

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 16 December 1992

Amended Proposal for a

COUNCIL DIRECTIVE

on the harmonization of provisions governing the placing
on the market and the supervision of explosives for civil uses

(presented by the Commission pursuant to Article 149(3)
of the EEC Treaty)

EXPLANATORY MEMORANDUM

During its session in October 1992, the European Parliament delivered an opinion on the proposal from the Commission set out in the document COM(92)123 final of 13 April 1992.

This proposal takes account of the amendments requested by the European Parliament insofar as the Commission was able to accept them.

Amended Proposal for a
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In response to the opinion delivered at first reading by the European Parliament¹ under the cooperation procedure on the Commission proposal for a Council Directive on the supervision and placing on the market of explosives for civil uses and the mutual recognition of approvals relating to such explosives, the Commission has decided to amend the proposal as follows:

1. The title of the Directive is amended to read:

"Council Directive on the harmonization of provisions governing the placing on the market and the supervision of explosives for civil uses."

2. The following first recital a is inserted:

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

3. The second recital is amended as follows:

"..., in particular, the free movement of explosives presupposes harmonization of laws on the placing of explosives on the market".

4. The fourth recital is deleted.

5. The fifth recital is amended as follows:

"Whereas, in order to ensure the free movement of these products, divergent national rules relating to approval procedures should be harmonized without lowering the best existing levels of safety and security".

6. The following seventh recital a is inserted:

"whereas the Council, in its Decision 90/683/EEC of 13 December 1990² 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".

7. The ninth recital is amended as follows:

"... to ensure the protection of consumers and the safety of the general public; whereas a further Directive is planned in this field".

8. The following tenth recital a is inserted:

"whereas the scope of this Directive covers munitions, but only as regards the rules governing controls on transfers and the associated arrangements; whereas, since munitions are transferred under conditions similar to those under which arms are transferred, transfers of munitions should be governed by provisions similar to those applicable to arms, as set out in Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons.³"

9. The following thirteenth recital is added:

2 OJ No L 380, 31.12.1990.

3 OJ No L 256, 13.9.1991.

"whereas this Directive does not affect the power of Member States to take measures with a view to preventing illegal trade in explosives".

10. Article 1 is amended as follows:

1. This Directive shall apply to explosives as defined in paragraph 2.
2. The term "explosives" means the materials and articles considered to be such in the "United Nations Recommendations on the Transport of Dangerous Goods" and falling within Category 1 of those Recommendations, the general part of which is reproduced in Annex 1".
3. This Directive shall not apply to:
 - explosives intended to be used, in accordance with national law, by the armed forces or the police; neither shall it apply to commercial transfers of explosives for military use;
 - pyrotechnical articles used for purposes of display or entertainment;
 - munitions, except as provided for in Articles 7, 7a, 8, 9 and 10.
4. For the purposes of this Directive:
 - "United Nations Recommendations" means the recommendations drawn up by the UN Committee of Experts on the Transport of Dangerous Goods (Orange Book) as published by the United Nations and as amended on the date of this Directive's adoption;
 - "safety" means the prevention of accidental explosions or fires, or falling this, limitation of their effects;

- "security" means prevention of the risk of use for unlawful purposes;
- "arms manufacturer/dealer" means any natural or legal person whose professional activity consists either wholly or in part in the manufacture, trade, exchange, hiring or repair or conversion of fire-arms and munitions;
- "approval" means the decision taken following the controls carried out in respect of projected transfers of explosives within the Community;
- "undertaking in the explosives sector" means any natural or legal person possessing a licence or authorization which entitles him to engage in the manufacture, storage, use and transfer of explosives or in trade in explosives;
- "placing on the market" means any disposal to third parties, against payment or free of charge, of explosives manufactured or released for free circulation in the Community.

5. This Directive shall not prevent Member States, in the interest of security, from designating certain substances as explosives pursuant to a national law or regulation".

11. Articles 2, 3, 4, 5 and 6 are amended as follows:

"CHAPTER 2

Harmonization of laws relating to explosives.

