

# COUNCIL OF THE EUROPEAN UNION

# Brussels, 10 February 2014

5931/14

Interinstitutional File: 2011/0349 (COD)

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# **INFORMATION NOTE**

from:	General Secretariat
to:	Permanent Representatives Committee/Council
Subject:	New Legislative Framework Alignement Package
	(Implementation of the Goods Package)
	- Proposal for a Directive of the European Parliament and of the Council on the
	harmonisation of the laws of the Member States relating to the making available
	on the market and supervision of explosives for civil uses
	<ul> <li>Outcome of the European Parliament's first reading</li> </ul>
	(Strasbourg, 3 to 6 February 2014)

# I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure <sup>1</sup>, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

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OJ C 145, 30.6.2007, p.5

In this context, the rapporteur, Ms Zuzana ROITHOVÁ (EPP, CZ) presented one compromise amendment (amendment 35) to the proposal for Directive, on behalf of the Committee on Internal Market and Consumer Protection. One further amendment (amendment 36) was tabled, it refers to a statement of the European Parliament. These amendments had been agreed during the informal contacts referred to above.

#### II. VOTE

When it voted on 5 February 2014, the plenary adopted the two amendments (amendments 35-36) to the proposal for a Directive. The Commission's proposal as thus amended and the legislative resolution constitute the Parliament's first-reading position<sup>1</sup>, it reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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The text of the amendments adopted and the European Parliament's legislative resolution are set out in the Annex. The compromise amendment is presented in the form of a consolidated text, where changes to the Commission's proposal are highlighted in *bold and italics*. The symbol " Indicates deleted text.

# Explosives for civil uses \*\*\*I

European Parliament legislative resolution of 5 February 2014 on the proposal for a directive of the European Parliament and of the Council 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) (COM(2011)0771 - C7-0423/2011 - 2011/0349(COD))

(Ordinary legislative procedure – recast)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0771),
- having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0423/2011),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 28 March 2012<sup>1</sup>,
- having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>2</sup>,
- having regard to the letter of 27 March 2012 from the Committee on Legal Affairs to the Committee on the Internal Market and Consumer Protection in accordance with Rule 87(3) of its Rules of Procedure.
- having regard to the undertaking given by the Council representative by letter of 11 October 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
- having regard to Rules 87 and 55 of its Rules of Procedure,
- having regard to the report of the Committee on the Internal Market and Consumer Protection (A7-0256/2012),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;

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<sup>&</sup>lt;sup>1</sup> OJ C 181, 21.6.2012, p. 105.

OJ C 77, 28.3.2002, p. 1.

- 1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
- 2. Approves its statement annexed hereto, which will be published in the L series of the *Official Journal of the European Union* together with the final legislative act;
- 3. Approves its statement annexed hereto, which will be published in the L series of the *Official Journal of the European Union* together with the final legislative act;
- 4. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
- 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

# P7\_TC1-COD(2011)0349

Position of the European Parliament adopted at first reading on 5 February 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council 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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national *parliaments*,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

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<sup>&</sup>lt;sup>1</sup> OJ C *181*, *21.6.2012*, p. *105*.

Position of the European Parliament of 5 February 2014.

#### Whereas:

- Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions (1) relating to the placing on the market and supervision of explosives for civil uses<sup>1</sup> has been substantially amended  $\blacksquare$  <sup>2</sup>. Since further amendments are to be made, *that Directive* should be recast in the interests of clarity.
- *(2)* It is necessary to clarify in this Directive that certain articles were identified following the United Nations recommendations on the transport of dangerous goods as being pyrotechnic articles or ammunition, thus falling outside the scope of this Directive. Commission Directive 2004/57/EC of 23 April 2004 on the identification of pyrotechnic articles and certain ammunition for the purposes of Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses<sup>3</sup>, which currently contains a list of such articles, should therefore be repealed.
- (3) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products \[ \begin{aligned} \ ^4 \text{ lays down rules on the accreditation of conformity assessment} \] bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (4) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products \[ \bigs\_5 \], lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 93/15/EEC should *therefore* be adapted to that Decision.

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<sup>1</sup> OJ L 121, 15.5.1993, p. 20.

<sup>2</sup> See Annex V, Part A.

<sup>3</sup> OJ L 127, 29.4.2004, p. 73.

<sup>4</sup> OJ L 218, 13.8.2008, p. 30.

<sup>5</sup> OJ L 218, 13.8.2008, p. 82.

- (5) Safety during storage is covered by Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances<sup>1</sup> which sets out safety requirements for establishments where explosives are present. Safety of explosives during transport is regulated by international conventions and agreements, including the United Nations recommendations on the transport of dangerous goods. Those aspects should therefore not fall under the scope of this Directive.
- (6) Pyrotechnic articles require appropriate measures to ensure the protection of *end-users* and the safety of the public. Pyrotechnic articles are covered by Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the *harmonisation of the laws of the Member States relating to the making available* on the market of pyrotechnic articles<sup>2</sup>. This Directive should therefore not apply to pyrotechnic articles.
- (7) The scope of this Directive should cover ammunition, but only as regards the rules governing controls on transfers and the associated arrangements. Since ammunition is transferred under conditions similar to those under which arms are transferred, transfers of ammunition should be governed by provisions similar to those applicable to arms, as set out in Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons<sup>3</sup>.

