which the transfer is to be effected all the particulars listed in the first subparagraph of paragraph 2.

4 Each Member State shall supply the other Member States with a list of the ammunition the transfer of which to its territory may be authorised without its prior consent.

Such lists of ammunition shall be communicated to dealers who have obtained approval for transferring ammunition without prior authorisation in accordance with the procedure laid down in paragraph 3.

5 Each Member State shall communicate all useful information at its disposal concerning definitive transfers of ammunition to the Member State, to the territory of which such a transfer has been effected.

All information that Member States receive in accordance with paragraphs 2 and 3 shall be communicated, not later than the time of the relevant transfers, to the Member States of destination and, where appropriate, not later than the time of transfer to the Member States of transit.

Article 13

Security derogations

By way of derogation from Article 11(2), (4), (5) and (6) and from Article 12, a Member State, in the event of serious threats to, or attacks on, public security as a result of illicit possession or use of explosives or ammunition, may take all necessary measures concerning transfers of explosives or ammunition in order to prevent such illicit possession or use.

The measures referred to in the first paragraph shall respect the principle of proportionality. They shall constitute neither a means of arbitrary discrimination nor a veiled restriction in trade between Member States.

Each Member State which adopts such measures shall notify the Commission of them forthwith. The Commission shall inform the other Member States thereof.

Article 14

Information exchange

1 Member States shall set up information exchange networks for the implementation of Articles 11 and 12. They shall notify the other Member States and the Commission of the national authorities responsible for forwarding or receiving information and for applying the procedures referred to in those Articles.

Member States shall keep at the disposal of the other Member States and of the Commission updated information concerning economic operators possessing licences or authorisations referred to in Article 16.

2 For the purposes of implementing this Directive, Regulation (EC) No 515/97, in particular the requirements thereof relating to confidentiality, shall apply mutatis mutandis.

Article 15

Identification and traceability of explosives

1 Economic operators shall adhere to a uniform system for the unique identification and traceability of explosives, that takes into account their size, shape or design, except where it is not necessary to place a unique identification on the explosive due to its low level of hazard, based on its characteristics and factors such as its low detonative effects, its uses and the low security risk it presents due to the low potential effects of misuse.

The system shall not apply to explosives transported and delivered unpackaged or in pump trucks for their direct unloading into the blast-hole, or explosives manufactured at blasting sites, and that are loaded immediately after being produced (in situ production).

2 That system shall provide for the collection and storage of data, including where appropriate by electronic means, enabling the unique identification and traceability of the explosive as well as for the placement of a unique identification on the explosive and/or its packaging enabling access to that data. Those data shall relate to the unique identification of the explosive, including its location while in the possession of economic operators and the identity of those economic operators.

3 The data referred to in paragraph 2 shall be tested at regular intervals and protected against accidental or malicious damage or destruction. Those data shall be stored for 10 years after the transaction took place or, where the explosives have been used or disposed of, 10 years after their use or disposal, even if the economic operator has ceased trading. They shall be immediately available at the request of the competent authorities.

4 The Commission may adopt implementing acts:

- a laying down the practical arrangements for the operation of the system of unique identification and traceability referred to in paragraph 1, taking into account the size, shape or design of the explosives, in particular the format and structure of the unique identification, as provided for in paragraph 2;
- b identifying the cases referred to in paragraph 1 where it is not necessary, due to the low level of hazard of an explosive, for economic operators to adhere to the system for the unique identification and traceability within the meaning of that paragraph.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 49(3).

Article 16

Licence or authorisation

Economic operators shall be in possession of a licence or authorisation which entitles them to engage in the manufacture, storage, use, import, export, transfer or trade of explosives.

The first paragraph shall not apply to employees of an economic operator possessing a licence or authorisation.

Article 17

Licensing of manufacturing activities

When a Member State issues a licence or authorisation referred to in Article 16 for manufacturing of explosives, it shall check in particular that the economic operators responsible are capable of complying with the technical commitments they assume.

Article 18

Seizures

Each Member State shall adopt the necessary measures to enable the competent authorities to seize any explosive if there is sufficient evidence that that explosive will be illicitly acquired, used or dealt in.

CHAPTER 4

CONFORMITY OF THE EXPLOSIVE

Article 19

Presumption of conformity of explosives

Explosives, which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements set out in Annex II covered by those standards or parts thereof.

Article 20

Conformity assessment procedures

For the assessment of the conformity of explosives the manufacturer shall follow one of the following procedures referred to in Annex III:

- (a) EU-type examination (Module B) and, at the choice of the manufacturer, any of the following:
 - (i) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2);
 - (ii) conformity to type based on quality assurance of the production process (Module D);
 - (iii) conformity to type based on product quality assurance (Module E);
 - (iv) conformity to type based on product verification (Module F);
- (b) conformity based on unit verification (Module G).

Article 21

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the essential 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 IV, shall contain the elements specified in the relevant modules set out in Annex III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the explosive is placed or made available on the market.

3 Where an explosive 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 explosive with the requirements laid down in this Directive.

Article 22

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 23

Rules and conditions for affixing the CE marking

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

2 The CE marking shall be affixed before the explosive 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 may be followed by any other mark indicating a special risk or use.

