EUROPEAN COMMISSION



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2011/0349 (COD)

NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT 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

(Recast)

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

This proposal is presented in the framework of the **implementation of the "goods package"** adopted in 2008. It is part of a package of proposals aligning ten product directives to Decision No 768/2008/EC establishing a common framework for the marketing of products.

Union (EU) harmonisation legislation ensuring the free movement of products has contributed considerably to the completion and operation of the Single Market. It is based on a high level of protection and provides economic operators with the means to demonstrate conformity, thus ensuring free movement through trust in the products.

Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses is an example of that Union harmonisation legislation, ensuring the free movement of explosives. It sets out essential safety requirements that explosives must comply with in order to be made available on the EU market. Manufacturers must demonstrate that an explosive has been designed and manufactured in compliance with the essential safety requirements and affix the CE marking.

Experience with the implementation of Union harmonisation legislation has shown – on a cross-sector scale – certain weaknesses and inconsistencies in the implementation and enforcement of this legislation, leading to:

- the presence of non-compliant or dangerous products on the market and consequently a certain lack of trust in CE marking;
- competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules;
- unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices;
- differing practices in the designation of conformity assessment bodies by national authorities;
- problems with the quality of certain notified bodies.

Furthermore the regulatory environment has become more and more complex, as frequently several pieces of legislation apply simultaneously to one and the same product. Inconsistencies in these pieces of legislation make it increasingly difficult for economic operators and authorities to correctly interpret and apply that legislation.

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the "New Legislative Framework" was adopted in 2008 as part of the goods package. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, Regulation (EC) No

765/2008 on accreditation and market surveillance and Decision No 768/2008 establishing a common framework for the marketing of products.

The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc.). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The provisions of the NLF Decision and those of the NLF Regulation are complementary and closely interlinked. The NLF Decision contains the corresponding obligations for economic operators and notified bodies allowing market surveillance authorities and authorities responsible for notified bodies to properly perform the tasks imposed on them by the NLF Regulation and to ensure an effective and consistent enforcement of EU product legislation.

However, unlike the NLF Regulation, the provisions of the NLF Decision are not directly applicable. To ensure that all economic sectors subject to Union harmonisation legislation benefit from the improvements of the NLF, the provisions of the NLF Decision need to be integrated into the existing product legislation.

A survey after the adoption of the goods package in 2008 showed that a majority of Union harmonisation legislation on products was due to be revised within the following 3 years, not only to address the problems observed throughout all sectors but also for sector-specific reasons. Any such revision would automatically include an alignment of the legislation concerned to the NLF Decision since Parliament, Council and Commission have committed themselves to use its provisions as much as possible in future legislation on products in order to further the utmost coherence of the regulatory framework.

For a number of other Union harmonisation directives, including Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance and notified bodies are nevertheless addressed in these sectors, and for the sake of consistency of the overall regulatory environment on products, it was decided to align these directives within a package to the provisions of the NLF Decision.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act¹, which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

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Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

The alignment of Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses to the NLF Decision has been discussed with the national experts responsible for the implementation of this Directive in the explosives working group, the Forum of notified bodies as well as in bilateral meetings with industry associations.

From June to October 2010 a public consultation was organised that comprised all the sectors involved in this initiative. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and the Commission services received 300 replies. The results are published at:

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

In addition to the general consultation a specific SME consultation was carried out. 603 SMEs were consulted through the Enterprise Europe Network in May/June 2010. The results are available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes_statistics_en.pdf

The consultation process revealed widespread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation. Certain concerns were expressed on some obligations which are, however, indispensable for increasing the efficiency of market surveillance. These measures will not entail significant costs for industry, and the benefits resulting from improved market surveillance should by far outweigh the costs.

Collection and use of expertise

The impact assessment for this implementation package has largely built on the impact assessment carried out for the New Legislative Framework. In addition to the expertise collected and analysed in that context, further consultation of sector-specific experts and interest groups, as well as horizontal experts active in the area of technical harmonisation, conformity assessment, accreditation and market surveillance, has taken place.

Impact assessment

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.

Option 1 – No changes to the current situation

This option proposes no changes to the current directive and relies exclusively on certain improvements that can be expected from the NLF Regulation.

Option 2 – Alignment to the NLF Decision by non-legislative measures

Option 2 considers the possibility of encouraging a voluntary alignment to the provisions set out in the NLF Decision by, e.g., presenting them as best practices in guidance documents.

Option 3 – Alignment to NLF Decision by legislative measures

This option consists in integrating the provisions of the NLF Decision into the existing directives.

Option 3 was found to be the preferred option because:

- it will improve the competitiveness of companies and notified bodies taking their obligations seriously, as opposed to those cheating on the system;
- it will improve the functioning of the internal market by ensuring equal treatment of all economic operators, notably importers and distributors, as well as notified bodies;
- it does not entail significant costs for economic operators and notified bodies; for those who are already acting responsibly, no extra costs or only negligible costs are expected;
- it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;
- options 1 and 2 do not provide answers to the problem of inconsistencies in the regulatory framework and therefore have no positive impact on the simplification of the regulatory environment.

3. MAIN ELEMENTS OF THE PROPOSAL

Horizontal definitions

The proposal introduces harmonised definitions of terms which are commonly used throughout Union harmonisation legislation and should therefore be given a consistent meaning throughout that legislation.

3.1. Obligations of economic operators and traceability requirements

The proposal clarifies the obligations of manufacturers and authorised representatives and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that the explosives are correctly marked and accompanied by the required instructions and safety information. They must keep a copy of the Declaration of conformity and ensure that the explosives bear a unique identification in accordance with Directive 2008/43/EC. Distributors must verify that the explosive bears the CE marking, the unique identification and that it is accompanied by the required documentation and instructions.

Importers and distributors must cooperate with market surveillance authorities and take appropriate actions when they have supplied non-compliant explosives.

3.2. Harmonised standards

Compliance with harmonised standards provides a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation² that sets out a horizontal legal framework for European standardisation. The proposal for the Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisations, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 93/15/EEC which cover the same aspects have been deleted in this proposal for reasons of legal certainty.

The provision conferring presumption of conformity to harmonised standards has been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential requirements.

3.3. Conformity assessment and CE marking

Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their explosives comply with the essential safety requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision.

General principles of the CE marking are set out in Article 30 of Regulation 765/2008, while the detailed provisions on the affixing of the CE marking to explosives have been inserted in this proposal.

3.4. Notified Bodies

The proposal reinforces the notification criteria for notified bodies. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements for notifying authorities are introduced, and the procedure for notification of notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. Where accreditation has not been used to evaluate the competence of a notified body, the notification must comprise the documentation demonstrating how the competence of that body has been evaluated. Member States will have the possibility to object to a notification.

3.5. Market surveillance and the safeguard clause procedure

The proposal revises the existing safeguard clause procedure. It introduces a phase of information exchange between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant explosive is found. A real safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or

COM(2011) 315 final - Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council.

not – is only launched when another Member State objects to a measure taken against an explosive. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

3.6. Comitology

The provisions on the operation of the Explosives Committee have been adapted to the new provisions on implementing acts laid down in 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 the Member States of the Commission's exercise of implementing powers³.

4. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

Subsidiarity principle

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses, namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of notified bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objective of this directive. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. In view of the increasing internationalisation of trade, the number of cross-border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and the general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

The new or modified obligations do not impose unnecessary burdens and costs on industry – especially on small and medium sized enterprises – or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

Legislative technique used

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Council Directive 93/15/EEC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts⁴.

The changes made to the provisions of Council Directive 93/15/EEC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, notified bodies, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope of Council Directive 93/15/EEC and the essential safety requirements.

5. BUDGETARY IMPLICATIONS

This proposal does not have any implications for the EU budget.

6. ADDITIONAL INFORMATION

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Council Directive 93/15/EEC on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses.

European Economic Area

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

⁴ OJ C 77, 28.3.2002, p.1.

Ψ 93/15/EEC (adapted)	
⇒ new	

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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 ⊠ establishing the European Economic Community, and in particular Article \(\simega\) 114 \(\simega\) 100a 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 Committee⁵,

Acting in accordance with the ordinary legislative procedure,

Whereas:

new

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 uses⁶ has been substantially amended several times. Since further amendments are to be made, it should be recast in the interests of clarity.

OJ C [], [], p. [] OJ L 121, 15.5.1993, p. 20.

- (2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁷ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC⁸, lays down common principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 93/15/EEC should be adapted to that Decision.

▶ 93/15/EEC recital 1 (adapted)

Whereas Article 8a of the Treaty provides that the internal market must be established not later than 31 December 1992; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaty;

▶ 93/15/EEC recital 2 (adapted)

Whereas Article 100a (3) of the Treaty provides that the Commission, in its proposals concerning safety, will take as a base a high level of protection;

♦ 93/15/EEC recital 9 (adapted) ⇒ new

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 which sets out safety requirements for establishments where explosives are present. ☐ As regards Seafety, the rules concerning the transport of explosives ☑ during transport is regulated ☑ are covered by international conventions and agreements. ☑ including the ☑ At international level, there are United Nations recommendations on the transport of dangerous goods. ☑ Those aspects should therefore not fall under the scope of this Directive ☑ (including explosives), the scope of which extends beyond the Community framework. In consequence, this Directive does not concern the transport rules.

OJ L 218, 13.8.2008, p. 30. OJ L 218, 13.8.2008, p. 82.

⁹ OJ L 10, 14.1.1997, p. 13.

♦ 93/15/EEC recital 12 (adapted) **♦** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

(5) The scope of this Directive eovers \boxtimes should cover \boxtimes 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 $\Rightarrow_1^{10} \leftarrow$.

▶ 93/15/EEC recital 10 (adapted)

(6) Pyrotechnical articles require appropriate measures to ensure the protection of consumers and the safety of the public. An additional directive is planned in this field.

□ Pyrotechnic articles are covered by Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles 11. This Directive should therefore not apply to pyrotechnic articles. □

◆ 93/15/EEC recital 11 (adapted)

(7) The definition of the ⊠ explosives ⊠ products covered by this Directive should be based on the definition of such products as set out in the ⊠ United Nations ⊠ abovementioned recommendations ⊠ on the transport of dangerous goods ⊠.<u>±</u>

♦ 93/15/EEC recital 3 (adapted) ⇒ new

(8)

☑ In order to ensure ☑ The free movement of goods presupposes that certain basic conditions—are—fulfilled.In—particular, the free movement of explosives ☑ it is necessary to harmonise ☑ presupposes harmonization of ☑ the ☑ laws ☑ relating to ☑ on the placing of ☑ making ☑ explosives ☑ available ☑ on the market.

◆ 93/15/EEC recital 4

Whereas explosives for civil uses are covered by detailed national regulations, mainly in respect of safety and security requirements; whereas such national regulations provide, in particular, that marketing authorizations be granted only where explosives have satisfactorily undergone a series of tests;

OJ L 256, 13.9.1991, p. 51.

OJ L 154, 14.6.2007, p. 1.