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OJ L 10, 14.1.1997, p. 13.

OJ L 178, 28.6.2013, p. 27.

OJ L 256, 13.9.1991, p. 51.

- (8) This Directive should apply to all forms of supply, including distance selling.
- (9) The definition of the explosives covered by this Directive should be based on the definition of such products as set out in the United Nations recommendations on the transport of dangerous goods.
- (10) In order to ensure the free movement of explosives it is necessary to harmonise the laws relating to making explosives available on the market.
- (11) Economic operators should be responsible for the compliance of explosives *with this Directive* in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons and public security and to guarantee fair competition on the Union market.
- (12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market explosives which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each *economic* operator in the supply and distribution *chain*.
- (13) In order to facilitate communication between economic operators, market surveillance authorities and end-users, Member States should encourage economic operators to include a website address in addition to the postal address.

- (14) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain *solely* the obligation of the manufacturer.
- (15) It is necessary to ensure that explosives from third countries entering the Union market comply with this Directive, and in particular that appropriate *conformity* assessment procedures have been carried out by manufacturers with regard to those explosives. Provision should therefore be made for importers to make sure that the explosives they place on the market comply with the requirements of this Directive and that they do not place on the market explosives which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of explosives and documentation drawn up by manufacturers are available for inspection by the *competent national* authorities.

- (16) The distributor makes an explosive available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the explosive does not adversely affect the compliance of the explosive.
- (17) Any economic operator that either places an explosive on the market under his own name or trade mark or modifies an explosive in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the explosive concerned.

(19) Unique identification of explosives is essential if accurate and complete records of explosives are to be kept at all stages of the supply chain. This should allow the identification and the traceability of an explosive from its production site and its placing on the market until its final user and its use with a view to preventing misuse and theft and to assisting law enforcement authorities in the tracing of the origin of lost or stolen explosives. An efficient traceability system also facilitates market surveillance authorities' task of tracing economic operators who made non-compliant *explosives* available on the market. When keeping the information required under this Directive for the identification of economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with an explosive or to whom they have supplied an explosive.

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- (20)The provisions of this Directive relating to the making available on the market should be limited to the expression of the essential safety requirements for explosives in order to protect the health and safety of persons, property and the environment. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for explosives which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation <sup>1</sup> for the purpose of expressing detailed technical specifications *of those requirements*.
- (21) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.

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OJ L 316, 14.11.2012, p. 12.

- In order to enable economic operators to demonstrate and the competent authorities to ensure that explosives made available on the market conform to the essential safety requirements it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid adhoc variants conformity assessment procedures should be chosen from among those modules. Because of their specific characteristics and the hazards involved, explosives should always be submitted to third party *conformity assessment*.
- (23) Manufacturers should draw up an EU declaration of conformity to provide information *required under this Directive* on the conformity of an explosive with *this Directive and* of *other* relevant Union harmonisation legislation.
- (24) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- The CE marking, indicating the conformity of an explosive, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

- (26) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- Experience has shown that the criteria set out in Directive 93/15/EEC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (28) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of *notified* bodies.
- (29) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.

- (30) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates *of conformity*, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out *that* evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

- (32) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the explosives to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of *conformity* assessment bodies to be notified and the monitoring of *notified* bodies cover also activities carried out by subcontractors and subsidiaries.
- (33) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (34) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

- (35) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (36) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to explosives. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (37) Member States should 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, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Explosives should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

- (38) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to *explosives* presenting a risk to the health *or* safety of persons, or to *property or the environment*. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such *explosives*.
- (39) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (40) In the event of a serious threat to, or attack on, public security as a result of illicit possession or use of explosives or ammunition Member States should be allowed to derogate, under certain conditions, from this Directive with regard to transfer of explosives and ammunition in order to prevent such illicit possession or use.

- (41) It is essential to establish administrative cooperation mechanisms between competent authorities of Member States. Therefore, the competent authorities should base their approach on Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs or agricultural matters<sup>1</sup>.
- (42) This Directive should not affect the power of Member States to take measures with a view to preventing illegal trade in explosives and ammunition.

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OJ L 82, 22.3.1997, p. 1.

- (43) In order to achieve the objectives of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of Union measures concerning adapting this Directive to United Nations recommendations on the transport of dangerous goods. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>1</sup>.

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OJ L 55, 28.2.2011, p. 13.

(45) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

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- (46) The examination procedure should be used for the adoption of the implementing acts in order to set up the *practical arrangements* for the operation of the system for the unique identification and traceability of explosives, as well as for setting out the technical arrangements for the application of the provisions on the transfer of explosives, in particular the model document to be used.
- (47) The examination procedure should also be used for the adoption of implementing acts with respect to compliant explosives which present a risk to the health or safety of persons or to other aspects of public interest protection.
- (48) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant explosives which present a risk to the health or safety of persons, or to property or the environment, imperative grounds of urgency so require.
- (49) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (50) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

- (51) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant explosives are justified or not.
- (52) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that *those rules* are *enforced*. *The* penalties *provided for* should be effective, proportionate and dissuasive.