Article 2

1. Member States may not prohibit, restrict or impede the placing on the market of explosives falling within the scope of this Directive and meeting the requirements set out in it.
2. Member States shall take all measures necessary to ensure that explosives falling within the scope of this Directive can be placed on the Community market only if they comply with all the provisions of this Directive, if they are provided with the CE mark as described in Article 6a and if they have undergone conformity assessment in accordance with the procedures referred to in Annex 3.
3. Where explosives falling within the scope of this Directive are covered by other Directives concerning other aspects and providing for the affixing of the CE mark, this mark shall indicate that the abovementioned products are presumed also to comply with the provisions of such other Directives as are applicable to them.

Article 3

Explosives falling within the scope of this Directive must meet the essential safety requirements applicable to them which are set out in Annex 2.

Article 4

1. Member States shall presume as complying with the essential safety requirements referred to in Article 3 explosives covered by this Directive which meet the relevant national standards transposing the harmonized standards of which the reference numbers have been published in the Official Journal of the European Communities. Member States shall publish the reference numbers of the national standards transposing the harmonized standards.

2. The Commission of the European Communities shall describe the work undertaken on the harmonization of standards in a report to the European Parliament on the results of the application of Directive 83/189/EEC as provided for in the second paragraph of Article 11 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 comply with the essential requirements referred to in Article 3, the Commission or the Member State concerned shall place the matter before the Standing Committee set up under Directive 83/189/EEC, setting out the grounds for this action. That Committee shall deliver an opinion as soon as possible.

In the light of that Committee's opinion, the Commission shall notify the Member States of the measures to be taken with regard to the standards and the publication referred to in Article 4.

Article 6

Conformity attestation procedure and notified bodies

1. The procedures for attesting the conformity of mass-produced explosives shall be:
 - (a) either the EC type-examination (Module B) referred to in Annex 3(1) and, at the choice of the manufacturer:
 - the conformity to type (Module C) referred to in Annex 3(2);
 - or the production quality assurance procedure (Module D) referred to in Annex 3(3);
 - or the product quality assurance procedure (Module E) referred to in Annex 3(4).
 - (b) or the unit verification (Module G) referred to in Annex 3(5).

2. Member States shall notify the Commission and the other Member States of the bodies which they have designated to carry out the conformity assessment tasks and of the identification numbers assigned by the Commission to the bodies involved in the production control phase. For information purposes, the Commission shall publish in the Official Journal of the European Communities the list of notified bodies together with any identification numbers which it may have assigned to them and shall ensure that such list is updated.

Member States shall apply the minimum criteria set out in Annex 4 for assessing the suitability of the bodies to be notified. The bodies which meet the assessment criteria laid down by the relevant harmonized standards shall be presumed to comply with the minimum pertinent criteria.

A Member State which has notified a body must withdraw that notification if it ascertains that that body no longer meets the criteria referred to above. It shall forthwith inform the other Member States and the Commission thereof.

12. The following Article 6a is inserted:

"Article 6a: CE mark of conformity

1. The CE mark of conformity shall be affixed visibly, legibly and indelibly to the explosives or to an identification plate attached to them. The identification plate must be so designed as to render re-use impossible.

The model to be used for the CE mark is presented in Annex 5.

2. It is prohibited to affix to the explosives any marks which may be confused with the CE mark. However, any other mark may be affixed to the explosives provided that it does not reduce the visibility and legibility of the CE mark.

The holder of a trade mark which was registered in a Member State before 30 June 1989 and actually used, but may be confused with the CE mark in meaning or design, may continue to use that

registered mark for a period of 10 years from the date of adoption of this text.

3. Where a Member State or a notified body finds that the CE mark has been improperly affixed, the manufacturer, his authorized representative or, failing that, the person responsible for placing the product in question on the Community market shall be obliged to bring the product in line with the rules and to put an end to the infringement under the conditions laid down by the Member State. Where improper affixing of the mark may have serious consequences for safety or where non-compliance persists, the Member State shall take all the necessary measures to prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market."

