



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the placing on the market of pyrotechnic articles**

(presented by the Commission)

**EN**

**EN**

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses explicitly excludes pyrotechnic articles from its scope. However, one of its recitals indicates that additional legislation on pyrotechnic articles is planned.

The present proposal aims to create a comprehensive and coherent legislative framework at Community level and introduces minimum safety requirements with the aim of:

- \* ensuring the free movement of pyrotechnic products within the EU,
- \* improving the overall protection of consumers and professionals,
- \* contributing to the reduction of accidents,
- \* harmonising the safety requirements applicable in the different Member States,

#### 1.1. The current situation

The legal framework for placing on the market and the use of pyrotechnic articles differs widely from Member State to Member State. In order to obtain an overview of the situation, in 2003 the Commission sent out a questionnaire concerning the legal framework in relation to pyrotechnic articles, notably fireworks. The questionnaire also aimed to collect statistics on accidents resulting from fireworks in the EU and EEA.

The data on accidents presented below concerns only fireworks and not other pyrotechnic articles such as stage effects and distress flares or pyrotechnic articles for the automotive industry. For these products no consistent system to report accidents exists in the Member States.

##### 1.1.1. *Placing fireworks on the market*

#### **Classification and approval**

Current legislation in the Member States divides fireworks into a number of classes. These classes are separated by the quantity of pyrotechnic substance contained within the firework, and in some cases, also by the location of use (indoors or outdoors) of the firework. Although these national classification systems display a similarity in being based on the quantity of pyrotechnic substance used, they are not the same.

Many Member States have approval systems for placing of fireworks on their markets linked to classification. These approval systems currently use national standards for the examination of fireworks. In recognition of these differences, CEN, the European Committee for Standardisation, is seeking to develop harmonised EU standards on fireworks. A first series of CEN standards for fireworks was published

in May 2003. Some Member States report that they have plans to adopt the CEN standards into their national legislation.

### **Consumer Restrictions**

There are significant differences in the types of fireworks that may be sold according to national restrictions. All Member States prohibit the sale of large fireworks to consumers. Three Member States ban the sale of all fireworks generally to all consumers. In addition, one Member State allows the sale of small fireworks to consumers and prohibits the rest.

Some Member States ban the sale of fireworks with bang effects (e.g. bangers). The sale of certain other types of fireworks is also banned in some Member States. The reasons behind these measures vary from safety concerns to concerns about nuisance effects.

Minimum age restrictions for different categories of fireworks differ widely throughout the EU.

Three Member States only allow the sale and/or use of fireworks on certain days, e.g. between Christmas and New Year's Day.

### **Labelling**

Labelling requirements vary to some extent throughout Member States. These requirements can include information on classification and certification and some information on safe use or age restrictions. All national legislations require the provision of information on safe handling and use.

#### *1.1.2. Accidents*

In response to the Commission questionnaire, only a minority of Member States and one EFTA Member provided numerical information on accidents involving fireworks. One reason for this might be that national systems for the recording of accidents do not contain specific information on fireworks as a cause of accidents.

It appears that accident rates vary significantly between countries. This may be in part due to local customs for the public usage of fireworks.

The recorded accident rate in Greece (about 1 per million) and Ireland (3.9) is lower than that in Denmark (5.4), the UK (60.1), Sweden (about 50) and Norway (4.5). The reasons for these differences are unclear. However it is interesting to note that the two Member States with the lowest reported rate have a ban on the sale of fireworks to consumers.

It should be noted that the information stated above only refers to reported accidents and is based on cases requiring hospital treatment. It does not include information on accidents which may have been treated by a General Practitioner or that may have occurred in the home and have not been reported. It is therefore possible that the number of accidents recorded underestimates the actual figure.

Given that it is not possible to read much into the information beyond stating factual data, any attempt to estimate a figure for the total number of accidents across the EU must be treated very cautiously. However, a lower accident rate might be in the region of 15 per million and an upper rate might be in the region of 100 per million. Using these rates for an enlarged EU population of 455 million would give a total number of accidents involving fireworks of between 7,000 and 45,000 for this area.

Information on whether accidents are a result of a malfunction or a misuse of a firework is also limited. The information presented suggests that the majority are the result of misuse, although it is interesting to note that in Denmark in 2002, almost half of the recorded accidents were the result of a malfunction of the firework. General concern over the quality and standard of some fireworks which might find their way onto the EU market was also expressed by some replying to the questionnaire.