- (53) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market without the need to comply with further product requirements of explosives that have already been placed on the market in accordance with Directive 93/15/EEC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply explosives that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (54) Since the objective of this Directive, namely to ensure that explosives on the market fulfil the requirements providing for a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

- The obligation to transpose this Directive into national law should be confined to those (55)provisions which represent a substantive amendment as compared to the earlier Directives . The obligation to transpose the provisions which are unchanged arises under *the earlier* Directives .
- (56)This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B,

#### HAVE ADOPTED THIS DIRECTIVE:

# CHAPTER 1

General provisions

Article 1

Scope

- This Directive shall apply to explosives for civil uses. 1.
- 2. This Directive shall not apply to:

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- (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:

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- (2) 'ammunition' means projectiles with or without propelling charges and blank ammunition used in portable firearms, other guns and artillery;
- 'safety' means the prevention of accidents and, where prevention fails, the containment of (3) 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;

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- (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;
- '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;
- '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;

'CE marking' means a marking by which the manufacturer indicates that the explosive is (24)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.

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#### **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.



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- 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 non-compliance 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:

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- (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;
- further to a reasoned request from a competent national authority, provide that (b) 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

- Importers shall place only compliant explosives on the market. 1.
- 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).

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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.

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- 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 non-compliance 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.

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# 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 endusers 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 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 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.

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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.

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#### 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.

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- 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;

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- (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.

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- 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.

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### 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;

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- (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.

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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.

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# 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.

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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).

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- 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;

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**(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.

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#### 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.

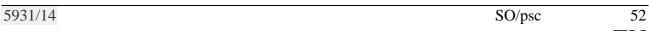
### **CHAPTER 4**

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.



# 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:

- EU-type examination (Module B) and, at the choice of the manufacturer, any of the (a) 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),
  - conformity to type based on product verification (Module F);
- (b) conformity based on unit verification (Module G).

# 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*.

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# 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.

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- 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.

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# 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.

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- 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.

# 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.

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# 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.

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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.

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- 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;

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(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;

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- (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.

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- 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.

### 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 in so far as the applicable harmonised standards cover those requirements.

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# 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.

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- 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.

## 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.

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- 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.

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### 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.

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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.

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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.

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- 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.

Appeal against decisions of notified bodies

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

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# 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.
- 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.

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## 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* 

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*.

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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.

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- 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.

## 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.

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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.

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- 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).

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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 noncompliance 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;
  - the identification number of the notified body, where that body is involved in the (c)production control phase, has been affixed in violation of Article 23 or has not been affixed;
  - the EU declaration of conformity has not been drawn up; (d)

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- the EU declaration of conformity has not been drawn up correctly; (e)
- (f) technical documentation is either not available or not complete;
- the information referred to in Article 5(5) or Article 7(3) is absent, false or **(g)** incomplete;
- any other administrative requirement provided for in Article 5 or Article 7 is not **(h)** 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.

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## 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 ...\*. 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.

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OJ, please insert the date of entry into force of this Directive.

- 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.

## 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).

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## 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.

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## **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 ...\*.

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<sup>\*</sup> OJ: Please insert date: day after two years after entry into force of this Directive.

- 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 shall continue to apply.

## Transposition

1. Member States shall adopt and publish, by ...\*, 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 ...\*\*.

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.

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OJ L 94, 5.4.2008, p. 8.

<sup>\*</sup> OJ: Please insert date: two years after entry into force of this Directive.

<sup>\*\*</sup> OJ: Please insert date: day after two years after entry into force of this Directive.

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 ...\*, 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.

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OJ: Please insert date: day after two years after entry into force of this Directive.

## 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 ...\*.

Article 55

Addressees

This Directive is addressed to the Member States.

Done at ...

For the European Parliament For the Council
The President The President

<sup>\*</sup> OJ: Please insert date: day after two years after entry into force of this Directive.

# ANNEX I Articles considered in the relevant United Nations recommendations to be pyrotechnic or ammunition

UN NO	NAME and	CLASS/DIVI	GLOSSARY (to be used as a guide for
	DESCRIPTION	-SION	information only)
Group G			
0009	Ammunition, Incendiary	1.2 G	Ammunition
	with or without burster,		Generic term related mainly to articles of
	expelling charge or		military application consisting of all kind
	propelling charge		of bombs, grenades, rockets, mines,
			projectiles and other similar devices.
			Ammunition, Incendiary
			Ammunition containing incendiary
			substance. Except when the composition
			is an explosive per se, it also contains one
			or more of the following: a propelling
			charge with primer and igniter charge; a
			fuze with burster or expelling charge.
0010	Ammunition, Incendiary	1.3 G	See Entry for UN No 0009
	with or without burster,		
	expelling charge or		
	propelling charge		
0015	Ammunition, Smoke with	1.2 G	Ammunition, Smoke
	or without burster,		Ammunition containing smoke-producing
	expelling charge or		substance. Except when the substance is
	propelling charge		an explosive per se, the ammunition also
			contains one or more of the following: a
			propelling charge with primer and igniter
			charge; a fuze with burster or expelling
			charge.
0016	Ammunition, Smoke with	1.3 G	See Entry for UN No 0015
	or without burster,		
	expelling charge or		