▶ 93/15/EEC recital 5 (adapted)

Whereas harmonization of provisions governing the placing of such explosives on the market presupposes that divergent national rules will be harmonized in order to ensure the free movement of these products without lowering optimum levels of safety and security;

▶ 93/15/EEC recital 6 (adapted)

Whereas this Directive defines only the essential requirements which must be met by explosives conformity tests; whereas, in order to facilitate the process of demonstrating compliance with the essential requirements, it would be very useful to process standards harmonized at European level concerning, inter alia, methods for testing explosives; whereas such standards do not exist at present;

▶ 93/15/EEC recital 7 (adapted)

Whereas standards harmonized at European level are drawn up by private bodies and must retain their status as non-mandatory text; whereas, in this connection, the European Committee for Standardization (CEN) has been recognized as one of the two bodies competent to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and CEN and Cenelce, ratified on 13 November 1984; whereas, for the purposes of this Directive, «harmonized standard» means a text setting out technical specifications adopted by CEN under a mandate conferred by the Commission, in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations and in keeping with the abovementioned general guidelines;

♦ 93/15/EEC recital 13

the health and safety of workers producing or using explosives must also be protected; whereas an additional directive is in the course of preparation covering, inter alia, the health and safety of workers engaged in activities relating to the manufacture, storage and use of explosives;

new

(9) Economic operators should be responsible for the compliance of explosives, 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.

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OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Commission Decision 90/230/EEC (OJ No L 128, 18. 5. 1990, p. 15).

- (10) 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 operator in the supply and distribution process.
- (11) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.
- (12) It is necessary to ensure that explosives from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate 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 and documentation of explosives drawn up by manufacturers are available for inspection by the supervisory authorities.
- (13) 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.
- (14) Any economic operator that either places an explosive on the market under his own name or trademark or modifies an explosive in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (15) 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.
- (16) 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 products available on the market.
- (17) The provisions of this Directive relating to the making available on the market should be based on the expression of essential safety requirements for explosives in order to protect users and to prevent accidents. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for explosives which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No [../..] of the European Parliament and of the

Council of [.....] on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council for the purpose of expressing detailed technical specifications for the design, manufacture and testing of explosives¹³.

(18) (EU) No [../..] [Standardisation Regulation] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy requirements of this Directive.

▶ 93/15/EEC recital 8 (new)

the Council, in its Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives introduced harmonized means of applying procedures for conformity assessment; whereas the application of these modules to explosives will make it possible to determine the responsibility of manufacturers and of bodies responsible for applying procedures for conformity assessment by taking account of the nature of the explosives concerned;

new

- (19) 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 ad-hoc 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 verification EU type examination. Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of an explosive with the requirements of the relevant Union harmonisation legislation.
- (20) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (21) 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.

OJ C [], [], p. []

OI No I 380 31 12 1000 p 13

- 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.
- (23) 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.
- (24) 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.
- (25) 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.
- (26) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, 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 this 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.
- (27) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the products to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (28) 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.
- (29) 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.
- (30) 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.

- 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.
- (32) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to products presenting a risk to the health and safety of persons or to other aspects of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.
- (33) 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.

▶ 93/15/EEC recital 14 (adapted)

[34] It is appropriate Lin the case of a serious threat to, or attack on, public Security as a result of Seafety by reason of the illicit possession or use of explosives or ammunition falling within this Directive, to allow Member States Seafety should be allowed Seafety to derogate, under certain conditions, from the provisions of this Directive with regard to transfer Seafety of explosives and ammunition in order to prevent such illicit possession or use Seafety.

▶ 93/15/EEC recital 15 (adapted)

(35) Finally, Lit is essential to establish administrative cooperation mechanisms ➤ between competent authorities of Member States ☒. ☒ Therefore, ☒ Lit is appropriate in this connection for the competent authorities ☒ should ☒ to base their approach on Council Regulation (EEC) No 1468/81 of 19 May 1981 (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 and ☒ or ☒ agricultural matters¹5.

OJ L 144, 2.6.1981, p. 1 82, 22.3.1997, p.1.

◆ 93/15/EEC recital 16 (adapted)

(36) This Directive does ★ should ★ not affect the power of Member States to take measures with a view to preventing illegal trade in explosives and ammunition.

new

- (37) 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 the Member States of the Commission's exercise of implementing powers¹⁶.
- (38) The examination procedure should be used for the adoption of the implementing acts in order to set up the conditions for a system for identification and keeping track of explosives.
- (39) 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 adopting 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.
- (40) 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 Council.
- (41) The Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (42) Since the objective of this Directive, namely to ensure that explosives on the market fulfil the requirements providing 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 and can therefore, 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.
- (43) It is necessary to provide for transitional arrangements that allow making available on the market explosives that have already been placed on the market in accordance with Directive 93/15/EEC.

-

OJ L 55, 28.2.2011, p.13.

- The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with Directive 93/15/EEC. The obligation to transpose the provisions which are unchanged arises under Directive 93/15/EEC.
- (45) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of Directive 93/15/EEC.

♦ 93/15/EEC (adapted)

 $HAS \boxtimes HAVE \boxtimes ADOPTED THIS DIRECTIVE:$

CHAPTER 11

GENERAL PROVISIONS

1. This Directive shall apply to

the following:

explosives as defined in paragraph 2.

new

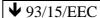
- (a) explosives for civil uses;
- (b) transfer of ammunition and information exchange on those transfers referred to in Articles 12, 13 and 14.

♦ 93/15/EEC

<u>32</u>. This Directive shall not apply to:

♦ 93/15/EEC (adapted)

- (a) explosives \boxtimes and \boxtimes ; including ammunition, intended for use, in accordance with national law, by the armed forces or the police:
- (b) pyrotechnical articles ⊠ falling within the scope of Directive 2007/23/EC. ⊠



ammunition, except as provided in Articles 10, 11, 12, 13, 17, 18 and 19.

♥ 93/15/EEC (adapted)

⇒ new

<u>§3</u>. This Directive shall not prevent Member States from designating certain substances not covered by this Directive as explosives under national law ⊠ laws ⊠ or regulations.

<u>Article 2</u> [Article R1 of Decision No 768/2008/EC] **∑ Definitions ∑**

 $\underline{4}$ For the purposes of this Directive \boxtimes the following definitions shall apply \boxtimes :

- (1) \(\frac{2}{\text{\tin}}}}}}}}}} mmeans}}}} \exectiting \text{\ti}}}}}}}}}} mmeans}}}} minimal}} encounty} encounty} encounty} en
- (3) <u>**</u>safety<u>**</u> shall mean ⊠ means ⊠ the prevention of accidents and, where prevention fails, the containment of their effects:
- $(\underline{4})$ $\underline{\underline{`}}$ security $\underline{\underline{`}}$ shall mean \boxtimes means \boxtimes the prevention of use contrary to law and order:
- (5) <u>'*dealer'* shall mean</u> ⊠ 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.
- (6) <u>**approval** shall mean</u> ⊠ means ⊠ the decision taken to allow envisaged transfers of explosives within the ⊠ Union ⊠ Community*; =
- wundertaking in the explosives sectors ⇒ 'economic operators' ⇒ shall mean ⇒ means ⋈ ⇒ the manufacturer, the authorised representative, the importer, the distributor and ⇔ any natural or legal person possessing a licence or authorization which entitles him to ⋈ who engages ⋈ engage in the manufacture, storage, use, transfer, ⇒ export ⇔ or trade ⋈ of ⋈ im explosives; transfer, ⇒ export ⇔ or trade ⋈ of ⋈ im explosives;
- (8) <u>**</u> 'transfer' <u>**</u> * shall mean ⊠ means ⊠ any physical movement of explosives within ⊠ the Union ⊠ Community territory ⊠ except ⊠ apart from movements within one and the same site; <u>*</u>

(9) ** 'placing ⇒ making available ⇔ on the market'* shall mean ⊗ means ⊗ any first disposal against payment or free of charge ⇒ supply ⇔ of ⊗ an explosive ⊗ explosives eovered by this Directive ⊗ for ⊗ with a view to their distribution and/or use on the Community ⊗ Union ⊗ market ⇒ in the course of a commercial activity, whether in return for payment or free of charge; ⇔ ₹

new

- (10) 'placing on the market' means the first making available of an explosive on the Union market;
- (11) 'manufacturer' means any natural or legal person who manufactures an explosive or has an explosive designed or manufactured, and markets explosives under his name or trademark;
- (12) '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;
- (13) 'importer' means any natural or legal person established within the Union who places explosives from a third country on the Union market;
- (14) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes explosives available on the market;
- (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 Article 2(1)(c) of Regulation (EU) No [../..] [Standardisation Regulation];
- (17) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
- 'national accreditation body' means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;
- (19) 'conformity assessment' means the process demonstrating whether the essential safety requirements 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) 'CE marking' means a marking by which the manufacturer indicates that the explosive is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (24) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

♦ 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

⇒ new

CHAPTER II

HARMONIZATION OF LAWS RELATING TO EXPLOSIVES

Article <u>32</u> **➣ Free movement ≪**

 \pm Member States may not prohibit, restrict or hinder the placing \Rightarrow making available \Leftarrow on the market of explosives which fall within the scope of this Directive and which satisfy the requirements of this Directive.

- Emalth 2 Member States shall take the necessary measures to ensure that explosives falling within the scope of this Directive may be \Rightarrow made available \Leftrightarrow placed on the market only if they comply with all the provisions of this Directive, are provided with the CE marking described in Article 7 and their conformity → 1 has been assessed ← in accordance with the procedures referred to in Annex II.
- 3. Where explosives falling within the scope of this Directive are subject to other Directives which cover other aspects and prescribe the fixing of the CE marking, this marking shall indicate that the abovementioned products are also presumed to conform to the provisions of these other directives which apply to them.

Article 3

Explosives falling within the scope of this Directive must comply with the essential safety \Rightarrow all the \Leftrightarrow requirements \boxtimes of this Directive \boxtimes set out in Annex I which apply to them.

CHAPTER 2

☒ OBLIGATIONS OF ECONOMIC OPERATORS **☒**

Member States shall keep at the disposal of the other Member States and the Commission updated information concerning undertakings in the explosives sector possessing licences or authorizations as referred to in Article 1(4).

new

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 6 [Article R2 of Decision No 768/2008/EC] **Obligations of manufacturers**

- 1. When placing explosives on the market or when using explosives themselves, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.
- 2. Manufacturers shall draw up the technical documentation referred to in Annex II and carry out the conformity assessment procedure referred to in Article 19 or have it 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.

The CE marking does not need to be affixed on explosives manufactured for own use, explosives transported and delivered unpackaged or in pump trucks for their direct unloading into the blast-hole, and explosives manufactured at the blasting sites which are loaded immediately after being produced (so-called in situ production).

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

- 5. Manufacturers shall ensure that their explosives bear the unique identification in accordance with Commission Directive 2008/43/EC¹⁷.
- 6. Manufacturers shall ensure that their explosives 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.
- 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 necessary corrective measures 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 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 necessary to demonstrate the conformity of the explosive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have placed on the market.

Article 7 [Article R3 of Decision No 768/2008/EC] Authorised representatives

- 1. A manufacturer may, by a written mandate, appoint an authorised representative.
 - The obligations laid down in Article 6(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.
- 2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the explosive has been placed on the market;
 - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an explosive;
 - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by explosives covered by the authorised representative's mandate.

OJ L 94, 5.4.2008, p. 8.

Article 8 [Article R4 of Decision No 768/2008/EC] Obligations of importers

- 1. Importers shall place only compliant explosives on the market.
- 2. Before placing an explosive on the market importers shall ensure that the appropriate conformity assessment procedure 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.

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 I, 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 ensure that the explosives imported by them bear a unique identification in accordance with Directive 2008/43/EC.
- 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, storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.
- 6. Importers who consider or have reason to believe that an explosive which they have placed on the market is not in conformity with the requirements of 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 to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
- 7. Importers shall, for at least 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 necessary to demonstrate the conformity of an explosive in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have placed on the market.