13. The following Article 6b is inserted:

"Article 6b

1. Where a Member State finds that an explosive which bears the CE mark and is being used in accordance with its intended purpose is likely to compromise safety, it shall take whatever provisional measures are necessary to withdraw that explosive from the market and to ban the sales and the free movement thereof.

The Member State shall forthwith inform the Commission of this measure, stating the reasons for its decision, particularly if non-conformity is due to:

- failure to comply with essential requirements,
- improper application of the standards, or
- a loophole in the standards.

2. The Commission shall consult the parties concerned at the earliest opportunity. Where the Commission finds, following such consultation, that the measure is justified, it shall forthwith inform the Member State which has taken this initiative and the other Member States thereof. Where it finds, following such consultation, that the measure is unjustified, it shall forthwith inform the Member State that has taken this decision and the manufacturer or his authorized representative established in the Community thereof.

Where the decision referred to in paragraph 1 is specifically prompted by a loophole in the standards, the Commission, after consulting the parties concerned, shall place the matter before the Standing Committee set up under Directive 83/189/EEC within a period of two months if the Member State that has taken the measures intends to continue to apply them and shall initiate the procedures referred to in Article 5.

3. Where an explosive which does not comply with the standards bears the CE mark of conformity, the competent Member State shall take appropriate measures against those responsible for drawing up the declaration and shall inform the Commission and the other Member States thereof."

14. Paragraphs 2, 3, 4 and 5 of Article 7 are amended as follows:

- "2. In order to transfer explosives, the person acquiring them must obtain an approval from the competent authority of the place of destination. The transit of explosives through the territories of Member States must be notified by the person responsible for the transfer to the competent authorities of those Member States.
3. If the competent authorities of the Member State of destination approve the transfer, they shall issue to the person acquiring the explosives a document containing all the information set out in paragraph 5. That document must accompany the explosives to the place of their destination. It must be produced whenever the competent authorities so request. A copy of that document shall be kept by the person acquiring the explosives, who shall produce it at the request of the competent authorities of the place of destination if they wish to pursue it.
4. Where the authorities of a Member State consider that special safety measures, such as those mentioned in paragraph 5, are unnecessary, explosives may be transferred within the territory of that Member State or part of that territory without advance provision of information within the meaning of paragraph 5. The competent authority of the place of destination shall in such cases issue an approval valid for a determined period, but liable to suspension or withdrawal at any time on the basis of a reasoned decision. The document referred to in paragraph 3 which accompanies the explosives to their place of destination shall refer solely to such approval.

5. Where transfers of explosives require special checks in order to ensure that they comply with safety requirements in the territory or part of the territory of a Member State, the following information shall be imparted prior to the transfer by the person acquiring the explosives to the competent authorities of the place of destination in the Member State to which the explosives are being transferred:

- the names and addresses of the operators concerned. These particulars must be detailed enough to enable the operators to be contacted and confirmation to be obtained that the persons in question are officially authorized to receive the consignment;
- the number and quantity of explosives being transferred;
- a description of the explosive in question and of the means of identification;
- the means of transfer and the itinerary;
- the scheduled dates of departure and of arrival.

The competent authorities of the place of destination shall examine the conditions under which the transfer is to take place, in particular with regard to the safety requirements. Where the safety requirements are met, the transfer shall be approved. In the event of transit through the territories of other Member States, these States shall likewise examine and approve the information on the transfer."

15. The following Article 7a is inserted:

- "1. Munitions may be transferred from one Member State to another only in accordance with the procedure laid down in the following paragraphs. These provisions shall also apply in the case of transfers of munitions following a mail-order sale.
2. Where munitions are to be transferred to another Member State, the person concerned shall, before such transfers take place, supply the following particulars to the Member State in which the munitions are located:

- the name and address of the vendor or transferor and of the purchaser or person acquiring the munitions and, where appropriate, of the owner;
- the address to which the munitions are to be dispatched or transported;
- the quantity of munitions making up the consignment or shipment;
- the particulars enabling the munitions to be identified and, in addition, information to the effect that they have been checked in accordance with the provisions set out in the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms;
- the means of transfer;
- the date of departure and the estimated date of arrival.