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	propelling charge		
0018	Ammunition, Tear- producing with burster, expelling charge or propelling charge	1.2 G	Ammunition, Tear-producing with burster, expelling charge or propelling charge  Ammunition containing tear-producing substance. It also contains one or more of the following: a pyrotechnic substance; a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.
0019	Ammunition, Tear- producing with burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0018
0039	Bombs, photo-flash	1.2 G	Bombs  Explosive articles which are dropped from aircraft. They may contain a flammable liquid with bursting charge, a photo-flash composition or a bursting charge. The term includes: bombs, photo-flash.
0049	Cartridges, Flash	1.1 G	Cartridges, Flash Articles consisting of a casing, a primer and flash powder, all assembled in one piece ready for firing.
0050	Cartridges, Flash	1.3 G	See Entry for UN No 0049

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TIN NO	NAME and	CLASS/DIVI	GLOSSARY (to be used as a guide for
UN NO	DESCRIPTION	-SION	information only)
0054	Cartridges, Signal	1.3 G	Cartridges, Signal
			Articles designed to fire coloured flares or
			other signals from signal pistols, etc.
0066	Cord, Igniter	1.4G	Cord, Igniter
			Article consisting of textile yarns covered
			with black powder or another fast
			burning pyrotechnic composition and of a
			flexible protective covering; or it consists
			of a core of black powder surrounded by
			a flexible woven fabric: It burns
			progressively along its length with an
			external flame and is used to transmit
			ignition from a device to a charge.
0092	Flares, Surface	1.3 G	Flares
			Articles containing pyrotechnic
			substances which are designed for use to
			illuminate, identify, signal or warn.
0093	Flares, Aerial	1.3 G	See Entry for UN No 0092
0101	Fuse, non-detonating	1.3 G	Fuse/Fuze
			Although these two words have a
			common origin (French fusée, fusil) and
			are sometimes considered to be different
			spellings, it is useful to maintain the
			convention that fuse refers to a cord-like
			igniting device whereas fuze refers to a
			device used in ammunition which
			incorporates mechanical, electrical,
			chemical or hydrostatic components to
			initiate a train by deflagration or
			detonation.

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			Fuse, instantaneous, non-detonating
			(quick-match)
			Article consisting of cotton yarns
			impregnated with fine black powder
			(quickmatch). It burns with an external
			flame and is used in ignition trains for
			fireworks, etc.
0103	Fuse, Igniter, tubular,	1.4G	Fuse, igniter, tubular, metal clad
	metal clad		Article consisting of a metal tube with a
			core of deflagrating explosive.
0171	Ammunition, illuminating	1.2 G	Ammunition, illuminating with or without
	with or without burster,		burster, expelling charge or propelling
	expelling charge or		charge
	propelling charge		Ammunition designed to produce a single
			source of intense light for lighting up an
			area. The ter includes illuminating
			cartridges, grenades and projectiles; and
			illuminating and target identification
			bombs.
0191	Signal devices, hand	1.4 G	Articles designed to produce signals.
0192	Signals, railway track,	1.1 G	See Entry for UN No 0191
	explosive		
0194	Signals, distress, ship	1.1 G	See Entry for UN No 0191

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TIM NO	NAME and	CLASS/DIVI	GLOSSARY (to be used as a guide for
UN NO	DESCRIPTION	-SION	information only)
0195	Signals, distress, ship	1.3 G	See Entry for UN No 0191
0196	Signals, smoke	1.1 G	See Entry for UN No 0191
0197	Signals, smoke	1.4 G	See Entry for UN No 0191
0212	Tracers for ammunition	1.3 G	Tracers for ammunition Sealed articles containing pyrotechnic substances, designed to reveal the trajectory of a projectile.
0254	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0171
0297	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.4G	See Entry for UN No 0254
0299	Bombs, photo-flash	1.3 G	See Entry for UN No 0039
0300	Ammunition, incendiary with or without burster, expelling charge or propelling charge	1.4G	See Entry for UN No 0009
0301	Ammunition, tear- producing with burster, expelling charge	1.4 G	See Entry for UN No 0018
0303	Ammunition, smoke with or without burster, expelling charge	1.4 G	See Entry for UN No 0015
0306	Tracers for ammunition	1.4 G	See Entry for UN No 0212
0312	Cartridges, signal	1.4G	Cartridges, signal Articles designed to fire coloured flares or other signals from signal pistols.