5 In cases of explosives manufactured for own use, explosives transported and delivered unpackaged or in Mobile Explosives Manufacturing Units (MEMUs) for their direct unloading into the blast-hole, and explosives manufactured at the blasting sites which are loaded immediately after being produced (in situ production), the CE marking shall be affixed to the accompanying documents.

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 5

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 24

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 25

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 Article 30.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

Article 26

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 27

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 28

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 explosive it assesses.

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 explosives nor the representative of any of those parties. This shall not preclude the use of explosives that are necessary for the operations of the conformity assessment body or the use of explosives 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, marketing, installation, use or maintenance of explosives 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 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 Annex III 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 explosives 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 the 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 safety requirements set out in Annex II, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and 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 Annex III 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 29

Presumption of conformity of conformity assessment 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 28 insofar as the applicable harmonised standards cover those requirements.

Article 30

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 28 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 Annex III.

Article 31

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 explosive or explosives 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 28.

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 28.

Article 32

Notification procedure

1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.

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 explosive or explosives concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate as referred to in Article 31(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 28.

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 33

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 34

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 28 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 35

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 49(2).

Article 36

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.

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 explosive with this Directive.

3 Where a notified body finds that the essential 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 an explosive 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 37

Appeal against decisions of notified bodies

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

Article 38

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 explosives with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 39

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 40

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 6

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

Article 41

Union market surveillance and control of explosives entering the Union market

Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to explosives.

Member States shall take all appropriate measures to ensure that explosives may be placed on the market only if, when properly stored and used for their intended purpose, they do not endanger the health or safety of persons.

Article 42

Procedure for dealing with explosives presenting a risk at national level

1 Where the market surveillance authorities of one Member State have sufficient reason to believe that an explosive presents a risk to the health or safety of persons, or to property or the environment, they shall carry out an evaluation in relation to the explosive 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 explosive 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 explosive into compliance with those requirements, to withdraw the explosive 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 explosives 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 explosive's being made available on their national market, to withdraw the explosive 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 explosive, the origin of the explosive, 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 explosive to meet requirements relating to the health or safety of persons, or to the protection of property or the environment; or
- b shortcomings in the harmonised standards referred to in Article 19 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 explosive 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 explosive from the market are taken in respect of the explosive concerned without delay.

Article 43

Union safeguard procedure

1 Where, on completion of the procedure set out in Article 42(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 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 explosive 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 explosive is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 42(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 44

Compliant explosives which present a risk

1 Where, having carried out an evaluation under Article 42(1), a Member State finds that although an explosive is in compliance with this Directive, it presents a risk to the health or safety of persons, or to property or the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the explosive concerned, when placed on the market, no longer presents that risk, to withdraw the explosive 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 explosives 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 explosive concerned, the origin and the supply chain of the explosive, 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 49(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, or to the protection of property or the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 49(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 45

Formal non-compliance

1 Without prejudice to Article 42, 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 23 of this Directive;
- b the CE marking has not been affixed;
- c the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 23 or has not been affixed;
- d the EU declaration of conformity has not been drawn up;
- e the EU declaration of conformity has not been drawn up correctly;
- f technical documentation is either not available or not complete;

- g the information referred to in Article 5(5) or Article 7(3) is absent, false or incomplete;
- h any other administrative requirement provided for in Article 5 or Article 7 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 explosive being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER 7

DELEGATED AND IMPLEMENTING POWERS AND COMMITTEE

Article 46

Delegated power

The Commission shall be empowered to adopt delegated acts in accordance with Article 47 updating Annex I in order to align it to the United Nations recommendations on the transport of dangerous goods.

Article 47

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 46 shall be conferred on the Commission for five years from 18 April 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of power referred to in Article 46 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 46 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 48

Implementing acts

The Commission shall adopt implementing acts setting out the technical arrangements for the application of Article 11, in particular the model document to be used.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 49(3).

Article 49

Committee procedure

1 The Commission shall be assisted by the Committee on Civil Explosives. 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.

CHAPTER 8

TRANSITIONAL AND FINAL PROVISIONS

Article 50

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 51

Transitional provisions

1 Member States shall not impede the making available on the market of explosives covered by Directive 93/15/EEC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

2 Certificates issued under Directive 93/15/EEC shall be valid under this Directive.

3 Until replaced by the measures adopted pursuant to Article 15 of this Directive, Commission Directive 2008/43/EC of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses⁽¹⁾ shall continue to apply.

Article 52

Transposition

1 Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with points 2, 7 to 13 and 15 to 24 of Article 2, Articles 3 to 10, Article 14(1), Articles 15 and 16, point (i) of point (a) of Article 20, Articles 21 to 27, Article 28(1) to (4), (6), (7), (10) and (11), Articles 29 to 45, 50 and 51 and Annexes III and IV. 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 53

Repeal

Directive 93/15/EEC as amended by the Regulations listed in Annex V, Part A, and Directive 2004/57/EC are repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law and the dates of application of the Directives set out in Annex V, Part B.

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

Article 54

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*.

Article 1, points 1, 3 to 6 and 14 of Article 2, Articles 11, 12 and 13, Article 14(2), Articles 17 to 19, points (ii) to (iv) of point (a) and point (b) of Article 20, Article 28(5), (8) and (9), Articles 46, 47, 48 and 49 and Annexes I, II, V and VI shall apply from 20 April 2016.

Article 55

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 94, 5.4.2008, p. 8.