Other pyrotechnic articles such as stage effects and distress flares are also subject to differing national legislations. However, the Commission does not have any statistics on malfunctions or accidents for these products, but it cannot be excluded that accidents due to malfunctions occur.

### *1.1.3. Placing automotive pyrotechnic articles on the market*

Many Member States have different approval processes for the placing of inflators, modules and safety devices for automotive and other uses on their markets. These approval processes currently use national regulations and laws for the approval of these products.

## **1.2. Intended effects of EU legislation**

EU legislation on the marketing and use of pyrotechnic articles is intended to develop the essential safety requirements which are necessary for the effectiveness of harmonised EU standards on pyrotechnic articles. The draft Directive also aims at developing a harmonised EU approach to the provision of information on the safe handling and use of pyrotechnic articles.

A harmonised EU approach on standards for pyrotechnic articles will ensure that sub-standard pyrotechnic articles are not placed on the EU market and should result in a significant reduction in the number of accidents caused through the malfunction of a firework. It extends the CE marking of pyrotechnic articles with the result that only CE marked pyrotechnic articles can be placed on the market.

A harmonised EU approach to the provision of information on the safe handling and use of pyrotechnic articles might also be helpful in reducing the number accidents resulting from misuse.

A harmonised approach to the categorisation, use of standards, and approval system in relation to pyrotechnic articles should lead to significant benefits in terms of product safety coupled with a single market for manufacturers and importers.

At the same time, taking into account the variety of different national regulations on the marketing and use of fireworks, the proposal leaves the possibility for Member

States to maintain their own regulations as far as the minimum age and the marketing and use of certain categories of fireworks are concerned.

### **1.3. Coherence with other community legislation**

Other pyrotechnic articles which already fall under existing EU legislation e.g. on marine equipment have been excluded from the scope of the Directive. It also does not apply to explosives falling within the scope of the Council Directive 93/15/EEC.

The Directive therefore is coherent with other Community legislation.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **Consultations**

As a working group for pyrotechnic articles at EU level did not previously exist, the consultation process for the Directive started in May 2003 with the sending out of the questionnaire, as described above. This was accompanied by a letter to the Permanent Representations of the Member States and to the Missions of the candidate and EFTA countries, which encouraged the circulation of the questionnaire to potential stakeholders, and which made clear that all persons were free to respond.

A first meeting of a stakeholder working group was organised on 23 September 2003, followed by two more meetings on 1 December 2003 and 16 March 2004 in Brussels. For these meetings, invitations were sent to Member State, candidate country and EFTA member administrations and to those associations which had replied to the questionnaire or which had declared their interest to participate in the working group.

The Pyrotechnics industry was represented by delegates from the European Pyrotechnics Association. The automotive components supplier industry was represented by CLEPA, their European association.

CEN, the European Committee for Standardisation, and in particular its technical committee for pyrotechnic articles have also been closely associated with the preparation of the Directive. It has assisted in the drafting of the essential safety requirements, which were finalised at a meeting hosted by the Netherlands in Delft on 17 to 18 November 2003.

Several earlier drafts of the Directive were widely distributed by the working group participants, and subsequently comments were received not only from the public authorities in charge of pyrotechnics, but also from several industry associations and individual companies (fireworks, automotive component suppliers and aerospace sectors).

In principle, most Member States and the associations of the pyrotechnics industry and the automotive component suppliers welcome the initiative for a Directive on pyrotechnic articles. However, the competent authorities of the UK and Sweden think that EU legislation in this area is not necessary, a point of view supported by some UK pyrotechnics manufacturers.

While the European automotive component suppliers have explicitly requested that airbags and other pyrotechnic car safety equipment be included in the scope of the Directive, there was a request to exclude aerospace parts because they were already covered by other international rules.

The main discussion with the Member States during the working group meetings concerned the extent to which Member States could maintain national restrictions on the sale and use of certain categories of fireworks.

Since there are markedly different cultural traditions when it comes to fireworks, the proposal foresees the possibility for Member States to restrict the use and/or sale to the public of category 2 and 3 fireworks.

Some Member States also want to be able to restrict the use and/or sale of category 1 fireworks (i.e. fireworks which present a very low hazard and which are intended for use in confined areas, including fireworks which are intended for use inside domestic buildings), from which there is by definition only very little risk. While we cannot accept this in principle, as it is necessary to create internal market conditions for this product group, the Commission is prepared to give a new mandate to CEN in order to redefine category 1 and to work on a list of those articles which can be regarded as harmless by all Member States and which should subsequently be able to circulate freely on the internal market.