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0313	Signals, smoke	1.2 G	See Entry for UN No 0195
0318	Grenades, practice, hand or rifle	1.3 G	Grenades hand or rifle  Articles which are designed to be thrown
	or rifte		
			by hand or to be projected by a rifle. The
			term includes: Grenades practice, hand or rifle.
0319	Primers, tubular	1.3 G	Primers, tubular
			Articles consisting of a primer for
			ignition and an auxiliary charge of
			deflagrating explosive such as black
			powder used to ignite the propelling
			charge in a cartridge case for eg cannon.
0320	Primers, tubular	1.4 G	See Entry for UN No 0319
0333	Fireworks	1.1 G	Fireworks
			Pyrotechnic articles designed for
			entertainment.
0334	Fireworks	1.2 G	See Entry for UN No 0333
0335	Fireworks	1.3 G	See Entry for UN No 0333

TIN NO	NAME and	CLASS/DIVI	GLOSSARY (to be used as a guide for
UN NO	DESCRIPTION	-SION	information only)
0336	Fireworks	1.4 G	See Entry for UN No 0333
0362	Ammunition, practice	1.4G	Ammunition, practice Ammunition without a main bursting charge, containing a burster or expelling charge. Normally it also contains a fuze and a propelling charge.
0363	Ammunition, proof	1.4G	Ammunition, proof  Ammunition containing pyrotechnic substances, used to test the performance or strength of new ammunition, weapon component or assemblies.
0372	Grenades, practice, hand or rifle	1.2 G	See Entry for UN No 0318
0373	Signal devices, hand	1.4 S	See Entry for UN No 0191
0403	Flares, aerial	1.4 G	See Entry for UN No 0092
0418	Flares, surface	1.2 G	See Entry for UN No 0092
0419	Flares, surface	1.1 G	See Entry for UN No 0092
0420	Flares, aerial	1.1 G	See Entry for UN No 0092
0421	Flares, aerial	1.2 G	See Entry for UN No 0092
0424	Projectiles, inert with tracer	1.3 G	Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm.  They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge. The term includes: Projectiles, inert, with tracer; projectiles with burster or expelling charge; projectiles with bursting charge.
0425	Projectiles, inert with	1.4 G	See Entry for UN No 0424

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	tracer		
0428	Articles, pyrotechnic for technical purposes	1.1 G	Articles, pyrotechnic for technical purposes  Articles which contain pyrotechnic substances and are used for technical purposes such as heat generation, gas generation, theatrical effects, etc. The term excludes the following articles which are listed separately: all ammunition; cartridges, signal; cutters, cable, explosive; fireworks; flares, aerial; flares, surface; release devices, explosive; rivets, explosive; signal devices, hand; signals, distress; signals, railway track, explosive; signals, smoke.
0429	Articles, pyrotechnic for technical purposes	1.2 G	See Entry for UN No 0428
0430	Articles, pyrotechnic for technical purposes	1.3 G	See Entry for UN No 0428
0431	Articles, pyrotechnic for technical purposes	1.4 G	See Entry for UN No 0428

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	NAME and	CLASS/DIVI	GLOSSARY (to be used as a guide for
UN NO	DESCRIPTION	-SION	information only)
0434	Projectiles with burster or	1.2 G	Projectiles
	expel-ling charge		Articles such as a shell or bullet which
			are projected from a cannon or other
			artillery gun, rifle or other small arm.
			They may be inert, with or without tracer,
			or may contain a burster or expelling
			charge or a bursting charge. The term
			includes: projectiles, inert, with tracer;
			projectiles with burster or expelling
			charge; projectiles with bursting charge.
0435	Projectiles with burster or	1.4 G	See Entry for UN No 0434
	expelling charge		
0452	Grenades, practice, hand or	1.4 G	See Entry for UN No 0372
	rifle		
0487	Signal, smoke	1.3 G	See Entry for UN No 0194
0488	Ammunition, practice	1.3 G	Ammunition, practice
			Ammunition without a main bursting
			charge, containing a burster or expelling
			charge. Normally it also contains a fuze
			and a propelling charge. The term
			excludes the following articles which are
			listed separately: Grenades, practice.
0492	Signals, railway track,	1.3 G	See Entry for UN No 0194
	explosive		
0493	Signals, railway track,	1.4 G	See Entry for UN No 0194
	explosive		
0503	Air bag inflators, or	1.4G	
	Airbag modules, or seat		
	belt pre-tensioners,		

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UN NO	NAME and	CLASS/DIVI	GLOSSARY to be used as a guide for
	DESCRIPTION	-SION	information only
Group S			
0110	Grenades, practice, hand or rifle	1.4 S	See Entry for UN No 0318
0193	Signals, railway track, explosive	1.4 S	See Entry for UN No 0194
0337	Fireworks	1.4 S	See Entry for UN No 0334
0345	Projectiles, inert with tracer	1.48	Projectiles Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge.
0376	Primers, tubular	1.4 S	See Entry for UN No 0319
0404	Flares, aerial	1.4 S	See Entry for UN No 0092
UN NO	NAME and DESCRIPTION	CLASS/DIVI- SION	GLOSSARY to be used as a guide for information only
0405	Cartridges, signal	1.48	Cartridges, Signal Articles designed to fire coloured flares or other signals from signal pistols, etc.
0432	Articles, pyrotechnic or technical purpose	1.4 S	