Article 9 [Article R5 of Decision No 768/2008/EC] **Obligations of distributors**

- 1. When making an explosive available on the market distributors shall act with due care in relation to the requirements of this Directive.
- 2. Before making an explosive available on the market distributors shall verify that the explosive bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by end-users in the Member State in which the explosive is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Directive 2008/43/EC.

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 I, 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, storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.
- 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 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 necessary to demonstrate the conformity of an explosive. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have made available on the market.

Article 10

Cases in which obligations of manufacturers apply to importers and distributors

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

CHAPTER 3HH

SECURITY Provisions COVERNING THE SUPERVISION OF TRANSFERS IN THE COMMUNITY

Article <u>119</u> **☒ Transfers of explosives ☒**

1. Explosives eovered by this Directive may be transferred only in accordance with the following paragraphs \boxtimes 2 to 8 \boxtimes .

♦ 93/15/EEC

2. Controls performed pursuant to Community law or national law in the event of transfers of the explosives governed by this Article shall no longer be performed as internal frontier controls but solely as part of the normal control procedures applied in a non-discriminatory fashion throughout the territory of the Community.

♦ 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

⇒ new

- Approval to transfer explosives shall be obtained by the consignee from the recipient competent authority in the Member State of the recipient in 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 authorised ations. The person responsible for the transfer must notify the competent authorities of the transit Member State in State in State in the Member States of in the states of explosives through in the Member States concerned in this or these States, whose in and shall obtain prior in approval shall be required in the transit Member States in the states of the transit Member States in the states in th
- 34. Where a Member State considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in paragraph 23, that Member State shall forward the available information on the subject to the Commission which ⇒ shall inform the other Member States thereof ⇒ will put the matter before the Committee provided for in → 1 Article 13 ← without delay.
- Where the recipient competent authority \boxtimes in the Member State of the recipient \boxtimes approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph $\underline{57}$. Such a document must accompany the

explosives until they arrive at their stated destination. It must be produced at the request of the relevant competent authorities. A copy of \boxtimes that \boxtimes this document shall be retained by the consignee who shall present it \boxtimes , upon request, \boxtimes for examination by the recipient competent authority at the latter's request \boxtimes in the Member State of the recipient \boxtimes .

▶ 93/15/EEC (adapted)

<u>57</u>. 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 recipient competent authority ⊠ in the Member State of the recipient ⊠:

♦ 93/15/EEC (adapted)

(a) the names and addresses of the operators concerned; this information must be detailed enough to enable the operators to be contacted and confirmation to be obtained that the persons in question are legally entitled to receive the consignment,

♦ 93/15/EEC **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

- (b) the number and quantity of the explosives being transferred;
- (c) a full description of the explosive in question and of the means of identification, including the United Nations identification number;
- (d) where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;
- (e) the means of transfer and the itinerary;
- (f) the expected dates of departure and \rightarrow_1 arrival $\leftarrow_{\underline{:}\underline{:}}$
- (g) where necessary, the precise points of entry to and exit from Member States.

♦ 93/15/EEC (adapted) **♦** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34 **⇒** new

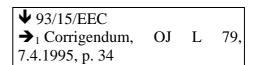
➤ The information referred to in point (a) of the first subparagraph must be detailed enough to enable the operators to be contacted and confirmation to be obtained that the persons concerned are entitled to receive the consignment. <

Recipient \boxtimes The \boxtimes competent \boxtimes authority \boxtimes authorities \boxtimes in the Member State of the recipient \boxtimes 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 \boxtimes case \boxtimes event of transit through the territory of other Member States, those \boxtimes Member \boxtimes States shall likewise examine and approve, in the same conditions, the particulars concerning the transfer.

- 6. Where the competent authority of a Member State considers that special security requirements such as those referred to in paragraph ₹4 → and 5 ← are unnecessary, explosives ean ⋈ may ⋈ be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph ₹₹. The recipient competent authority ⋈ in the Member State of the recipient ⋈ shall then grant an approval for a fixed period, ⋈ which is ⋈ and liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph ₹₹, which must accompany the explosives until they arrive at their destination, shall refer solely to ⋈ that ⋈ the abovementioned approval.
- <u>7\frac{3}{8}</u>. Without prejudice to the normal checks which the Member State of departure shall carry out in its territory, at the request of the competent authorities concerned, the consignees and the ≥ economic ≥ operators concerned in the explosives sector shall forward to the authorities of the Member State of departure and to those of the Member State of transit all relevant information they →₁ possess ← concerning the transfer of explosives.
- 89. No supplier may transfer explosives unless the consignee has obtained the necessary authorise ations for the transfer in accordance with the provisions of \rightarrow_1 paragraphs \leftarrow 23, 45, 56 and 67.

Article <u>1210</u> **➣ Transfers of ammunition ☒**

1. Ammunition may be transferred from one Member State to another only in accordance with the procedure laid down in the following paragraphs ≥ 2 to 5 ≥ 1. These ≥ Those ≥ provisions ≥ 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:
 - 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 \rightarrow_1 address \leftarrow to which the ammunition is to be consigned or transported;
 - (c) the quantity of ammunition to be consigned or transported;
 - data making it possible to identify the ammunition and also an indication that the ammunition has undergone a check in accordance with the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms;
 - (e) the means of transfer:
 - (f) the date of departure and the estimated date of arrival.

◆ 93/15/EEC (adapted)

The information referred to in the last two indents points (e) and (f) of the first subparagraph need not be supplied in the case case 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: Lit shall be produced whenever so required by the competent authorities of the Member States.

♦ 93/15/EEC

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 authoriszation referred to in paragraph 2. To that end it shall issue an authoriszation valid for three years which may at any time be suspended or cancelled by reasoned decision. A document referring to that authoriszation must accompany the ammunition until it reaches its destination. It must be produced whenever so required by the competent authorities of the Member States.

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

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

▶ 93/15/EEC (adapted)

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

♦ 93/15/EEC

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.

♦ 93/15/EEC (adapted)

All information that Member States receive by way of the procedures laid down in \boxtimes accordance with paragraphs 2 and 3 \boxtimes this Article 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.

By derogation from Article $\underline{119}$ (3), (5), (6) and (7), and from Article $\underline{1240}$, a Member State, in case of \boxtimes serious \boxtimes grave threats to, or attacks upon, public security \boxtimes as a result of \boxtimes through the illicit possession or use of explosives or ammunition eovered by the Directive, may take all necessary measures concerning transfers of explosives or ammunition in order to prevent such illicit possession or use.

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

♦ 93/15/EEC

Each Member State which adopts such measures shall notify the Commission of them forthwith. <u>†</u> Tthe Commission shall inform the other Member States thereof.

◆ 93/15/EEC (adapted)

CHAPTER IV

OTHER PROVISIONS

1. Member States shall set up information exchange networks for the implementation of Articles $\underline{119}$ and $\underline{1210}$. 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 \boxtimes those \boxtimes the said Articles $\underline{9}$ and $\underline{10}$.

new

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 5.

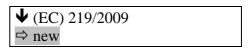
▶ 93/15/EEC (adapted)

2. For the purposes of implementing this Directive, the provisions of Regulation (EEC) No 515/97, in particular those \boxtimes the requirements \boxtimes relating to confidentiality, shall apply *mutatis mutandis*.

♦ (EC) 219/2009 (adapted) ⇒ new

<u>Article 15</u> **Identification and traceability of explosives ✓**

Member States shall ascertain ⊠ that ⊠ whether such undertakings ⇒ economic operators ⇔ possess a system for keeping track of explosives such that those holding explosives can be identified at any time.



The Commission may adopt $\frac{\text{measures}}{\text{measures}} \Rightarrow \text{implementing acts} \Leftrightarrow \text{setting the conditions for the application of } \frac{\text{this}}{\text{the first}} \text{ paragraph} \Rightarrow \text{to set up a system for the unique identification and traceability at Union level} \Leftrightarrow \text{. Those } \frac{\text{measures, designed to amend non-essential elements of this Directive by supplementing it,}}{\text{this Directive by supplementing it,}} \Rightarrow \text{implementing acts} \Leftrightarrow \text{shall be adopted in accordance with the } \frac{\text{regulatory}}{\text{referred to in Article }} \Rightarrow \text{examination} \Leftrightarrow \text{procedure } \frac{\text{with scrutiny}}{\text{scrutiny}} \Rightarrow \text{to set up a system for the unique identification and traceability at Union level} \Leftrightarrow \text{implementing acts} \Leftrightarrow \text{shall be adopted in accordance}$

♦ 93/15/EEC
⇒ new

Undertakings in the explosives sector \Rightarrow Economic operators \Leftrightarrow shall keep such records of their transactions as are necessary to fulfil the obligations set out in the first paragraph this Article.

The documents referred to in the first and second paragraph this Article must be kept for at least three \Rightarrow ten \Leftarrow years after the end of the calendar year in which the recorded transaction took place, even if the undertaking \Rightarrow economic operator \Leftarrow has ceased trading. They must be immediately available for inspection at the request of the competent authorities.

Article 15

Member States shall ensure that explosives are properly marked.

♦ 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

Article 16 **➣ Licensing of manufacturing activities ☒**

When a Member State issues a licence or \rightarrow 1 authorise ation $\leftarrow \boxtimes$ 2 referred to in Article 5 \boxtimes 3 for the purpose of allowing an explosives manufacturing \boxtimes 3 of explosives \boxtimes 3 activity to be exercised, it shall check in particular that the persons responsible are capable of complying with the technical commitments they assume.

Each Member State shall adopt, in the context of its national law, the necessary measures to enable the competent authorities to seize any \boxtimes explosive \boxtimes product coming within the scope of this Directive if there is sufficient evidence that that \boxtimes explosive \boxtimes product will be \rightarrow 1 illicitly \leftarrow acquired, used or dealt in.

◆ 93/15/EEC (adapted)

CHAPTER 4

☒ CONFORMITY OF THE EXPLOSIVE **☒**

Article <u>184</u> [Article R8 of Decision No 768/2008/EC]

EX Presumption of conformity EX

<u>1.Member States shall consider explosives falling within the scope of this Directive</u> \boxtimes Explosives, \boxtimes which \boxtimes are in conformity \boxtimes comply with the relevant national standards transposing the harmoniszed standards \boxtimes or parts thereof and \boxtimes the references of which have been published in the *Official Journal of the European Communities* \boxtimes *Union*, shall be presumed \boxtimes to be in conformity with the essential safety requirements referred to in Article 3. Member States shall publish the references of the national standards transposing \boxtimes covered by \boxtimes those harmonized standards \boxtimes or parts thereof, set out in Annex I \boxtimes .

new

Where a harmonised standard satisfies the requirements which it covers and which are set out in Annex I or Article 27, the Commission shall publish the references of those standards in the *Official Journal of the European Union*.

♦ 93/15/EEC

2. The Commission will give specific details of the work conducted in the field of harmonized standards in the framework of the report submitted to the European Parliament and the Council on the application of Directive 83/189/EEC and provided for in Article 11 (2) of that Directive.

Article 5

Where a Member State or the Commission considers that the harmonized standards referred to in Article 4 do not fully satisfy the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up by Directive 83/189/EEC, giving its reasons. The Committee shall deliver its opinion without delay.

In the light of the Committee's opinion the Commission shall inform the Member States of the measures to be taken regarding the standards and the publication referred to in Article 4.