Another controversial issue raised by a number of Member States was that of the minimum age limits. However, the Commission has made it clear that these are minimum requirements and that the Member States have the right to impose stricter limits if deemed necessary. For those Member States which do not yet have minimum age limits for the sale of fireworks to end consumers, these minimum age limits are expected to have a positive effect on the number of fireworks-related accidents.

#### **Impact assessment**

The EU market for fireworks for sale to consumers (categories 1, 2 and 3) is estimated to be around €700 million per year. The EU market for fireworks for sale to professionals only is also estimated to be around €700 million per year. Few fireworks are manufactured in the EU. Many of the fireworks which are manufactured in the EU are for professional use (category 4).

It is estimated that automotive occupant restraint systems are placed in around 20 million vehicles in the EU each year. In the case of airbags, this amounts to around 80 million systems being placed on the market each year with a value of around €3.5 billion. And in the case of seat belt pre-tensioners, around 90 million units are placed on the market each year with a value of around €2 billion.

The proposed Directive would create a single market for pyrotechnical articles. This is expected to result in the elimination of barriers to trade currently caused through national provisions in place throughout the EU. The Directive will set out essential safety requirements for pyrotechnical articles with Member State competent authorities assessing the compliance of these articles against the requirements. Articles which are considered to meet the safety requirements can be CE marked,

guaranteeing their free circulation within the EU, whilst at the same time ensuring a high level of protection to consumers.

The Directive is expected to lead to a considerable reduction in costs as a single CE assessment of conformity will replace up to 25 parallel national approval procedures.

The main benefits are therefore: reduced burdens on enterprises through a harmonised approval system for the placing of pyrotechnic articles on the market along with the creation of a single market, and a high level of protection to consumers.

Pyrotechnic articles intended for use by the armed forces, police, in aircraft or falling within the scope of the Marine Equipment Directive (96/98/EC) will be excluded from the Directive.

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **Legal Basis**

The legal basis of the proposal is Article 95 of the Treaty.

The present Directive will determine the conditions for placing and using pyrotechnic products on the EU market by harmonising the essential requirements. The objective will be to introduce minimum safety requirements to protect the general public and professionals while eliminating or avoiding barriers to trade and preventing distortion of competition due to divergent regulatory systems. The focus is therefore on protecting users whilst improving the conditions for the functioning of the internal market.

Article 95 of the EC Treaty is therefore appropriate for harmonising the conditions of marketing and use of pyrotechnic products whilst improving the protection of users.

#### **Subsidiarity and proportionality principles**

Legislation on the marketing and use of pyrotechnic articles is currently determined nationally throughout the EU and such divergent national legislation is liable to cause barriers to intra-community trade.

Therefore, the Commission's intention is to create a genuine internal market for certain categories of pyrotechnic articles and to introduce essential safety requirements. This is only possible by using a Directive or Regulation.

As far as accidents are concerned, and taking into account that it is very easy to transport fireworks illegally from one Member State to another over open borders, it is not easy for authorities to control the placing on the market of fireworks. Without the definition of essential safety requirements, it can be expected that the number of accidents due to the effective fireworks would further increase.

However, subsidiarity will also be taken into account as the proposed Directive will not preclude Member States from taking measures on grounds of public security or safety to restrict the placing on the market of certain categories of fireworks. The

proposed Directive also will allow Member States to maintain higher minimum age limits for the sale of fireworks to consumers again on grounds of public security or safety.

The proposed Directive is proportionate to the aims of improving consumer safety and creating the internal market for pyrotechnic articles.

#### **Choice of instruments**

The Commission has chosen a Directive as the best instrument for achieving its objectives, since there is the necessity to harmonise the differing national legislations on pyrotechnic articles. An alternative would have been a Regulation, however, this has never been done before for the New Approach, and a number of provisions contained in the Directive (e.g. obligation of the Member States to notify notified bodies and to engage in market surveillance) could not be contained in the Regulation, because it is directly applicable.

#### **4. BUDGETARY IMPLICATIONS**

There are no immediate budgetary implications from the proposed Directive. The Committee referred to in Article 18 will decide upon the possibility to establish a Register of European Union registration numbers for pyrotechnic articles that will make it easier to identify pyrotechnic articles and their manufacturer or the authorised representative in case of accidents through malfunctioning. This provision could have budgetary implications later on which need to be studied in detail when such a proposal is being made.



Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the placing on the market of pyrotechnic articles**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>3</sup>,

Whereas:

- (1) The laws, regulations and administrative provisions in force in the Member States with regard to the placing on the market and use of pyrotechnic articles are different, in particular as regards aspects such as safety and performance characteristics.
- (2) These provisions, being liable to cause barriers to trade within the Community should be harmonised in order to guarantee the free movement of pyrotechnical articles within the internal market whilst ensuring a high level of protection of human health and safety of consumers.
- (3) Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses<sup>4</sup> states that pyrotechnic articles require appropriate measures to ensure the protection of consumers and the safety of the public and that additional legislation is planned in this field.

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<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C , , p. .

<sup>4</sup> OJ L 121, 15.5.1993, p. 20.

- (4) Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (called "Seveso II Directive")<sup>5</sup>, extended by Directive 2003/105/EC<sup>6</sup> of the European Parliament and of the Council of 16 December 2003 establishes safety requirements for establishments where among other dangerous substances explosives including pyrotechnics are present.
- (5) In order to ensure appropriately high levels of protection, pyrotechnic articles should be categorised according to their type of use, or their purpose and level of hazard.
- (6) Given the dangers inherent in the use of pyrotechnic articles, it is appropriate to lay down age limits for their sale to consumers and their use, and to ensure that their labelling displays sufficient and appropriate information on safe use, in order to protect human health and safety and the environment. Provision should be made for certain pyrotechnic articles to be made available only to authorised specialists with the necessary knowledge, skills and experience.
- (7) The use of pyrotechnics and in particular the use of fireworks, is subject to markedly different cultural customs and traditions in different Member States. This makes it necessary to allow Member States to take national measures to limit the use or sale of certain categories of fireworks to the general public for public security or safety reasons.
- (8) It is appropriate to establish essential safety requirements for pyrotechnic articles.
- (9) Responsibility for ensuring that pyrotechnic articles comply with this Directive and in particular with those essential safety requirements should rest with the manufacturer, who should be established in the Community or appoint an authorised representative.
- (10) It should not be possible, where the essential safety requirements are satisfied, for Member States to prohibit, restrict or hinder the free movement of pyrotechnic articles.
- (11) In order to facilitate the process of demonstrating compliance with the essential safety requirements, harmonised standards are being developed related to the design, manufacture and testing of such articles.
- (12) European harmonised standards are drawn up, adopted and modified by the Committee for European Standardisation (CEN), the Committee for Electro-technical Standardisation (CENELEC) and the European Telecommunication Standards Institute (ETSI). These organisations are recognised as competent for the adoption of harmonised standards, which they draw up in accordance with the general guidelines for co-operation between themselves and the Commission<sup>7</sup>, and with the procedure laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>8</sup>.

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<sup>5</sup> OJ L 10, 14.1.1997 P. 13

<sup>6</sup> OJ L 345, 31/12/2003 P. 0097 - 0105

<sup>7</sup> OJ L 91, 16.4.2003 P. 7.

<sup>8</sup> OJ L 204, 21.7.1998, p. 37, as last amended by Directive 98/48/EC (OJ L 217, 5.8.1998, P.18).

- (13) The Council, in its Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives, introduced harmonised means of applying procedures for conformity assessment. The application of these modules to pyrotechnic articles will make it possible to determine the responsibility of manufacturers and of bodies involved in the conformity assessment procedure by taking account of the nature of the pyrotechnic articles concerned.
- (14) Pyrotechnic articles should bear the CE marking indicating their conformity with the provisions of this Directive to enable them to move freely within the Community.
- (15) As regards safety in transportation, the rules concerning the transport of pyrotechnic articles are covered by international conventions and agreements, including the United Nations recommendations on the transport of dangerous goods.
- (16) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (17) It is vital to provide for a transitional period to allow national laws in specified fields to be gradually adapted.
- (18) Since the objectives of this Directive cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. 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 those objectives.
- (19) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC<sup>9</sup>,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Objectives and scope**

1. This Directive establishes rules designed to achieve the free movement of pyrotechnic articles in the internal market while, at the same time ensuring a high degree of protection of human health and safety of consumers.
2. This Directive establishes the essential safety requirements which pyrotechnic articles must fulfil with a view to their placing on the market.
3. This Directive shall apply to pyrotechnic articles as defined in article 2.