## ANNEX II

## **ESSENTIAL SAFETY REQUIREMENTS**

- I. General requirements
- 1. Each explosive must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment under normal, foreseeable conditions, in particular as regards the safety rules and standard practices until it is used.
- 2. Each explosive must attain the performance characteristics specified by the manufacturer in order to ensure maximum safety and reliability.
- 3. Each explosive must be designed and manufactured in such a way that when appropriate techniques are employed it can be disposed of in a manner which minimizes effects on the environment.
- II. Special requirements
- 1. As a minimum, the following information and properties, where appropriate, must be considered or tested:

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- (a) design and characteristic properties, including chemical composition, degree of homogeneity and, where appropriate, dimensions and grain size distribution;
- (b) the physical and chemical stability of the explosive in all environmental conditions to which it may be exposed;
- (c) sensitiveness to impact and friction;
- (d) compatibility of all components as regards their physical and chemical stability;
- (e) the chemical purity of the explosive;
- (f) resistance of the explosive against influence of water where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by water;
- (g) resistance to low and high temperatures, where the explosive is intended to be kept or used at such temperatures and its safety or reliability may be adversely affected by cooling or heating of a component or of the explosive as a whole;
- (h) the suitability of the explosive for use in hazardous environments (e.g. firedamp atmospheres, hot masses) if it is intended to be used under such conditions;

- (i) safety features intended to prevent untimely or inadvertent initiation or ignition;
- (j) the correct loading and functioning of the explosive when used for its intended purpose;
- (k) suitable instructions and, where necessary, markings in respect of safe handling, storage, use and disposal [ ;
- (l) the ability of the explosive, its wrapping or other components to withstand deterioration during storage until the «use by» date specified by the manufacturer;
- (m) specification of all devices and accessories needed for reliable and safe functioning of the explosive.
- 2. Each explosive shall be tested under realistic conditions. If this is not possible in a laboratory, the tests shall be carried out in the conditions in which the explosive is to be used.
- 3. Requirements for the groups of explosives

- 3.1. Blasting explosives shall also comply with the following requirements:
  - (a) the proposed method of initiation must ensure safe, reliable and complete detonation or deflagration as appropriate, of the blasting explosive. In the particular case of black powder, it is the capacity as regards deflagration which shall be checked;
  - (b) blasting explosives in cartridge form must transmit the detonation safely and reliably from one end of the train of cartridges to the other;
  - (c) the fumes produced by blasting explosives intended for underground use may contain carbon monoxide, nitrous gases, other gases, vapours or airborne solid residues only in quantities which do not impair health under normal operating conditions.
- 3.2. Detonating cords, safety fuses, other fuses and shock tubes shall also comply with the following requirements:

- (a) the covering of detonating cords, safety fuses, other fuses *and shock tubes* must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal mechanical stress;
- (b) the parameters for the burning times of safety fuses must be indicated and must be reliably met;
- (c) detonating cords must be capable of being reliably initiated, be of sufficient initiation capability and comply with requirements as regards storage even in particular climatic conditions.
- 3.3. Detonators (including delay detonators) and relays shall also comply with the following requirements:
  - (a) detonators must reliably initiate the detonation of the blasting explosives which are intended to be used with them under all foreseeable conditions of use;
  - (b) delay connectors for detonating cords must be reliably initiated;

- (c) the initiation capability must not be adversely affected by humidity;
- (d) the delay times of delay detonators must be sufficiently uniform to ensure that the probability of overlapping of the delay times of adjacent time steps is insignificant;
- (e) the electrical characteristics of electric detonators must be indicated on the packaging (e.g. no-fire current, resistance);
- (f) the wires of electric detonators must be of sufficient insulation and mechanical strength including the solidity of the link to the detonator, taking account of their intended use.
- 3.4. Propellants and rocket propellants shall also comply with the following requirements:
  - (a) these materials must not detonate when used for their intended purpose;
  - (b) propellants where necessary (e.g. those based on nitrocellulose) must be stabilized against decomposition;
  - (c) solid rocket propellants, when in compressed or cast form, must not contain any unintentional fissures or gas bubbles which dangerously affect their functioning.

# **ANNEX III** CONFORMITY ASSESSMENT PROCEDURES

## **MODULE B**

## EU-type examination

- 1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an explosive and verifies and attests that the technical design of the explosive meets the requirements of this Directive that apply to it.
- 2. EU-type examination shall be carried out as an assessment of the adequacy of the technical design of the explosive through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete product (combination of production type and design type).
- 3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

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The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the explosive's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the explosive. The technical documentation shall contain wherever applicable, at least the following elements:
  - (i) a general description of the explosive;
  - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, *etc.*;
  - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the explosive;

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- (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (v) results of design calculations made, examinations carried out, etc.;
- (vi) test reports;
- (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out *in accordance with other relevant technical specifications* by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the explosive:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the explosive.