The particulars referred to in the last two indents need not be provided in the event of transfers between arms manufacturers/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 authorizes the transfer, it shall issue a licence incorporating all the particulars referred to in the first indent. Such licence must accompany the munitions until they reach their destination; it must be produced whenever the authorities of the Member States so require.

3. Each Member State may grant arms manufacturers/dealers the right to effect transfers of munitions from its territory to an arms manufacturer/dealer established in another Member State without prior authorization within the meaning of paragraph 2. To this end, it shall issue an approval valid for a period of three years which may at any time be suspended or cancelled on the basis of a reasoned decision. A document referring to that approval must

accompany the munitions until they reach their destination. It must be produced whenever the authorities of the Member States so require.

No later than the time of transfer, the arms manufacturers/dealers shall communicate to the authorities of the Member State from which the munitions are to be transferred all the particulars listed in the first indent of paragraph 2.

4. Each Member State shall provide the other Member States with a list of munitions in respect of which transfer to its territory may be authorized without prior agreement. Such lists of munitions shall be communicated to arms manufacturers/dealers who have obtained approval to transfer munitions without prior authorization under the procedure laid down in paragraph 3."
5. Each Member State shall communicate all relevant information at its disposal concerning definitive transfers of munitions to the Member State in the territory of which the destination of such transfers is located.
6. The information received by the Member States under the procedures laid down in the preceding paragraphs of this Article shall be communicated, no later than the time of the transfer, to the Member State of destination and, where appropriate, no later than the time of transfer, to the Member States of transit."

15. The end of Article 8(1) is amended as follows:

"... and for applying the procedures referred to in Articles 7 and 7a."

16. Article 11 is amended as follows:

"Member States shall keep available for the other Member States and the Commission their information concerning undertakings in the explosives sector which possess a licence or an authorization such as referred to in Article 1(4).

Member States shall determine whether such undertakings in the explosives sector possess a system for keeping track of explosives such that those in possession of explosives can be identified at any time.

The conditions of application of this paragraph shall be adopted in accordance with the Committee procedure set out in Article 10.

The undertakings in question in the explosives sector shall keep such records of their transactions as are necessary to fulfil the obligations set out in this Article.

The documents referred to in this Article must be kept for a minimum period of three years from the end of the calendar year in which the transaction recorded took place, even if the undertaking has ceased trading. The records must be kept readily available for inspection by the competent authorities at their request".

16a. The following Article 12a is inserted:

"Each Member State shall shall adopt the measures necessary to enable the competent authorities to seize any product falling within the scope of this Directive if adequate proof exists that such product will be unlawfully acquired, used or traded."

17. Article 13 is amended as follows:

1. Member States shall bring into force the provisions necessary to comply with Articles 7, 7a, 8, 9 and 10 before [date of publication in the Official Journal].
2. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with the provisions other than those mentioned in paragraph 1 of this Article before [31 December 1994]. They shall forthwith inform the Commission thereof. They shall apply these provisions as from [1 January 1995].
3. However, Member States shall permit, for the period up to [31 December 2002], the placing on the market of explosives complying with the national regulations in force in their territories on the date of this Directive's adoption.

4. When these provisions are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States;
5. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

18. Annexes 1 and 2 are amended as follows:

"ANNEX 1

LIST OF EXPLOSIVES

Category 1: Explosive materials and articles¹

1.11 Category 1 comprises:

- (a) Explosive materials (a material which, while not itself explosive, may form an explosive mixture if present in the form of a gas, vapour or dust, does not fall within Category 1) except those which are too dangerous to be transported and those whose main risk falls within another category;
- (b) explosive articles, except for devices containing explosive materials in quantity or of a type such that, if ignited or activated in error or by accident during transport, they do not produce any discharge, fire, smoke, heat or intense noise outside the device; and
- (c) materials and articles not mentioned in (a) or (b) above which are manufactured for the purpose of producing a practical effect involving an explosion or pyrotechnics.