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<sup>9</sup> OJ L 184, 17.7.1999, p. 23.

4. This Directive shall not apply to:
- Pyrotechnic articles intended for use, in accordance with national law, by the armed forces or the police;
  - Articles falling within the scope of Council Directive 96/98/EC of 20 December 1996 on marine equipment<sup>10</sup>;
  - Pyrotechnic articles intended for use in aircraft;
  - Pyrotechnic articles falling within the scope of Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys<sup>11</sup>;
  - Explosives falling within the scope of Council Directive 93/15/EEC<sup>12</sup> of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses;
  - Ammunitions, meaning projectiles and propelling charges used in small arms, artillery, and other guns.

## *Article 2*

### **Definitions**

#### **For the purposes of this Directive:**

1. 'Pyrotechnic article' means any article containing substances or a mixture of substances designed to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions for both entertainment and other purposes.
2. 'Placing on the market' means the first making available on the Community market of an individual product intended for end use, with a view to distribution and/or use, whether in return of payment or free of charge.
3. 'Firework' means pyrotechnic article for entertainment.
4. 'Automotive pyrotechnic article' means articles which contain pyrotechnic substances used to activate safety devices or other devices in motor vehicles.
5. 'Manufacturer' means the natural or legal person who designs and/or manufactures a product covered by this Directive or who has such a product designed and manufactured, with a view to its placing on the market or for his own professional or private use, under his own name or trademark; or places a product covered by this Directive on the market under his own name or trademark.

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<sup>10</sup> OJ L 46, 17.2.1997, p. 25.

<sup>11</sup> OJ L 187, 16.07.1988 p. 1.

<sup>12</sup> OJ L 121, 15.5.1993 p. 20.

6. 'Authorised representative' means any natural or legal person established within the Community who has received a written mandate from the manufacturer to act on his behalf with regard to the latter's responsibilities under this Directive.
7. 'Harmonised standard' means a European Standard adopted by a European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC compliance with which is not compulsory.
8. 'Person with specialist knowledge' means a person authorised by Member States to possess and/or use on their territory category 4 fireworks and/or category 2 other pyrotechnic articles as defined in Article 3.

### *Article 3*

#### **Categorisation**

1. Pyrotechnic articles falling within the scope of this Directive shall be categorised by the manufacturer according to their type of use, or their purpose and level of hazard. Notified bodies shall confirm the categorisation as part of the conformity assessment procedures according to Article 9.

Categorisation shall be as follows:

#### **a) Fireworks**

Category 1: fireworks which present a very low hazard and which are intended for use in confined areas, including fireworks which are intended for use inside domestic buildings;

Category 2: fireworks which present a low hazard and which are intended for outdoor use in confined areas;

Category 3: fireworks which present a medium hazard and which are intended for outdoor use in large open areas;

Category 4: fireworks which present a high hazard and which are intended for use by persons with specialist knowledge only, commonly known as "fireworks for professional use".

#### **b) Other pyrotechnic articles**

Category 1: pyrotechnic articles other than fireworks which present a low hazard;

Category 2: pyrotechnic articles other than fireworks which are intended for handling or use by persons with specialist knowledge only.

2. Member States shall inform the Commission of the procedures whereby they identify and authorise persons with specialist knowledge.

#### *Article 4*

##### **Obligations of the manufacturer**

1. Manufacturers shall ensure that pyrotechnic articles falling within the scope of this Directive comply with the essential safety requirements set out in Annex I which apply to them as well as all the relevant provisions of this Directive.
2. Manufacturers of pyrotechnic articles shall be established in the Community or appoint an authorised representative.

The authorised representative may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to those obligations that the representative has been mandated to carry out.

3. Manufacturers of pyrotechnic articles shall:
  - (a) Submit the product to a notified body which will perform a conformity assessment procedure in accordance with Article 9;
  - (b) Affix the CE-marking and label of the pyrotechnic article in accordance with Articles 11 and 12.

#### *Article 5*

##### **Placing on the market**

Member States shall take all appropriate measures to ensure that pyrotechnic articles which fall within the scope of the present Directive may be placed on the market only if they comply with the obligations of this Directive, they bear the EC marking, and they comply with the obligations relating to the conformity assessment.

Member States shall take all appropriate measures to ensure that pyrotechnic articles shall not unduly bear the CE marking.