For the specimen(s):

- 4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards , as well as the elements which have been designed *in accordance with other relevant technical specifications*;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards , these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer *applying other relevant technical specifications* meet the corresponding essential safety requirements of this Directive;

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- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
- 5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
- 6. Where the type meets the requirements of this Directive *that apply to the explosive concerned*, the notified body shall issue an EU-type examination certificate to the manufacturer. *That* certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The *EU-type examination* certificate may have one or more annexes attached.

The *EU-type examination* certificate and its annexes shall contain all relevant information to allow the conformity of manufactured *explosives* with the examined type to be evaluated and to allow for in-service control.

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

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

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

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

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Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and /or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning *such* certificates and/or additions thereto which it has issued.

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

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

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10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

### MODULE C 2

Conformity to type based on internal production control plus supervised product checks at random intervals

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the explosives concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

# 2. Manufacturing

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

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### 3. Product checks

A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by *that* body, in order to verify the quality of the internal checks on the explosive, taking into account, *inter alia*, the technological complexity of the explosives and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or equivalent tests *set out in other relevant* technical specifications, shall be carried out to check the conformity of the explosive with the type described in the EU-type examination certificate and with the relevant requirements of this Directive. Where a sample does not conform to the acceptable quality level, the *notified* body shall take appropriate measures.

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

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

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- 4. **CE** marking and **EU** declaration of conformity
- 4.1. The manufacturer shall affix the *CE* marking to each individual *explosive* that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written *EU* declaration of conformity for *each explosive type* and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive *type* for which it has been drawn up.

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

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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### **MODULE D**

Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the explosives concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

#### 2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the explosives concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

#### 3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the explosives concerned.

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The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the explosive category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.
- 3.2. The quality system shall ensure that the explosives are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

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It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality ;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, *etc.*;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of \bigcup the relevant harmonised standard \bigcup.

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In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point (*e*) of point 3.1 to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the explosive with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

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- It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
- 4. Surveillance under the responsibility of the notified body
- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, *etc.*
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

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- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
- 5. **CE** marking and **EU** declaration of conformity
- 5.1. The manufacturer shall affix the *CE* marking , and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual *explosive* that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written *EU* declaration of conformity for each *explosive type* and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The *EU* declaration of conformity shall identify the explosive *type* for which it has been drawn up.

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

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- 6. The manufacturer shall, for a period ending 10 years after the explosive has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1;
  - (b) the *information relating to the* change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
- 7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## **MODULE E**

Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the explosives concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

#### 2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the explosives concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

#### 3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the explosives concerned.

The application shall include:

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- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the *explosive* category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.
- 3.2. The quality system shall ensure compliance of the explosives with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

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- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) *the* quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc;
- (d) the means of monitoring the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in *point* 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of  $\blacksquare$  relevant harmonised standard  $\blacksquare$ .

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point (e) of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the explosive with those requirements.

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- The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 4. Surveillance under the responsibility of the notified body
- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, *etc*.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
- 5. *CE* marking and *EU* declaration of conformity

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- 5.1. The manufacturer shall affix the *CE* marking , and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual *explosive* that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written *EU* declaration of conformity for each *explosive type* and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The *EU* declaration of conformity shall identify the explosive *type* for which it has been drawn up.

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

- 6. The manufacturer shall, for a period ending 10 years after the explosive has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1;
  - (b) the *information relating to* the change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

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- 7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.
  - Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

# 8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## **MODULE F**

Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the explosives concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

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#### 2. Manufacturing

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

#### 3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the explosives with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the explosives with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 4 or by examination and testing of the explosives on a statistical basis as specified in point 5.

Verification of conformity by examination and testing of every product 4.

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- 4.1. All explosives shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.
- 4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved explosive or have it affixed under its responsibility.
  - The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the explosive has been placed on the market.
- 5 Statistical verification of conformity
- 5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his explosives for verification in the form of homogeneous lots.

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- 5.2. A random sample shall be taken from each lot . All explosives in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.
- 5.3. If a lot is accepted, all explosives of the lot shall be considered approved, except for those explosives from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved *explosive* or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the explosive has been placed on the market.

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- 5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent the placing on the market of that lot. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.
- 6. CE marking and *EU* declaration of conformity
- 6.1. The manufacturer shall affix the *CE* marking , and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual *explosive* that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 6.2. The manufacturer shall draw up a written *EU* declaration of conformity for each *explosive type* and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The *EU* declaration of conformity shall identify the explosive *type* for which it has been drawn up.

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

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the explosives.

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If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the explosives during the manufacturing process.

# 7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

### **MODULE G**

Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the explosive concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

### 2. Technical documentation

2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the explosive's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the explosive. The technical documentation shall, wherever applicable, contain at least the following elements:

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- (a) a general description of the explosive;
- conceptual design and manufacturing drawings and schemes of components, sub-(b) assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the explosive;
- a list of the harmonised standards applied in full or in part the references of which (d) have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc., and
- (f) test reports.
- 2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the explosive has been placed on the market.