Ψ 93/15/EEC (adapted)	
⇒ new	

Article <u>19€</u> **∠ Conformity assessment procedures** ∠

 \pm The procedures for the \pm assessment \boxtimes of the conformity of explosives shall be \boxtimes any of the following procedures \boxtimes \pm either:

- (a) EC ➤ EU ➤ type examination (Module B) ➤ set out ➤ referred to in Annex II (1), and, at the choice of the manufacturer, ➤ any of the following procedures ➤ either:
 - (i) the type conformity \Rightarrow to type based on internal production control plus supervised product checks at random intervals \Leftrightarrow (Module C2) \boxtimes set out \boxtimes referred to in Annex II $\stackrel{\frown}{(2)}$,
 - (ii) or the production ⊠ conformity to type based on ⊠ quality assurance ⊠ of the production process ⊠ procedure (Module D) ⊠ set out ⊠ referred to in Annex II (3),
 - (iii) or the \boxtimes conformity to type based on \boxtimes product quality assurance procedure (Module E) \boxtimes set out \boxtimes referred to in Annex II $\stackrel{\text{(4)}}{\longleftarrow}$,
 - (iv) or the ⊠ conformity to type based on ⊠ product verification (Module F) ⊠ set out ⊠ referred to in Annex II (5); or
- (b) the \boxtimes conformity based on \boxtimes unit verification (Module G) \boxtimes set out \boxtimes referred to in Annex II $\textcircled{\underline{6}}$.

↓ new

Article 20 [Article R10 of Decision No 768/2008/EC] **EU declaration of conformity**

- 1. The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Annex I has been demonstrated.
- 2. The EU declaration of conformity shall have the model structure set out in Annex III to Decision No 768/2008/EC, shall contain the elements specified in the relevant modules set out in Annex II to this Directive and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the explosive is placed or made available.
- 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 acts concerned including the publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the explosive.

◆ 93/15/EEC (adapted)
 ⇒ new

ANNEX IV

CONFORMITY MARKING

The CE conformity marking shall ⇒ be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008. ⇔ consist of the initials «CE» taking the following form:

If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

Article $\underline{227}$ [Article R12 of Decision No 768/2008/EC] \boxtimes Rules and conditions for affixing the CE marking \boxtimes

1. The CE marking of conformity shall be affixed ⊠ visibly, legibly and indelibly to ⊠ in such a way as to be visible, easily legible and indelible on the explosives. themselves or, if this ⊠ Where that ⊠ is not possible ➡ or not warranted on account of the nature of the explosive, it shall be affixed to ➡, on an identification plate attached thereto or, in the last resort, if the first two methods cannot be used, on the packaging ➡ and to the accompanying documents ➡. The identification plate must be so designed as to make its reuse impossible.

new

- 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.
- 4. 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.

5. The CE marking and, where applicable, the identification number referred to in paragraph 3 may be followed by a pictogram or any other mark indicating a special risk or use.

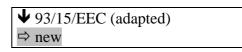
♦ 93/15/EEC (new) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

The model to be used for the CE marking shall be that reproduced in Annex IV.

2. It shall be prohibited to affix on explosives any mark or inscription which may confuse third persons as to the meaning and style of writing of the CE marking. Any other mark may be affixed on explosives provided the →₁ visibility ← and legibility of the CE marking is not impaired.

3. Without prejudice to the provisions of Article 8:

- (a) where a Member State establishes that the CE marking has been unduly affixed, the manufacturer, his agent or, failing these, the person responsible for placing the product in question on the Community market shall be obliged to restore the product to conformity with regard to the provisions on marking and end the infringement under conditions imposed by the Member States:
- (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 8.



CHAPTER 5

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

<u>Article 23</u> [Article R13 of Decision No 768/2008/EC] **☒ Notification ☒**

<u>2</u> Member States shall inform \Rightarrow notify \Leftarrow the Commission and the other Member States of the bodies \Rightarrow authorised \Leftarrow which they have appointed to carry out the procedures for assessing the conformity referred to above together with the specific \Rightarrow third-party conformity assessment \Leftarrow tasks \Rightarrow under this Directive \Leftarrow which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

□ new

Article 24 [Article R14 of Decision No 768/2008/EC] 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 29.
- 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 25 [Article R15 of Decision No 768/2008/EC] Requirements relating to notifying authorities

- 1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
- 2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
- 3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
- 4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
- 5. A notifying authority shall safeguard the confidentiality of the information it obtains.
- 6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 26 [Article R16 of Decision No 768/2008/EC] 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.

♦ 93/15/EEC (new) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

Member States shall apply the minimum criteria set out in Annex III for the assessment of bodies of which the Commission is to be notified. Bodies which meet the assessment criteria laid down by the relevant harmonized standards shall be presumed to satisfy the relevant minimum criteria.

A Member State which \rightarrow has \leftarrow notified the Commission of a given body shall withdraw the notification if it discovers that that body no longer meets the criteria referred to in the second subparagraph. It shall immediately inform the other Member States and the Commission accordingly.

♦ 93/15/EEC (adapted)

ANNEX III

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

<u>Article 27</u> [Article R17 of Decision No 768/2008/EC] **В Requirements relating to notified bodies ⊗**

new

- 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 national law and have legal personality.
- 3. A conformity assessment body shall be a third-party body independent of the organisation or the explosive it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of explosives, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

♦ 93/15/EEC (adap	oted)		
→ ₁ Corrigendum,	OJ	L	79,
7.4.1995, p. 34			
⇒ new			

4½. The ☒ A conformity assessment ☒ body, its ☒ top level management ☒ director and the ☒ personnel ☒ staff responsible for carrying out the ☒ conformity assessment tasks ☒ verification tests shall not be the designer, manufacturer, supplier, or installer ⇨, purchaser, owner, user or maintainer ⇨ of explosives which they inspect, nor the authorised representative of any of these ☒ 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 such products for personal purposes. ⇨

They \boxtimes A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks \boxtimes shall not be either \boxtimes directly \boxtimes involved directly or as authorized representatives in the design, \Rightarrow manufacture or \rightleftharpoons construction, \Rightarrow marketing \Leftarrow \Rightarrow , installation, use \rightleftharpoons or maintenance of \boxtimes those \boxtimes such explosives \Rightarrow or represent the parties engaged in those activities \rightleftharpoons . This does not preclude the possibility of exchanges of technical information between the manufacturer and the body. \Rightarrow 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. \hookleftarrow

⇒ 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. ⇔

52. The body ➤ Conformity assessment bodies ☒ and ☒ their personnel ☒ its staff shall carry out the verification tests ☒ 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, → 1 particularly financial, which might influence their judgement ← or the results of ☒ their conformity assessment activities ☒ the inspection, especially ☒ as regards ☒ from persons or groups of persons with an interest in the result ☒ results ☒ of ☒ those activities ☒ verifications.

new

A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 19 and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of explosives in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

♦ 93/15/EEC (adapted) **→**₁ Corrigendum, OJ L 79, 7.4.1995, p. 34 **⇒** new

 $\underline{3}$ \boxtimes It \boxtimes The body shall have at \bullet 1 its \leftarrow disposal the \boxtimes means \boxtimes necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical \boxtimes and administrative \boxtimes tasks connected with \boxtimes the conformity assessment activities in an appropriate manner \boxtimes verification; it \boxtimes and \boxtimes shall also have access to the \boxtimes all necessary \boxtimes equipment \boxtimes or facilities \boxtimes required for special verification.

- <u>74.</u> The \boxtimes personnel \boxtimes staff responsible for inspection \boxtimes conformity assessment activities \boxtimes shall have \boxtimes the following \boxtimes :
 - (a) sound technical and professional ⊗ vocational ⊗ training ⇒ covering all the conformity assessment activities in relation to which the conformity assessment body has been notified; ⇔_₹
 - (b) satisfactory knowledge of the →₁ requirements of the tests ⋈ assessments ⋈ they carry out and adequate ← ⋈ authority to carry out those assessments; ⋈ experience of such tests,

new

(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and national legislation;

♦ 93/15/EEC (adapted) **♦** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34 **♦** new

- (d) the ability to draw up the certificates, records and reports

 demonstrating that assessments have been carried out

 required to authenticate the performance of the tests.

 the ability to draw up the certificates, records and reports

 demonstrating that assessments have been carried out

 required to authenticate the performance of the tests.
- 85. The impartiality of inspection staff \boxtimes the conformity assessment bodies, their top level management and of the assessment personnel \boxtimes shall be guaranteed.

The ir remuneration \boxtimes of the top level management and assessment personnel of a conformity assessment body \boxtimes shall not depend on the number of tests \boxtimes assessments \boxtimes carried out or on the results of \boxtimes those assessments \boxtimes tests.

- <u>96</u>. The body \boxtimes Conformity assessment bodies \boxtimes shall take out <u>eivil</u> liability insurance unless its liability is \rightarrow ₁ assumed ← by the State in accordance with national law, or the Member State itself is directly responsible for the \boxtimes conformity assessment \boxtimes tests.
- <u>107</u>. The ⊠ personnel ⊠ <u>staff</u> of <u>the</u> ⊠ a conformity assessment ⊠ body shall <u>be bound to</u> observe professional secrecy with regard to all information ⊠ obtained ⊠ <u>gained</u> in carrying out ⊠ their ⊠ <u>its</u> tasks (<u>except</u> → 1 (*vis-à-vis*) ←) the competent administrative authorities of the State in which its activities are carried out) under ⊠ Annex II ⊠ <u>this Directive</u> 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 ⋈.

new

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 28 [Article R18 of Decision No 768/2008/EC] Presumption of conformity

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

Article 29 [Article R20 of Decision No 768/2008/EC] **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 27 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 II.

Article 30 [Article R22 of Decision No 768/2008/EC] **Application for notification**

- 1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
- 2. That application 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 27.
- 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 27.

Article 31 [Article R23 of Decision No 768/2008/EC] Notification procedure

- 1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27.
- 2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
- 3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and explosive or explosives concerned and the relevant attestation of competence.
- 4. Where a notification is not based on an accreditation certificate as referred to in Article 30(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 27.

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 Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 32 [Article R24 of Decision No 768/2008/EC] 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 allocated to them and the activities for which they have been notified.

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

Article 33 [Article R25 of Decision No 768/2008/EC] 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 27 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
- 2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 34 [Article R26 of Decision No 768/2008/EC] 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 body concerned.
- 3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
- 4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including denotification if necessary.

Article 35 [Article R27 of Decision No 768/2008/EC] Operational obligations of notified bodies

- 1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.
- 2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
 - In doing so 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 I or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.
- 4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an explosive no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
- 5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 36 **Appeal against decisions of notified bodies**

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

Article 37 [Article R28 of Decision No 768/2008/EC] 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 and conditions for notification;
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
- 2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 38 [Article R29 of Decision No 768/2008/EC] **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 39 [Article R30 of Decision EC 768/2008] 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 products entering the Union market and Safeguard procedures

Article 40

Union market surveillance and control of products entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to explosives.

▶ 93/15/EEC (adapted)

♦ 93/15/EEC

1. Where a Member State establishes that an explosive bearing CE conformity marking and being used for its intended purpose may compromise safety, it shall take all interim measures necessary to withdraw the explosive from the market or prohibit its being placed on the market or its freedom of movement.

The Member State shall immediately inform the Commission of such measures, indicating the reasons for its measures and, in particular, whether non-conformity is the result of:

non-compliance with essential requirements,

incorrect application of standards, or

a shortcoming in the standards.

new

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that an explosive presents a risk to the health or safety of persons or to public security, they shall carry out an evaluation in relation to the explosive concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

2. Where, in the course of that evaluation, 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 action 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.