#### *Article 6*

##### **Free Movement**

1. Member States shall not prohibit, restrict or hinder the placing on the market of pyrotechnic articles which fall within the scope of this Directive and which satisfy the requirements of this Directive.
2. The provisions of this Directive shall also not preclude measures by a Member State which are justified on grounds of public security or safety to restrict the use and/or the sale to the general public of category 2 and 3 fireworks.

3. At trade fairs, exhibitions and demonstrations for marketing purposes, Member States shall not prevent the showing of pyrotechnic articles not in conformity with the provisions of this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability for sale until brought into conformity by the manufacturer or by his authorized representative established within the Community. During such events, appropriate safety measures shall be taken in accordance with any requirements laid down by the competent authority of the Member State concerned in order to ensure the safety of persons.
4. Member States shall not prevent the free movement and use of automotive pyrotechnic articles manufactured for the purpose of research, development and testing and which are not in conformity with the provisions of this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability for sale.

#### *Article 7*

#### **Age limits**

1. Pyrotechnic articles shall not be sold or made otherwise available to consumers below the following age limits:
  - a) **Fireworks**
    - Category 1: 12 years.
    - Category 2: 16 years.
    - Category 3: 18 years.
  - b) **Other pyrotechnic articles**
    - Category 1: 18 years.
2. Member States may increase the age limits under paragraph 1 where justified on grounds of public security or safety. Member States may also lower the age limits for persons vocationally trained or undergoing such training.
3. Manufacturers and distributors shall not sell or otherwise make available the following pyrotechnic articles except to persons with specialist knowledge only:
  - (a) Fireworks of category 4,
  - (b) Other pyrotechnic articles of category 2.

## *Article 8*

### **Harmonised standards**

1. The Commission may, in accordance with the procedures laid down by Directive 98/34/EC, request the European standardisation bodies to draw up or revise European standards in support of this Directive.
2. The Commission shall publish in the Official Journal of the European Union the references of such harmonised standards.
3. Member States shall consider pyrotechnic articles falling within the scope of this Directive which comply with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union, to be in conformity with the essential safety requirements referred to in Article 4(1).

When Member States adopt national transposition of the harmonised standards they shall publish the reference numbers of these transpositions.

4. Where a Member State or the Commission considers that the harmonised standards referred to in this Article do not fully satisfy the essential safety requirements referred to in Article 4(1), the Commission or the Member State concerned shall bring the matter before the Standing Committee set up by Directive 98/34/EC, 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 harmonised standards and the publication referred to in paragraph 2.

## *Article 9*

### **Conformity assessment procedures**

1. For the attestation of conformity of pyrotechnic articles the Manufacturer shall follow one of the following procedures:
  - (a) EC type-examination (Module B) procedure referred to in Annex II (1), and, at the choice of the manufacturer, either:
    - the conformity to type (Module C) procedure referred to in Annex II (2), or
    - the production quality assurance (Module D) procedure referred to in Annex II (3), or
    - the product quality assurance (Module E) procedure referred to in Annex II (4), or
    - the product verification (Module F) procedure referred to in Annex II (5); or



- (b) the unit verification (Module G) procedure referred to in Annex II (6).

#### *Article 10*

##### **Notified bodies**

1. Member States shall inform the Commission and the other Member States of the bodies which they have appointed to carry out the procedures for assessing the conformity referred to in Article 9 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.
2. The Commission shall publish on the Commission's Internet web site 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.
3. 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 harmonised standards relevant for notified bodies shall be presumed to satisfy the relevant minimum criteria.
4. A Member State which has 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 paragraph 3. It shall immediately inform the other Member States and the Commission accordingly.

#### *Article 11*

##### **Obligation to affix CE marking**

1. After having completed the conformity assessment successfully according to Article 9, manufacturers shall affix the CE marking, in such a way as to be visible, legible and indelible on the pyrotechnic articles themselves or, if this is not possible, on an identification plate attached thereto or, in the last resort, if the first two methods cannot be used, on the packaging. The identification plate must be so designed as to make its reuse impossible.  

The model to be used for the CE marking shall be in accordance with Council Decision 93/465/EEC.
2. Manufacturers shall not affix on pyrotechnic articles any marking or inscription which may confuse third persons as to the meaning and form of the CE marking. Any other marking may be affixed on pyrotechnic articles provided the visibility and legibility of the CE marking is not impaired.
3. Where pyrotechnic articles falling within the scope of this Directive are subject to other European Union legislation which cover other aspects and prescribe the fixing of the CE marking, this marking shall indicate that the above mentioned products are also presumed to conform to the provisions of the other legislation which apply to them.