1.11.1 The transport of explosive materials which are so sensitive or reactive that they are subject to spontaneous reaction is prohibited.

1.11.2 For the purposes of this Annex:

- (a) "Explosive material" means a material (or a mixture of materials), solid or liquid, which can itself, by chemical reaction, emit gases at a temperature and pressure and at a speed which are such that damage is caused to the surrounding area; pyrotechnic

¹ Text reproduced from the "United Nations Recommendations on the Transport of Dangerous Goods, Including Explosives (Category 1 thereof)".

materials are included in this definition even if they do not emit gases;

- (b) "pyrotechnic material" means a material (or a mixture of materials) intended to produce heat, light, sound, gas or smoke or a combination of these as a result of non-detonating, self-sustained, exothermic chemical reactions;
- (c) "explosive article" means an article containing one or more explosive materials.

1.12 Category 1 has six divisions:

Division 1.1 - materials and articles presenting a risk of mass explosion (a "mass" explosion is an explosion which affects nearly the whole charge almost instantaneously).

Division 1.2 - materials and articles presenting the risk of discharge, without risk of mass explosion

Division 1.3 - materials and articles presenting a risk of fire with a slight risk of blast or of discharge or of both, without risk of mass explosion. This division comprises materials and articles:

- (a) whose combustion produces intense heat radiation; or
- (b) which burn one after the other with slight effects of blast or of discharge or of both.

Division 1.4 - materials and articles not presenting any notable risks. This division comprises materials and articles which present only a slight risk when ignited or activated during transport. The effects are mostly contained within the package and do not usually cause any discharge of sizeable fragments over a notable distance. Exposure to an external fire must not result in nearly all the contents of the package exploding almost instantaneously.

NOTE - The materials and articles in this division - act or designed in such a way that any dangerous effect due to accidental operation remains contained within the packaging (unless the

packaging has been damaged by fire, in which case all effects of blast or discharge must be sufficiently small so as not to greatly hamper efforts to deal with the fire or other emergency action in the immediate vicinity of the package) - are assigned to compatibility group S.

Division 1.5 - materials of minimal sensitivity presenting a risk of mass explosion. This division comprises materials which present a risk of mass explosion, but are of such minimal sensitivity that there is a very low probability of activation or of combustion followed by detonation under normal conditions of transport.

NOTE - The probability of combustion followed by detonation is higher when large quantities of material are transported on a ship.

Division 1.6 - articles of extremely low sensitivity not presenting any risk of mass explosion. This division comprises articles which contain detonating materials of extremely low sensitivity for which it has been established that there is a negligible probability of accidental activation or propagation.

NOTE - Articles in Division 1.6 only present a risk of isolated explosion.

1.13 Category 1 is unique in that the type of packaging often has a decisive effect on the risk and, consequently, on assignment to a particular division. The appropriate division is determined by the method described in Chapter 4.

ANNEX 2

ESSENTIAL SAFETY REQUIREMENTS

I. General requirements

1. Each explosive must be designed, manufactured and supplied in such a way as to present a minimum risk to human life and health and to prevent damage to property and the environment under normal, foreseeable conditions, including those obtaining until such time as it is used.
2. Each explosive must attain the performance characteristics specified by the manufacturer in order to ensure the maximum attainable level of safety and reliability.
3. Each explosive must be designed and manufactured in such a way that it can be disposed of in a safe and environmentally compatible manner in accordance with the state of technology.

II. Special requirements

1. In order to ensure compliance with the conditions set out in Section I above, at least the following properties must be considered and verified for each explosive where their relevance has been appropriately established:
 - (a) Structure and characteristics, including chemical composition, the level of homogeneity and, where appropriate, dimensions and grain-size distribution.
 - (b) The chemical stability of the explosive at all temperatures to which it may be exposed.
 - (c) Sensitivity to impact and friction.