- 3. 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.
- 4. 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.
- 5. 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.

- 6. The information referred to in 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 other aspects of public interest protection laid down in this Directive;
 - (b) shortcomings in the harmonised standards referred to in Article 18 conferring a presumption of conformity.
- 7. Member States other than the Member State initiating the procedure 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 notified national measure, of their objections.

- 8. Where, within 6 months of receipt of the information referred to in 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.
- 9. Member States shall ensure that appropriate restrictive measures are taken in respect of the explosive concerned without delay.

♦ 93/15/EEC

2. The Commission shall consult the parties concerned as soon as possible. Where the Commission establishes, after consultation, that the measures are justified, it shall immediately inform the Member State which took the initiative, as well as the other Member States. Where the Commission establishes, after consultation, that the measures are unjustified, it shall immediately inform the Member State which took the decision.

In the particular case where the measures referred to in paragraph 1 are based on a shortcomings in the standards, the Commission shall first consult the parties concerned and then within two months bring the matter before the Standing Committee set up by Directive 83/189/EEC if the Member State which took the measures intends to maintain them and initiates the procedures referred to in Article 5.

new

Article 42 [Article R32 of Decision No 768/2008/EC] Union safeguard procedure

1. Where, on completion of the procedure set out in Article 41(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 decide 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 measures necessary 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 the measure.
- 3. Where the national measure is considered justified and the non-compliance of the explosive is attributed to shortcomings in the harmonised standards referred to in

Article 18 of this Directive, the Commission shall apply the procedure provided for in Article 8 of (EU) No [../..] [Standardisation Regulation].

Article 43 [Article R33 of Decision No 768/2008/EC] Compliant explosives which present a risk to health and safety

- 1. Where, having performed an evaluation under Article 41(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 other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the explosive concerned, when placed on the market, no longer presents that risk, to withdraw the explosive from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.
- 2. The economic operator shall ensure that corrective action is taken in respect of all the explosives concerned that he has made available on the market throughout the Union.
- 3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the explosive concerned, the origin and the supply chain of the explosive, the nature of the risk involved and the nature and duration of the national measures taken.
- 4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.
- The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

♦ 93/15/EEC (adapted)

<u>Article 44</u> [Article R34 of Decision No 768/2008/EC] **Solution** Formal non-compliance ✓

3. Where CE conformity marking is borne by an explosive which does not comply with the requirements, the competent Member State shall take appropriate measures in respect of the person who affixed the marking and shall inform the Commission and the other Member States.

new

- 1. Without prejudice to Article 41, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
 - (a) the conformity marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 22 of this Directive;
 - (b) the conformity marking has not been affixed;
 - (c) the EU declaration of conformity has not been drawn up;
 - (d) the EU declaration of conformity has not been drawn up correctly;
 - (e) technical documentation is either not available or not complete.
- 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 POWERS AND COMMITTEE

Article 45 **Delegated power**

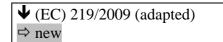
The Commission shall be empowered to adopt delegated acts in accordance with Article 46 concerning the identification of pyrotechnic articles referred to in Article 1(2)(b) and of certain ammunition referred to in Article 1(1)(b) on the basis of the United Nations recommendations on the transport of dangerous goods.

Article 46 **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 delegation of power referred to in Article 45 shall be conferred for an indeterminate period of time from [insert a date the date of entry into force of this Directive].
- 3. The delegation of powers referred to in Article 45 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day

following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

- 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 5. A delegated act adopted pursuant to Article 45 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 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 2 months at the initiative of the European Parliament or the Council.



1. The Commission shall be assisted by

the

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mmittee

on Civil

Explosives

□.

That committee shall be a committee within the meaning of

Regulation (EU) No 182/2011.

□



- 2. The committee shall examine any matter concerning the application of this Directive.
- Where reference is made to this paragraph, Article $\frac{1}{2}$ ⇒ 5 ⇔ $\frac{4 \text{ and } 7}{4 \text{ of}}$ of ⇒ Regulation (EU) No 182/2011 ⇔ $\frac{1999/468}{1999/468}$ shall apply, having regard to the provisions of Article 8 thereof.
- 4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- 5 The Commission shall, in accordance with the management procedure referred to in paragraph 3, adopt implementing measures in particular to take account of any future amendments to the United Nations recommendations.

▶ 93/15/EEC (adapted)

CHAPTER ¥8

▼ TRANSITIONAL AND **▼** FINAL PROVISIONS

Article <u>4817</u> **Ø Penalties Ø**

Each Member States shall determine \boxtimes lay down rules on \boxtimes the penalties \boxtimes applicable \boxtimes to be applied for infringement \boxtimes infringements \boxtimes of the \boxtimes national \boxtimes provisions adopted \boxtimes pursuant to \boxtimes in implementation of this Directive \boxtimes and shall take all measures necessary to ensure that they are enforced \boxtimes . The penalties shall be sufficient to promote compliance with those provisions.

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

new

Member States shall notify those provisions to the Commission by [insert the date specified in Article 50(1)] at the latest and shall notify it without delay of any subsequent amendment affecting them.

♦ 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

⇒ new

Member States shall \Rightarrow not impede the making available on the market of explosives covered by Directive 93/15/EC which are in conformity with that Directive and which were placed on the market before [Insert date - date referred to in the second subparagraph of Article 48(1)] \Leftarrow bring into force the provisions necessary to comply with Articles 9, 10, 11, 12, 13 and 14 before 30 September 1993.

⇒ Certificates of conformity issued under Directive 93/15/EEC shall be valid under this Directive. ←

Article 50 ★ Transposition ★

Member States shall adopt and publish \boxtimes , by [insert date – 2 years after adoption] at the latest, \boxtimes before 30 June 1994 the laws, regulations and administrative provisions necessary to comply with \boxtimes Articles 2 (7), 2 (9)-(24), 3-10, 14 (1), 19 (1) (a) (i), 20-26, 27 (1)-(4), 27 (6)-(7), 27 (10)-(11), 28-44, 48, 49 and Annex II \boxtimes the provisions other than those mentioned in paragraph 1. They shall forthwith inform \boxtimes communicate to \boxtimes the Commission thereof \boxtimes the text of those provisions and a correlation table between those provisions and this Directive \boxtimes .

They shall apply \boxtimes those \boxtimes these provisions as from \boxtimes [day after the date mentioned in the first subparagraph] \boxtimes 1 January 1995.

- End When Member States adopt the provisions referred to in paragraphs 1 and 2 those provisions. In they I shall contain a reference to this Directive or shall be accompanied by such in a I reference on the occasion of their official publication. In 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. I he methods of making such a reference shall be determined by the Member States in the shall determine how such reference is to be made and how that statement is to be formulated I.
- 4. However, during the period up to 31 December 2002, Member States shall allow the placing on the →₁ market ← of explosives complying with the national regulations in force in their territory before 31 December 1994.
- <u>25</u>. Member States shall communicate to the Commission the \boxtimes text of the main \boxtimes provisions of national law which they adopt in the field \boxtimes covered \boxtimes governed by this Directive.



Article 51 **Repeal**

Directive 93/15/EEC as amended by the acts listed in Annex III is repealed with effect from [day after the date set out in the second subparagraph of Article 48(1) of this Directive].

References to Directive 93/15/EEC shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

Article 52 Entry into force

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

Articles 1, 2 (1) – (6), 2 (8), 11, 12, 13, 14 (2), 15, 16, 17, 18, 19 (1) (a) (ii) – (iv), 19 (1) (b), 27 (5), 27 (8), 27 (9), 45-47 and Annexes I, III and IV shall apply from [day after the date set out in the second subparagraph of Article 48 (1)].

♦ 93/15/EEC

Article <u>5320</u>

This Directive is addressed to the Member States.

Done at [...].

For the European Parliament The President For the Council The President

♥ 93/15/EEC

ANNEX I

ESSENTIAL SAFETY REQUIREMENTS

I. GENERAL REQUIREMENTS

- **♦** 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34
- 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 →₁ standard practices until such time as it is used. ←

♦ 93/15/EEC

- 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

- **♦** 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34
- 1. As a minimum, the following information and properties. where appropriate _ ____ where appropriate _ ____ where appropriate _ ____ a must be considered or tested _ ____ € Each explosive should be tested under realistic conditions. If this is not possible in a laboratory, the tests should be carried out in the conditions in which the explosive is to be used.

♦ 93/15/EEC			
\rightarrow ₁ Corrigendum,	OJ	L	79,
7.4.1995, p. 34			

- (a) → 1 d esign and characteristic properties, including chemical composition, degree of homogeneity ← and, where appropriate, dimensions and grain size distribution:
- (b) <u>t</u>he physical and chemical stability of the explosive in all environmental conditions to which it may be exposed; <u>=</u>
- (c) <u>s</u>ensitiveness to impact and friction;
- (d) <u>c</u>eompatibility of all components as regards their physical and chemical stability:
- (e) \underline{t} he 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) <u>resistance</u> 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:

◆ 93/15/EEC (adapted)			
→ ₁ Corrigendum,	OJ	L	79,
7.4.1995, p. 34			

(h) <u>t</u>he suitability of the explosive for use in hazardous environments →₁ (e.g. firedamp atmospheres, hot masses <u>tete.</u>) ← if it is intended to be used under such conditions;

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♦ 93/15/EEC → 1 Corrigendum, OJ L 79, 7.4.1995, p. 34
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- (i) <u>s\u2228</u> afety features intended to prevent untimely or inadvertent initiation or ignition; <u>=</u>
- (j) <u>t</u>he correct loading and functioning of the explosive when used for its intended purpose:
- (k) <u>s</u><u>s</u><u>s</u>uitable instructions and, where necessary, markings in respect of safe handling, storage, use and disposal in the official language or languages of the recipient Member State;
- (l) →₁ <u>t</u>he 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.

♦ 93/15/EEC (adapted)

- $\underline{2}$ 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. $\underline{\boxtimes}$
- 32. The various Requirements for the ☐ groups of explosives must at least also comply with the following requirements:
- 3.1 \triangleq . Blasting explosives \bowtie shall also comply with the following requirements: \bowtie

♦ 93/15/EEC			
\rightarrow ₁ Corrigendum,	OJ	L	79,
7.4.1995, p. 34			

- (a) <u>t</u>he 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) <u>b</u>Belasting explosives in cartridge form must transmit the detonation safely and reliably from one end of the train of cartridges to the other; ∃
- (c) → 1 (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.

▶ 93/15/EEC (adapted)				
→ ₁ Corrigendum,	OJ	L	79,	
7.4.1995, p. 34				

3.2 \blacksquare .
→ 1 Detonating cords, safety fuses, other fuses and shock tubes ← \boxtimes shall also comply with the following requirements: \boxtimes

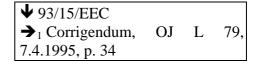
♦ 93/15/EEC			
→ ₁ Corrigendum,	OJ	L	79,
7.4.1995, p. 34			

(a) $\underline{\underline{t}}$ he covering of detonating cords, safety fuses \rightarrow 1 and other fuses must \leftarrow be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal mechanical stress:

- (b) <u>t</u>he parameters for the burning times of safety fuses must be indicated and must be reliably met.
- (c) <u>decentered</u> etonating 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.