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## 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured *explosive* with the applicable requirements of this Directive.

### 4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests *set out in other relevant* technical specifications, to check the conformity of the explosive with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved explosive, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the explosive has been placed on the market.

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- 5. **CE** marking and **EU** declaration of conformity
- 5.1. The manufacturer shall affix the *CE* marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each explosive that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive for which it has been drawn up.

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

6. Authorised representative

> The manufacturer's obligations set out in points 2.2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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### ANNEX IV

## EU DECLARATION OF CONFORMITY (No XXXX)<sup>1</sup>

- 1. No ... (product, type, batch or serial number):
- 2. Name and address of the manufacturer and, where applicable, his authorised representative:
- *3*. This declaration of conformity is issued under the sole responsibility of the manufacturer.
- 4. Object of the declaration (identification of product allowing traceability):
- The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
- References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
- 7. The notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
- 8. Additional information: Signed for and on behalf of: (place and date of issue): (name, function) (signature):

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It is optional for the manufacturer to assign a number to the declaration of conformity.

### ANNEX V

## Part A

# Repealed Directives with list of the successive amendments thereto (referred to in Article 53)

Council Directive 93/15/EEC

(OJ L 121, 15.5.1993, p. 20)

Regulation (EC) No 1882/2003 of the

Only point 13) of Annex II

European Parliament and of the

**Council** 

(OJ L 284, 31.10.2003, p. 1)

Regulation (EC) No 219/2009 of the

Only point 2.2 of the Annex

European Parliament and of the

**Council** 

(OJ L 87, 31.3.2009, p. 109)

Regulation (EU) No 1025/2012 of the

Only point (b) of Article 26(1)

European Parliament and of the

Council

(OJ L 316, 14.11.2012, p. 12)

Commission Directive 2004/57/EC

(OJ L 127, 29.4.2004, p. 73)

Part B Time-limits for transposition into national law and dates of application (referred to in Article 53)

Directive	Time-limit for transposition	Date of application
93/15/EEC (articles 9, 10, 11, 12, 13 and 14)	30 September 1993	30 September 1993
93/15/EEC (all other articles)	30 June 1994	1 January 1995
2004/57/EC	31 December 2004	<i>31 January 2005</i>

# ANNEX VI Correlation table

Directive 93/15/EEC	Directive 2004/57/EC	This Directive
Article 1(1)		Article 1(1)
Article 1(2)		Article 2(1)
Article 1(3)		Article 1(2)
Article 1(4)		Article 2(3) to (6), (8), (13) and (14)
-		Article 2(2), (7), (9) to (12) and (15) to (24)
Article 1(5)		Article 1(3)
Article 2(1)		Article 3
Article 2(2)		Article 4
Article 2(3)		Article 22
Article 3		Article 4 and Article 5(1)
-		Article 5(2) to (8)
-		Article 6
-		Article 7
-		Article 8
-		Article 9
		Article 10
Article 4(1)		Article 19

Article 4(2)	-
Article 5	Article 43(3)
Article 6(1)	Article 20
-	Article 21
-	Articles 24 to 27
Article 6(2)	Articles 28 to 40

Article 7(1)	Articles 22 and 23
Article 7(2)	Article 22
Article 7(3)	Article 22
-	Article 41
Article 8(1)	Articles 42 and 44
Article 8(2)	Article 43
Article 8(3)	Article 45
Article 9(1)	Article 11(1)
Article 9(2)	-
Article 9(3)	Article 11(2)
Article 9(4)	Article 11(3)

Article 9(5)	Article 11(4)
Article 9(6)	Article 11(6)
Article 9(7)	Article 11(5)
Article 9(8)	Article 11(7)
Article 9(9)	Article 11(8)
Article 10(1)	Article 12(1)
Article 10(2)	Article 12(2)
Article 10(3)	Article 12(3)
Article 10(4)	Article 12(4)
Article 10(5)	Article 12(5)
Article 11	Article 13

Article 12(1)	Article 14(1)
Article 12(2)	Article 14(2)
Article 13(1)	Article 49(1)
Article 13(2)	-
Article 13(3)	Articles 46 and 47
_	Article 48
Article 13(4)	Article 49(2) to (5)
Article 13(5)	Articles 46 and 47
Article 14, first paragraph	Article 16
Article 14, second paragraph	Article 15(1) and (4)
Article 14, third paragraph	Article 15(2) and (4)
Article 14, fourth paragraph	Article 15(3)

Article 15		-
Article 16		Article 17
Article 17		Article 50
Article 18		Article 18
Article 19		Articles 51 and 52
-		Article 53
-		Article 54
Article 20		Article 55
	Article 1	-
	Article 2	-
	Article 3	-
	Article 4	-
	Article 5	-
	Annex I	Annex I
	Annex II	-
Annex I		Annex II
Annex II		Annex III
Annex III		Article 28
Annex IV		Article 22
-		Annex IV
-		Annex V

	-		Annex VI
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## ANNEX TO THE LEGISLATIVE RESOLUTION

## STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as "comitology committees" within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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