- (d) Compatibility of all constituents in respect of their physical and chemical stability.
 - (e) The mechanical and chemical purity of the explosive.
 - (f) The protection of the explosive against the effects of water where it is intended to be used in a damp environment and where its safety or reliability may be adversely affected by the action of water.
 - (g) Stability at low and high temperatures where the explosive is intended to be used at such temperatures and its reliability or safety may be adversely affected by the cooling or heating of a constituent or of the explosive as a whole.
 - (h) The suitability of the explosive for use in environments deemed to be dangerous such as mines where firedamp is present, hot masses, etc., if it is intended to be used under such conditions.
 - (i) Safety in respect of premature or inadvertent combustion or ignition.
 - (k) Reliable and complete detonation of the explosive when it is used for its intended purpose.
 - (l) Instructions and, where they are necessary, markings relating to handling, storage, use and disposal must be provided in the language of the country of destination.
 - (m) Any deterioration likely to be suffered by the explosives, their coverings or any other component during storage until the final date of use specified by the manufacturer.
 - (n) Specification of all devices and accessories necessary to the reliable and safe functioning of the explosives.
2. The various groups of explosives must also comply at least with the following requirements:

(A) Blasting explosives

- (a) The proposed method of ignition must ensure safe, reliable and complete detonation of the blasting explosive.
- (b) Blasting explosives in cartridge form must transmit the detonation safely and reliably from one end of a column of cartridges to the other.
- (c) The gases 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 and ventilation conditions.

(B) Detonating cords and safety fuses

- (a) The covering of detonating cords and safety fuses must be of adequate mechanical strength and adequately protect the explosive when exposed to normal mechanical stresses.
- (b) The burning times of safety fuses must be indicated.
- (c) Detonating cords must be capable of being reliably initiated, be of sufficient initiation capability and comply with the relevant requirements, even after storage under damp and warm conditions.

(C) Electric and non-electric detonators (including delay elements)

- (a) Detonators must reliably initiate the detonation of the blasting explosives which are intended to be used with them.
- (b) The initiation capability must not be effected by humidity.

- (c) The delay times of delay detonators must be sufficiently uniform to ensure that the delay times of adjacent time steps do not overlap.
 - (d) The electrical characteristics of electric detonators must be indicated.
 - (e) The wires of electric detonators must be of adequate mechanical strength.
- (D) Propellant charges and solid rocket propellants
- (a) These materials must neither explode nor detonate when used for their intended purpose.
 - (b) Propellants based on nitrocellulose must be stabilized against spontaneous decomposition.
 - (c) Solid rocket propellants, when in compressed or cast form, must not contain either fissures or gas bubbles."

19. The following Annexes 3, 4 and 5 have been added:

"ANNEX 3

(1) Module B: EC type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of this Directive that apply to it.
2. The application for the EC type-examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation, as described in point 3.

The application shall place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called "type". The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the product and shall contain to the extent necessary for the assessment:
 - a general type-description,

- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the standards referred to in Article 4, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in the said Article have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

4. The notified body shall:

- 4.1 examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 4, as well as the components which have been designed without applying the relevant provisions of those standards;**
- 4.2 perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 4 have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the Directive;**
- 4.3 perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;**
- 4.4 agree with the applicant the location where the examinations and necessary tests shall be carried out.**

5. Where the type meets the relevant provisions of this Directive, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative established within the Community is denied a type certificate, the notified body shall provide detailed reasons for such denial.

Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications of the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.
7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative established within the Community shall keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least two years after the last date on which the product was manufactured.

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

2. Module C: Conformity to type

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the explosives concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive that applied to them. The manufacturer shall affix the CE mark to each explosive and draw up a written declaration of conformity.
2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate.
3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least ten years after the last date on which the product was manufactured.

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

4. A notified body chosen by the manufacturer shall carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 4, or equivalent tests, shall be carried out to check the conformity of production with the relevant requirements of the Directive. In those cases where one or more specimens of the products checked do not conform, the notified body shall take appropriate measures.