▶ 93/15/EEC (adapted)

 $\underline{3.3}$ ■ Detonators (including delay detonators) and relays \boxtimes shall also comply with the following requirements: \boxtimes



- (a) <u>dectorators</u> must reliably initiate the detonation of the blasting explosives which are intended to be used with them under all foreseeable conditions of use:
- (b) $\rightarrow_1 \underline{d}\underline{D}$ elay connectors for detonating cords must be reliably initiated:
- (c) <u>t</u> he initiation capability must not be adversely affected by humidity; <u>=</u>
- (d) <u>t</u>he 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:

▶ 93/15/EEC (adapted)

(e) $\underline{\underline{t}}$ he electrical characteristics of electric detonators must be indicated on the packaging (e.g. no-fire current, resistance $\underline{\underline{t}}$:

♦ 93/15/EEC

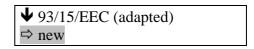
(f) <u>t</u>he wires of electric detonators must be of sufficient insulation and mechanical strength including the solidity of the link to the detonator, taking account of their intended use.

♦ 93/15/EEC (adapted)

<u>3.4Ð</u>. Propellants and rocket propellants \boxtimes shall also comply with the following requirements: \boxtimes

♥ 93/15/EEC

- (a) $\underline{\underline{t}}$ hese materials must not detonate when used for their intended purpose;
- (b) \underline{pP} ropellants where necessary (e.g. those based on nitrocellulose) must be stabilized against decomposition:
- (c) <u>ss</u>olid rocket propellants, when in compressed or cast form, must not contain any unintentional fissures or gas bubbles which dangerously affect their functioning.



ANNEX II

☒ CONFORMITY ASSESSMENT PROCEDURES **☒**

<u>±</u> MODULE B<u>±</u>

EC ⊠ EU **<** type **=**examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that an example, representative of the production envisaged, meets the relevant provisions of the Directive.

new

- 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 examination of a specimen, representative of the production envisaged, of the complete product (production type).

♦ 93/15/EEC (adapted)

 $\underline{\underline{23}}$. The \boxtimes manufacturer shall lodge \boxtimes application for EC type-examination is lodged by the manufacturer or his authorized representative established within the Community \boxtimes an application for EU type examination \boxtimes with a \boxtimes single \boxtimes notified body of his choice.

The application $\frac{\text{must}}{\text{must}} \boxtimes \text{ shall } \boxtimes \text{ include:}$

the name and address of the manufacturer and, if the application is lodged by the authoriszed representative, \boxtimes his \boxtimes the name and address \boxtimes as well \boxtimes ; in addition.

◆ 93/15/EEC

(b) a written declaration that the same application has not been lodged with any other notified body;

♦ 93/15/EEC (adapted)	
⇒ new	

- the technical \boxtimes documentation \boxtimes documents, as described in Section 3. The applicant must place at the disposal of the notified body an example representative of the production envisaged, hereinafter called «type». The notified body may request further examples if needed for carrying out the test programme. The technical \boxtimes documentation \boxtimes documents must enable \boxtimes shall make it possible to assess \boxtimes the \boxtimes explosive's \boxtimes conformity of the appliance with the \boxtimes applicable \boxtimes requirements of the \boxtimes this \boxtimes Directive \boxtimes and shall include an adequate analysis and assessment of the risk(s) \boxtimes to be assessed. They must \Longrightarrow The technical documentation shall specify the applicable requirements and cover \leftrightarrows , as far as is relevant for \boxtimes the \boxtimes such assessment, cover the design, manufacture and operation of the \boxtimes explosive. \boxtimes appliance and \boxtimes The technical documentation shall \boxtimes contain \boxtimes wherever applicable, at least the following elements \boxtimes as far as is relevant for assessment:
 - (i) a general type-description ≥ of the explosive ≤;
 - (ii) conceptual design and manufacturing drawings and ⊠ schemes ⊠ diagrams of ⊠ e.g. ⊠ components, sub-assemblies, circuits;_ete._
 - (iii) descriptions and explanations necessary for the understanding of the

 ★ those ★ drawings and ★ schemes ★ diagrams and the operation of the
 ★ explosive ★; product,
 - a list of the ☒ harmonised ☒ standards ☒ and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union* ☒ referred to in Article 4, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the ☒ this ☒ Directive where the ☒ those harmonised ☒ standards referred to in Article 5 have not been applied. ☒ ☐ In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied. ☐

♦ 93/15/EEC

- (v) results of design calculations made, examinations carried out, etc.;
- <u>(vi)</u> test reports;<u>=</u>

new

(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) 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 and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

♦ 93/15/EEC (adapted) ⇒ new

- 4. The notified body \boxtimes shall \boxtimes must:
 - \boxtimes For the explosive: \boxtimes
- 4.1. examine the technical \boxtimes documentation \boxtimes \Rightarrow and supporting evidence to assess the adequacy of the technical design of the explosive. \Leftrightarrow documents,
 - \boxtimes For the specimen(s): \boxtimes
- 4.2. verify that the ⊠ specimen(s) have ⊠ type has been manufactured in conformity with ⊠ the technical documentation ⊠ those documents and identify the elements which have been designed in accordance with the ⊠ applicable provisions of the ⊠ relevant provisions of the ⊠ harmonised ⊠ standards ⊠ and/or technical specifications, as well as the elements ⊠ referred to in Article 4 as well as the components which have been designed without applying the relevant provisions of those standards:
- 4.3.4.2. perform or have performed the ⊠ carry out ⊠ appropriate examinations and necessary tests ⊠, or have them carried out, ⊠ to check whether, where the ⊠ manufacturer has chosen to apply ⊠ standards referred to in Article 4 have not been applied, the solutions ⊠ in the relevant harmonised standards and/or technical specifications, these have been applied correctly ⊠ adopted by the manufacturer meet the essential requirements of the Directive;
- 4.4.4.3. perform or have performed the \boxtimes carry out \boxtimes appropriate examinations and necessary tests \boxtimes , or have them carried out, \boxtimes to check whether, where the \boxtimes solutions in \boxtimes manufacturer has chosen to apply the relevant \boxtimes harmonised \boxtimes standards these \boxtimes and/or technical specifications \boxtimes have \boxtimes not \boxtimes necessary been applied \Longrightarrow , the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive \leftrightarrows ;
- 4.5.4.4 agree with the applicant \boxtimes manufacturer on a \boxtimes the location where the examinations and necessary tests \boxtimes will \boxtimes are to be carried out.

new

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.

♦ 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

⇒ new

Where the type meets the ⊠ requirements ⊠ relevant provisions of this Directive, the notified body ⊠ shall ⊠ issues an EC ⊠ EU ⊠ type examination certificate to the ⊠ manufacturer ⊠ applicant. The certificate ⊠ shall contain ⊠ contains 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 certificate may have one or more annexes attached. ⇐

new

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

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.

♦ 93/15/EEC

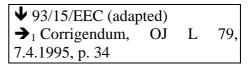
A list of the relevant parts of the technical documents is annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative established in the Community is refused a type certificate, the notified body must provide detailed reasons for such refusal.

Provision must be made for an appeals procedure.

new

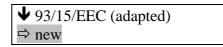
7. The notified body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so,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



§ The \boxtimes manufacturer shall inform \boxtimes applicant informs the notified body that holds the technical documents \boxtimes documentation relating to \boxtimes concerning the \boxtimes EU \boxtimes type \cong examination certificate of all \Rightarrow 1 modifications \leftarrow to the approved \boxtimes type \boxtimes appliance which must receive additional approval where such changes \boxtimes that \boxtimes may affect the conformity \boxtimes of the explosive \boxtimes with the essential \boxtimes safety \boxtimes requirements \boxtimes of this Directive \boxtimes or the prescribed conditions for \boxtimes validity of the certificate \boxtimes use of the product. This \boxtimes Such modifications shall require \boxtimes additional approval is given in the form of an addition to the original \boxtimes \boxtimes EU \boxtimes type \cong examination certificate.

new

8. Each notified body shall inform its notifying authorities 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 authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.



 $\underline{\underline{+}}$ Each notified body \boxtimes shall inform \boxtimes must communicate to the other notified bodies the relevant information concerning the \boxtimes EU \boxtimes EC type examination certificates and \boxtimes /or any \boxtimes additions \Rightarrow thereto which it has refused, \Leftrightarrow issued and withdrawn \Rightarrow , suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued \Leftrightarrow .

The \Rightarrow Commission, the Member States and the \Leftarrow other notified bodies may \boxtimes , on request, obtain a copy \boxtimes receive eopies of the $EC \boxtimes EU \boxtimes$ type examination certificates and/or their additions \boxtimes thereto \boxtimes . The Annexes to the certificates must be kept at the disposal of the other notified bodies. \Rightarrow 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 the certificate. \leftrightarrows

9. The manufacturer or his authorized representative established within the Community must ⊠ shall ⊠ keep with the technical documents ⊠ a copy ⊠ copies of EC ⊠ EU ⊠ type examination certificate and their ⊠ its annexes and ⊠ additions ⊠ together with the technical documentation at the disposal of the national authorities ⊠ for a period of at least 10 years after the ⇒ explosive has been placed on the market ⇔ last date of manufacture of the product concerned.

new

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.

♦ 93/15/EEC ⇒ new

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the Community market.

2. MODULE C 2÷

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



- 1. This module describes that part of the □ 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 or his authorized representative established within the Community □ 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 as described in the □□ □ EU □ □ type □ examination certificate and satisfy the requirements of this Directive that apply to them. The manufacturer must affix the CE mark to each explosive and draw up a written declaration of conformity.

The manufacturer \boxtimes shall \boxtimes must take all measures necessary \boxtimes so \boxtimes to ensure that the manufacturing process \boxtimes and its monitoring \boxtimes \boxtimes ensure \boxtimes assures the conformity of the manufactured products with the type as described in the \boxtimes EU \boxtimes type =examination certificate \boxtimes and \boxtimes with the essential safety requirements of the \boxtimes this \boxtimes Directive \boxtimes that apply to them \boxtimes .

new

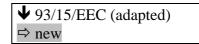
3. Product checks

A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the 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 technical specifications, or equivalent tests, 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 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.

Where the tests are carried out by notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

- 4. Conformity marking and declaration of conformity
- 4.1. The manufacturer shall affix the required conformity marking set out in this Directive to each individual product that is in conformity with the type described in the EU type examination certificate and satisfies the applicable requirements of this Directive.

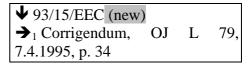


4.2.3. The manufacturer or his authorized representative must ⇒ shall draw up a written declaration of conformity for the explosive and ⇔ keep a copy of the declaration of conformity ⇒ it at the disposal of the national authorities ⇔ for a period of at least 10 years after the ⇒ explosive has been placed on the market. The declaration of conformity shall identify the explosive for which it has been drawn up ⇔ last date of manufacture of the product concerned.

[□] new

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.

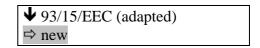


Where neither the manufacturer nor his is established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the Community market.

4. A notified body chosen by the manufacturer must perform or have performed examinations of the product at random intervals. A suitable sample of the finished products, taken on the spot by the notified body, is examined ▶₁ and appropriate tests, ← defined in the applicable standard or standards referred to in Article 4 or equivalent tests are carried out to check the conformity of the product with the requirements of the corresponding Directive. In the event of one or more samples of the products examined not conforming, the notified body must take the appropriate measures.

Under the responsibility of the notified body the manufacturer shall affix the identification symbol of that body during the manufacturing process.

3- MODULE D±



igtherightharpoonup Conformity to type based on igtherightharpoonup Quality assurance igtherightharpoonup of the production process igtherightharpoonup

1. This module describes the

Conformity to type based on quality assurance of the production process is the part of a conformity assessment

procedure whereby the manufacturer

fulfils

who satisfies the obligations

laid down in points 2 and 5, and

of Section

ensures and declares

on his sole responsibility

that the explosives concerned are in conformity with the type

set described in the

EC

EU

type

examination certificate and satisfy the requirements of this

Directive

that apply to them

. The manufacturer affixes the CE mark to each

explosive and draws up a written declaration of conformity. The CE mark is
accompanied by the identification symbol of the notified body responsible for the
ehecks referred to in Section 4.

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

3. Quality system

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

The application $\frac{\text{must}}{\text{must}} \boxtimes \text{shall} \boxtimes \text{include}$:

new

- (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;

◆ 93/15/EEC (adapted)

- (c) all relevant information for the explosive → product ✓ category envisaged;
- (d) the documents \boxtimes documentation \boxtimes concerning the quality system;
- (e) the technical documents \boxtimes documentation of \boxtimes pertaining to the approved type and a copy of the \boxtimes EU \boxtimes type-examination certificate.
- 3.2. The quality system $\xrightarrow{\text{must}} \boxtimes \text{shall} \boxtimes \text{ensure} \boxtimes \text{that the} \boxtimes \xrightarrow{\text{conformity of}} \text{explosives} \boxtimes \text{are in conformity} \boxtimes \text{with the type } \xrightarrow{\text{shall}} \boxtimes \text{ensure} \boxtimes \text{that the} \boxtimes \text{ensure} \boxtimes \text{conformity} \xrightarrow{\text{of}} \text{explosives} \boxtimes \text{EU} \boxtimes \text{type } \xrightarrow{\text{gen}} \text{examination certificate} \text{ and } \boxtimes \text{comply} \boxtimes \text{ with the requirements of this Directive that apply to them.}$

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

It $\frac{\text{must}}{\text{must}} \boxtimes \text{shall}$, in particular, $\boxtimes \text{contain } \frac{\text{in particular}}{\text{must}}$ an adequate description of:

- (a) the quality objectives and the organis <u>≠</u>ational structure, responsibilities and powers of the management with regard to the <u>★</u> product <u>★</u> quality of the explosives:
- (b) the ⊠ corresponding ⊠ manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

♦ 93/15/EEC

(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;

♦ 93/15/EEC (adapted)				
→ ₁ Corrigendum,	OJ	L	79,	
7.4.1995, p. 34				
⇒ new				

- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports ⊠ on ⊠ of the personnel concerned; etc.;
- (e) the means of monitoring the achievement of the required \boxtimes product \boxtimes quality of explosive and the effective operation of the quality system.
- 3.3. The notified body $must \boxtimes shall \boxtimes assess$ the quality system to determine whether it satisfies the requirements referred to in $\boxtimes point \boxtimes 3.2$.

It $\frac{\text{must}}{\text{must}} \boxtimes \text{shall} \boxtimes \text{ presume conformity with those requirements in respect of } \boxtimes \text{ the elements of the } \boxtimes \text{ quality system} \text{ that } \Longrightarrow \text{ comply with the corresponding specifications of the national standard that } \leftrightarrows \text{ implement} \text{ implement} \text{ the relevant harmoni} \text{ standard } \boxtimes \text{ and/or technical specifications } \boxtimes \text{.}$

The decision $\stackrel{\cdot}{\text{is}} \boxtimes$ shall be \boxtimes notified to the manufacturer. The notification $\stackrel{\text{must}}{\boxtimes}$ shall \boxtimes contain the $\stackrel{\bullet}{\rightarrow}_1$ conclusions $\stackrel{\bullet}{\leftarrow}$ of the $\stackrel{\text{examination}}{\boxtimes} \boxtimes$ audit \boxtimes and the \boxtimes reasoned \boxtimes $\stackrel{\text{duly substantiated}}{\boxtimes}$ assessment decision.

- 3.4. The manufacturer must ⊠ shall ⊠ undertake to fulfil the obligations arising out of the quality system as approved and ⊠ to ⊠ maintain it ⊠ so that it remains ⊠ at an adequate and efficient level.
- 3.5. The manufacturer or his authorized representative must \boxtimes shall \boxtimes keep the notified body that has approved the quality system informed of any \boxtimes intended \boxtimes proposed change \boxtimes to \boxtimes in the quality system.

The notified body $\stackrel{\text{must}}{\Longrightarrow}$ shall evaluate \boxtimes $\stackrel{\text{assess}}{\Longrightarrow}$ the $\stackrel{\text{loop}}{\Longrightarrow}$ any proposed $\stackrel{\text{changes}}{\Longrightarrow}$ changes $\stackrel{\text{proposed}}{\Longrightarrow}_1$ and $\stackrel{\text{changes}}{\longleftarrow}$ decide whether the $\stackrel{\text{loop}}{\Longrightarrow}$ modified $\stackrel{\text{loop}}{\boxtimes}$ altered quality system will $\stackrel{\text{loop}}{\Longrightarrow}$ continue to $\stackrel{\text{loop}}{\boxtimes}$ satisfy the requirements referred to in $\stackrel{\text{loop}}{\Longrightarrow}$ point $\stackrel{\text{loop}}{\boxtimes}$ 3.2 or whether $\stackrel{\text{loop}}{\Longrightarrow}$ reassessment is $\stackrel{\text{loop}}{\Longrightarrow}$ necessary $\stackrel{\text{loop}}{\boxtimes}$ required.

It $\frac{\text{must}}{\text{must}} \boxtimes \text{shall} \boxtimes \text{notify}$ the manufacturer of its decision. The notification $\boxtimes \text{shall} \boxtimes \frac{\text{must}}{\text{must}}$ contain the conclusions of the examination and the $\boxtimes \text{reasoned} \boxtimes \frac{\text{substantiated}}{\text{substantiated}}$ assessment decision.

- 4. Surveillance Monitoring under the responsibility of the notified body
- 4.1. The purpose of ⊠ surveillance ⊠ monitoring is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer must ⋈ shall, for assessment purposes, ⋈ allow the notified body access for inspection purposes to the ⋈ manufacture ⋈ manufacturing, inspection, testing and storage ⋈ sites ⋈ premises and ⋈ shall ⋈ provide it with all necessary information, in particular:

 - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports ⊠ on ⊠ of the personnel concerned; etc.
- 4.3. The notified body must ★ shall ★ periodically carry out ★ periodic ★ audits to make sure that the manufacturer maintains and applies the quality system and provides an audit report to the manufacturer ★ with an audit report ★
- 4.4 ☑ In addition, ☑ Additionally the notified body may pay ☑ unexpected ☑ unannounced 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 if necessary, Ithe notified body must ☑ shall ☑ provide the manufacturer with a visit report and, if a test has ☑ tests have been carried out ☑ taken place, with a test report.

new

- 5. Conformity marking and declaration of conformity
- 5.1. The manufacturer shall affix the required conformity marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product 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 declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The declaration of conformity shall identify the explosive for which it has been drawn up.

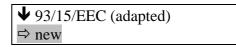
A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

♥ 93/15/EEC (adap	oted)		
\rightarrow ₁ Corrigendum,		L	79,
7.4.1995, p. 34			
⇒ new			

- <u>65</u>. The manufacturer \implies shall \implies , for a period of at least 10 years after the \implies explosive has been placed on the market \iff last date of manufacture of the product, keep at the disposal of the national authorities:
 - (a) the document \boxtimes documentation \boxtimes referred to in the second indent of point 3.1:
 - (b) the \boxtimes change \boxtimes updating referred to in point 3.5, \boxtimes as approved \boxtimes second paragraph of 3.4;
 - (c) the decisions and reports \rightarrow_1 from $\leftarrow \boxtimes$ of \boxtimes the notified body which are referred to in the final paragraph of 3.4, points 3.5, and in 4.3 and 4.4.

new

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.



Each notified body must give \boxtimes shall inform \boxtimes the other notified bodies the relevant information concerning the \boxtimes of \boxtimes quality system approvals \boxtimes which it has \boxtimes issued and \Rightarrow refused, suspended, \Leftarrow withdrawn \Rightarrow or otherwise restricted, and, upon request, of quality system approvals which it has issued \Leftarrow .

new

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.

4. MODULE E**±**

IX Conformity to type based on **IX** <u>p</u>**P**roduct quality assurance

- 1. This module describes the ⇒ Conformity to type based on product quality assurance is that part of a conformity assessment ⇒ procedure whereby the manufacturer ⇒ fulfils ⊲ who satisfies the obligations ⇒ laid down in points 2 and 5, and ⊲ of Section 2 ensures and declares ⇒ on his sole responsibility ⊲ that the explosives ⇒ concerned ⊲ are in conformity with the type sole described in the EC ⇒ EU ⊲ type =examination certificate ⇒ and satisfy the requirements of this Directive that apply to them. ⇒ The manufacturer must affix the CE mark to each explosive and draw up a written declaration of conformity. The CE mark must be accompanied by the identification symbol of the notified body responsible for the checks referred to in Section 4.

The manufacturer \longrightarrow shall \boxtimes operate an approved quality system for final \longrightarrow product \boxtimes inspection and testing \boxtimes of the explosives concerned \boxtimes as specified in \longrightarrow noint \longrightarrow surveillance \boxtimes the checks \boxtimes as specified \boxtimes referred to in point \longrightarrow 4.

- 3. Quality system
- 3.1. The manufacturer ⊠ shall lodge ⊠ lodges an application ⊠ for assessment of his quality system ⊠ with a ⊠ the ⊠ notified body of his choice, for the assessment of the quality system for ⊠ the ⊠ his explosives ⊠ concerned ⊠.

The application must ⋈ shall ⋈ include:

□ new

- (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;

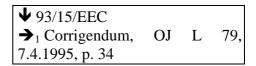
♦ 93/15/EEC (adapted) ⇒ new

- (c) all relevant information for the explosive → product ✓ category envisaged:
- (d) the quality system's documentation ⊠ concerning the quality system ⊠;

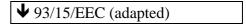
- (e) the technical \boxtimes documentation \boxtimes documents \boxtimes of \boxtimes pertaining to the approved type and a copy of the \boxtimes EU \boxtimes type =examination certificate.
- 3.2. Under <u>T</u>the quality system, each explosive is examined and appropriate tests as defined in the relevant standard(s) referred to in Article 4 or equivalent tests are earried out in order to verify its conformity ⇒ shall ensure compliance of the explosives with the type described in the EU type examination certificate and ⇔ with the ⊠ applicable ⊠ relevant requirements of the ⊠ this ⊠ Directive.

All the elements, requirements and provisions adopted by the manufacturer $must \boxtimes shall \boxtimes be$ documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation $must \boxtimes shall permit \boxtimes enable \boxtimes a consistent interpretation of <math>\boxtimes$ the quality programmes, plans, manuals and records to be interpreted in a uniform manner.

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



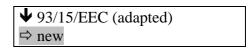
- the quality objectives and the organis<u>≠</u>ational structure, → 1 responsibilities ← and powers of the management with regard to product quality:
- (b) the examinations and tests that will be carried out after manufacture:



 $\underline{\text{(c)}}$ quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned $\underline{\underline{\cdot}}$: etc.



(d) the means of monitoring the effective operation of the quality system.



3.3. The notified body \implies shall \bowtie assess the quality system to determine whether it satisfies the requirements referred to in 3.2.