3. Module D: Production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the explosives concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. The manufacturer shall affix the CE mark to each explosive and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for the monitoring as specified in point 4.
2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in point 3 and shall be subject to monitoring as specified in point 4.

3. Quality system

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

The application shall include:

- all relevant information for the product category envisaged,
- the documentation concerning the quality system,
- the technical documentation of the approved type and a copy of the EC type-examination certificate.

- 3.2 The quality system shall ensure compliance of the explosives with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them.

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

a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the explosives' quality,
- the manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required quality of the explosives and the effective operation of the quality system.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard. The auditing team shall have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

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

3.4 The manufacturer shall undertake to fulfill the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

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

4. Surveillance under the responsibility of the notified body.

4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2 The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and shall provide it with all necessary information, in particular:

- the quality system documentation,

- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3 The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4 Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer shall, for a period ending at least ten years after the last date on which the product was manufactured, keep at the disposal of the national authorities:
 - the documentation referred to in the second indent of point 3.1,
 - the updating referred to in the second paragraph of point 3.4,
 - the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.
6. Each notified body shall give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

4. Module E: Product quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the explosives concerned are in conformity with the type as described in the EC type-examination certificate. The manufacturer shall affix the CE mark to each explosive and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.
2. The manufacturer shall operate an approved quality system for final inspection and testing of the explosives as specified in point 3 and shall be subject to surveillance as specified in point 4.
3. Quality system
 - 3.1 The manufacturer shall lodge an application for assessment of his quality system for the explosives concerned with a notified body of his choice.

The application shall include:

- all relevant information for the category of explosives envisaged,

- the quality system documentation,
- the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2 Under the quality system, each explosive shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the Directive. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the examinations and tests that will be carried out after manufacture,
- the means to monitor the effective operation of the quality system,
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team shall have at least one member experienced as

an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

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

- 3.4 The manufacturer shall undertake to discharge the obligations arising out of the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative shall keep the notified body which has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 or whether a re-assessment is required.

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

4. Surveillance under the responsibility of the notified body

- 4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2 The manufacturer shall allow the notified body entrance for inspection purposes to be locations of inspection, testing and storage and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3 The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and

shall provide an audit report to the manufacturer.

- 4.4 Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.
5. The manufacturer shall, for a period ending at least ten years after the last date on which the product was manufactured, keep at the disposal of the national authorities:
 - the documentation referred to in the third indent of point 3.1,
 - the updating referred to in the second paragraph of point 3.4,
 - the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.
6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

5. Module G: Unit verification

1. This module describes the procedure whereby the manufacturer ensures and declares that the explosive concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of the Directive that apply to it. The manufacturer shall affix the CE mark to the explosive and draw up a declaration of conformity.
2. The notified body shall examine the explosive and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 6, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

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

3. The aim of the technical documentation is to enable conformity with the requirements of the Directive to be assessed and the design, manufacture and operation of the explosive to be understood.

The documentation shall contain so far as relevant for assessment:

- a general description of the type;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of the said drawings and schemes and the operation of the protection apparatus or system;
- a list of the standards referred to in Article 4, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 4 have not been applied;
- results of design calculations made, examinations carried out etc.;
- test reports.

ANNEX 4

Minimum criteria to be taken into account by the Member States for the notification of bodies

1. The body, its manager and the personnel responsible for performing the verification operations may not be the designer, the constructor, the supplier, the installer of the explosives which they examine or the

authorized representative of any one of these persons. They may not intervene either directly or as authorized representatives in the design, the construction, the marketing or the maintenance of these explosives. This does not preclude the possibility of an exchange of technical information between the constructor and the body.

2. The body and the personnel responsible for the examination must carry out the verification operations with the greatest professional integrity and the greatest technical competence and must be free of all pressures and incentives, in particular of a financial nature, that might influence their judgment or the results of their examination, particularly from persons or groups of persons interested in the results of the verifications.
3. The body must possess both the personnel and the resources necessary to accomplish adequately the technical and administrative tasks associated with the performance of verifications; it must also have access to the equipment necessary for exceptional verifications.
4. The personnel responsible for examinations must possess:
 - proper technical and professional training,
 - satisfactory knowledge of the procedures to be applied to the examinations they perform and sufficient experience of such examinations,
 - the ability to prepare certificates, records and reports setting out the results of the examinations performed.
5. The independence of the personnel responsible for the examination must be assured. The remuneration of each staff member must not depend either on the number of examinations he performs or on the results of such examinations.
6. The body must take out an insurance policy covering third-party liability unless such liability is covered by the State on the basis of national law or the examinations are performed directly by the Member State.

7. The staff members of the body shall be bound by professional secrecy (save in respect of the competent administrative authorities of the State where they perform their activities) under this Directive or under any provision of national law giving effect to this Directive.

ANNEX 5

Mark of conformity

The mark of conformity shall comprise the symbol CE as shown below and the two last digits of the year in which the mark was affixed.

Where the mark is increased or reduced in size, the proportions indicated in respect of the design presented above must be complied with."

ANNEX

Commission's position regarding the amendments that were not adopted

Amendment No 1: amends the title of the text to:

"Proposal for a Council Regulation ..."

Commission's position

The Regulation formula does have advantages; it enables Community rules to enter into force more rapidly and to be applied in a more homogeneous manner. However, it requires that the procedures for the application of the Community standard be set out in detail. Since this aspect was not taken into account in the Directive's preparatory phase, it was not possible to adopt the Regulation formula.

Amendment No 4: In the 6th recital, the term "very useful" is replaced by "essential".

Commission's position

Within the framework of the "new approach", the conformity of products is assessed in relation to the "essential requirements". The standards are only a means of facilitating the process of demonstrating compliance with the essential requirements. In this sense, they are "very useful" but not essential.

Amendment no 5: In the 7th recital, deletes the wording "and must retain their status as non-mandatory (voluntary) standards".

Commission's position

Within the framework of the "new approach", it is the essential requirements which are mandatory, and not the standards. The latter are only a means of ensuring compliance with the essential requirements.

Amendment No 6: Introduces an 8th recital a, as follows:

"Whereas the "Seveso" Directive should be amended to cover explosives companies"

Commission's position

It is true, to be sure, that the Commission (DG XI) is working on an amendment to the "Seveso" Directive along these lines. However, such a decision has not yet been taken by the Commission. The amendment is hence premature. Furthermore, it would be out of place in an "internal market" Directive.

Amendment No 12: amends Article 4 as follows:

"authorizations to place explosives on the market which have been granted in a Member State pursuant to this Regulation shall be accepted by the other Member States as marketing authorizations which are valid within their territories."

Commission's position

In this instance, account must be taken of the fact that explosives do not form a sector in which acceptance procedures can be automatic. Factors associated with specific uses, for example, may have to be taken into account. For this reason, the formula of automatic acceptance proposed by Parliament cannot be adopted.

Amendment No 18: modifies Article 8 by providing, in particular, that the Member States should set up information exchange networks for the implementation of this Directive no later than 31 December 1993 (and not 1992).

Commission's position

This Directive is one of the instruments necessary to the abolition of frontier controls; for this reason, the arrangements for cooperation between national administrations must enter into effect on 31 December 1992.

Amendment No 19: adds the following sentence to Article 9:

"These amendments shall not seek to alter the scope of this Regulation."

Commission's position

The scope of this Directive is defined by reference to the contents of the United Nations Recommendations on the Transport of Dangerous Goods. If these Recommendations are amended, it must be possible to adapt the contents of the Directive accordingly without excessive delay.

Amendment No 21: deletes Article 14

Commission's position

The same comment applies here as in the case of amendment No 1.

Amendment No 23: adds a third indent a to Annex 2:

"the conditions under which the explosive can be used and the steps to be taken in the event of an accident".

Commission's position

The manufacturer's declaration is linked with the placing of the explosive on the market. It is therefore not possible to consider it as an instrument for verifying either the use or the transport conditions.

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