It $\frac{\text{must}}{\text{must}} \boxtimes \text{ shall} \boxtimes \text{ presume conformity with } \frac{\text{these}}{\text{those}} \boxtimes \text{ those} \boxtimes \text{ requirements in respect of } \boxtimes \text{ the elements of the } \boxtimes \text{ quality system} \cong \text{ that } \Longrightarrow \text{ comply with the corresponding specifications of the national standard that } \hookrightarrow \text{ implement}$

 \boxtimes implements \boxtimes the relevant harmoniszed standard \boxtimes and/or technical specification \boxtimes .

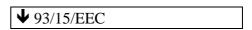
 \boxtimes The decision shall \boxtimes The manufacturer must be notified \boxtimes to the manufacturer \boxtimes of the decision. The notification must \boxtimes shall \boxtimes contain the conclusions of the \boxtimes audit \boxtimes examination and the \boxtimes reasoned \boxtimes substantiated assessment decision.

- 3.4. The manufacturer must ⊠ shall ⊠ undertake to fulfil the obligations arising out of the quality system as approved and ⊠ to ⊠ maintain it ⊠ so that it remains ⊠ at an adequate and efficient level.
- 3.5. The manufacturer or his authorized representative must \boxtimes shall \boxtimes keep the notified body \boxtimes that \boxtimes which has approved the quality system informed of any \boxtimes intended \boxtimes proposed change \boxtimes to \boxtimes in the quality system.

The notified body $\frac{\text{must}}{\text{must}} \boxtimes \text{shall}$ evaluate $\boxtimes \frac{\text{assess}}{\text{modified}} \boxtimes \text{any proposed} \boxtimes \frac{\text{the}}{\text{changes}}$ changes $\frac{\text{proposed}}{\text{proposed}}$ and decide whether the $\boxtimes \text{modified} \boxtimes \frac{\text{altered}}{\text{altered}}$ quality system will $\boxtimes \text{continue}$ to $\boxtimes \frac{\text{still}}{\text{stisfy}}$ satisfy the requirements referred to in $\frac{\text{point}}{\text{still}}$ 3.2 or whether a reassessment is $\boxtimes \text{necessary} \boxtimes \frac{\text{required}}{\text{still}}$.

It $\frac{\text{must}}{\text{must}} \boxtimes \text{shall} \boxtimes \text{notify}$ the manufacturer of its decision. The notification $\boxtimes \text{shall} \boxtimes \frac{\text{must}}{\text{must}}$ contain the conclusions of the examination and the $\boxtimes \text{reasoned} \boxtimes \frac{\text{substantiated}}{\text{substantiated}}$ assessment decision.

- $\underline{\underline{4}}$ \boxtimes Surveillance under the responsibility of the notified body \boxtimes
- 4.1. The purpose of ⊠ surveillance ⊠ monitoring is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer \implies shall, for assessment purposes, \bowtie allow the notified body access for inspection purposes to the \implies manufacture, \iff inspection, testing and storage \implies sites \bowtie premises and \implies shall \bowtie provide it with all necessary information, in particular:



(a) the quality system documentation;

- **♦** 93/15/EEC (adapted) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports \boxtimes on \boxtimes of the personnel concerned = etc.
- 4.3. The notified body must ⊠ shall ⊠ periodically carry out ⊠ periodic ⊠ audits to ⊠ make sure ⊠ ensure that the manufacturer maintains and applies the quality system and must ⊠ shall ⊠ provide ⊠ the manufacturer with ⊠ an audit report to the manufacturer.
- 4.4.

 In addition

 Additionally, the notified body may pay

 unexpected

 unannounced visits to the manufacturer. During such visits the notified body may

 if necessary,

 carry out

 product

 tests₁ or have them carried out.

 if necessary,

 the notified body

 must

 shall

 provide the manufacturer with a visit report and, if

 test has

 tests have

 been carried out,

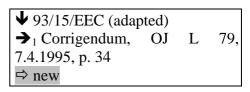
 ₁ with a test report.

 .

₽ new

- 5. Conformity marking and declaration of conformity
- 5.1. The manufacturer shall affix the required conformity marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product 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 declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The declaration of conformity shall identify the explosive for which it has been drawn up.

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



<u>65</u>. The manufacturer \implies shall, \bowtie for a period \implies ending \iff at least 10 years after the \implies the explosive has been placed on the market, \iff last date of manufacture of the product keep at the disposal of the national authorities:

- the documents \boxtimes documentation \boxtimes referred to in the second indent of point 3.1:
- (b) the change $\underline{\underline{s}}$ referred to in $\underline{\underline{the second paragraph of}}$ point $\underline{3.53.4}$, \boxtimes as approved; \boxtimes
- (c) the decisions and reports \boxtimes of \boxtimes \rightarrow_1 from \leftarrow the notified body which are referred to in the final paragraph of points 3.53.4, and in 4.3 and 4.4.

new

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

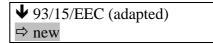
♦ 93/15/EEC (adapted)

Each notified body $must \boxtimes shall inform \boxtimes forward to the other notified bodies <math>\boxtimes of \boxtimes the relevant information concerning the quality system approvals <math>\boxtimes which it has \boxtimes the refused, suspended or <math>\Leftrightarrow withdrawn \Rightarrow the province of the other notified bodies the other notified bodies <math>\bowtie the relevant information concerning the quality system approvals which it has issued <math>\Leftrightarrow the other notified bodies the other notified bodies <math>\bowtie the relevant information concerning the quality system approvals which it has issued <math>\Leftrightarrow the other notified bodies <math>\bowtie the relevant information concerning the quality system approvals which it has issued <math>\Leftrightarrow the other notified bodies <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approvals <math>\bowtie the relevant information concerning the quality system approval information c$

new

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.



5. MODULE F±

☒ Conformity to type based on **☒** <u>p</u>**P**roduct verification

1. This module describes the

Conformity to type based on product verification is the part of a conformity assessment

procedure whereby

the

manufacturer of his authorized representative established within the Community checks and attests

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

the conformity to type based on product verification is the part of a conformity of the conformity to type based on product verification is the part of a conformity assessment

the conformity assessment

the conformity to type based on product verification is the part of a conformity assessment

the conformity asse

subject to the provisions of <u>point</u> $3_{\underline{*}}$ are in conformity with the type $\underset{\Xi}{\text{es}}$ described in the $\underset{\Xi}{\text{EC}} \boxtimes EU \boxtimes \text{ type } \underset{\Xi}{\text{examination certificate and satisfy the }}$ requirements of $\underset{\Xi}{\text{the}} \boxtimes \text{ this } \boxtimes \text{ Directive } \boxtimes \text{ that apply to them } \boxtimes \text{.}$

The manufacturer shall take all measures necessary \boxtimes so \boxtimes in order that the manufacturing process \boxtimes and its monitoring \boxtimes ensures conformity of the \boxtimes manufactured products \boxtimes explosives with the \boxtimes approved \boxtimes type as described in the \boxtimes EU \boxtimes type examination certificate and with the requirements of the \boxtimes this \boxtimes Directive that apply to them. He shall affix the CE mark to each explosive and shall draw up a declaration of conformity.

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

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

♦ 93/15/EEC

The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last explosive has been manufactured.

- **♦** 93/15/EEC (adapted) **♦** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34 **⇒** new
- 4.1. All ☒ products ☒ explosives shall be individually examined and appropriate tests as set out in the relevant ☒ harmonised ☒ standard(s) ☒ and/or technical specifications, ☒ referred to in Article 4 or equivalent tests, shall be carried out in order to verify their conformity with the relevant ☒ approved ☒ type ☒ described in the EU type examination certificate ☒ and ☒ with the appropriate ☒ requirements of the ☒ 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 \boxtimes shall issue a certificate of conformity in respect of the examinations and tests carried out, and $\boxtimes \rightarrow_1$ shall affix. \longleftarrow or cause to be affixed, its identification symbol \boxtimes number \boxtimes to each approved \boxtimes product \boxtimes explosive \boxtimes or have it affixed under its responsibility \boxtimes and draw up a written certificate of conformity relating to the tests carried out.

new

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.

♦ 93/15/EEC

4.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

new

- 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 products for verification in the form of homogeneous lots.
- 5.2. A random sample shall be taken from each lot according to the requirements of this Directive. All products in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EU type examination certificate and to ensure their conformity 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 products of the lot shall be considered approved, except for those products 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 product 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.

5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot is being placed on the market. In the event of the

frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

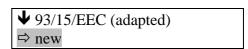
- 6. Conformity marking and declaration of conformity
- 6.1. The manufacturer shall affix the required conformity marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product that is in conformity 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 declaration of conformity for each product model and keep it at the disposal of the national authorities, for 10 years after the explosive has been placed on the market. The declaration of conformity shall identify the explosive for which it has been drawn up.

A copy of the 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.

- 7. 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.
- 8. 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 **☒** uUnit verification

1. This module describes the □ 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 □ issued with the certificate referred to in Section 2 conforms to the relevant requirements of the □ this □ Directive □ that apply to it □. The manufacturer must affix the □ mark to the explosive and draw up a declaration of conformity.

♦ 93/15/EEC (new) **→** 1 Corrigendum, OJ L 79, 7.4.1995, p. 34

2. The notified body must examine the explosive and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 4, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

The notified body must affix, → 1 or cause ← to be affixed, its identification symbol on the approved explosive and draw up a certificate of conformity concerning the tests carried out.

♦ 93/15/EEC (adapted) ⇒ new

2. ☒ Technical documentation ☒

3. The aim of Arr The manufacturer shall establish Arr the technical documents Arr documentation Arr and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the explosive's Arr enable conformity with the Arr relevant Arr requirements Arr, 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, Arr of the Directive to be assessed and the design, manufacture and operation of the explosive to be understood. The Arr technical Arr documents Arr documentation Arr must Arr shall, wherever applicable, Arr contain Arr at least the following elements Arr, in so far as is necessary for the assessment:

(a) a general description of the ⊗ explosives ⊗ type:

♦ 93/15/EEC

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

- (c) descriptions and explanations necessary for the understanding of ⊠ those ⊠ the said drawings and schemes and the operation of the explosive or protection system; 5
- a list of the ⊠ harmonised ⊠ standards ⇒ and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, ⇔ referred to in Article 4, applied in full or in part, and descriptions of the solutions adopted to meet the essential

requirements of the \boxtimes this \boxtimes Directive where the \boxtimes those harmonised \boxtimes standards referred to in Article 4 have not been applied. $\rightrightarrows \bowtie$ In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied; \hookleftarrow

- (e) results of design calculations made, examinations carried out, etc., ⋈ and ⋈
- <u>(f)</u> test reports.

new

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.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product 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 technical specifications, or equivalent tests, 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 and/or technical specification 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 product, 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.

5. Conformity marking and declaration of conformity

- 5.1. The manufacturer shall affix the required conformity marking set out in this Directive and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written 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 declaration of conformity shall identify the explosive for which it has been drawn up.

A copy of the 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 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.



ANNEX III

Repealed Directive with list of its successive amendments

(referred to in Article 51)

Council Directive 93/15/EEC (OJ L 121, 15.5.1993, p. 20)

Regulation (EC) No 1882/2003 Only point 13) of Annex II.

(OJ L 284, 31.10.2003, p. 1.)

Regulation (EC) No 219/2009 Only point 2.2 of the Annex.

(OJ L 87, 31.3.2009, p. 109.)

ANNEX IV

CORRELATION TABLE

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