## *Article 12*

### **Labelling**

1. Manufacturers shall ensure that pyrotechnic articles are properly labelled in the official language(s) of the country in which the article is sold to the consumer.
2. The labelling of pyrotechnic articles shall state as a minimum, the name of manufacturer or its authorised representative, the name and type of the article, minimum age limits as indicated in Article 7 paragraphs 1 and 2, the relevant category and instructions for use and, where appropriate, safety distance. Labelling shall also refer to the Class/Division (1.1-1.6) of the substance or mixture of substances contained in the article in accordance with the UN/ADR classification scheme or state comparable information on the hazard (mass explosion hazard, projection hazard, blast hazard, fire hazard).
3. Fireworks shall additionally contain the following minimum information:
  - Category 1: where appropriate: "for outdoor use only" and minimum safety distance
  - Category 2: "for outdoor use only" and, where appropriate, minimum safety distance(s)
  - Category 3: "for outdoor use only" and minimum safety distance(s)
  - Category 4: "for use by person with specialist knowledge only" and minimum safety distance(s)
4. If the pyrotechnic article does not provide sufficient space for the labelling requirements referred to in paragraphs 2 and 3, the information shall be provided on the packaging.
5. The provisions of paragraphs 1 to 4 shall not apply to fireworks of category 4 and other pyrotechnic articles of category 2 which are being publicly displayed by the manufacturer.

## *Article 13*

### **Market surveillance**

1. Member States shall take all appropriate measures to ensure that pyrotechnic articles falling in the scope of this Directive may be placed on the market only if, when properly stored and used for their intended purpose, they do not endanger the health and safety of persons.
2. Member States shall organise and perform appropriate surveillance of products placed on the market taking due account of the presumption of the conformity of products bearing the CE marking.

3. Where a Member State ascertains that products covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose, is liable to compromise the health and safety of persons it shall take all appropriate provisional measures to withdraw such product from the market, to prohibit the placing on the market or to restrict free movement thereof. The Member State shall inform the Commission and the other Member States of this.

#### *Article 14*

#### **Rapid information on products presenting serious risks**

Where a Member State has sufficient reasons to believe that a product covered by this Directive presents a serious risk that could compromise the health and/or safety of persons in the European Union, it shall inform the Commission and the other Member States thereof and shall perform an appropriate evaluation. It shall inform the Commission and the other Member States of the background for and of the results of the evaluation.

#### *Article 15*

#### **Safeguard clause**

1. Where a Member State has justifiable grounds for believing that a pyrotechnic article is not in conformity with the requirements of this Directive it shall, in the information procedure referred to in Article 13, paragraph 3 and 14, indicate the reasons for its decision and, in particular whether the non-conformity is due to:
  - (a) failure to satisfy the essential requirements referred to in Article 4 (1);
  - (b) incorrect application of the harmonised standards referred to in Article 8;
  - (c) shortcomings in the harmonised standards themselves referred to in Article 8.
2. The Commission shall enter into consultation with the parties concerned without delay. The Commission shall consider, after this consultation, if the measures taken by the Member State are justified or not, and it shall communicate its opinion to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.
3. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards, the Commission shall refer the matter to the committee instituted by Directive 98/34/EC if the Member State at the origin of the measures maintains its position, and the Commission or the Member State shall initiate the procedure referred to in Article 8.
4. Where a pyrotechnic article does not conform and bears the CE marking, the competent Member State shall take appropriate action against whoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.

5. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.

#### *Article 16*

##### **Measures entailing refusal or restriction**

1. Any measure taken, pursuant to this Directive,
  - (a) to prohibit or restrict the placing on the market of a product; or
  - (b) to withdraw a product from the market, shall state the exact grounds on which it is based. Such measures shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State concerned and of the time limits to which such remedies are subject.
2. In the event of a measure referred to in Article 16(1), the manufacturer should have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken, as justified in particular by public health or safety requirements.

#### *Article 17*

##### **Implementing measures**

Where necessary, the following measures for the implementation of this Directive shall be adopted in accordance with the procedure referred to in Article 18(2);

- Adaptations necessary to take account of any future amendments to United Nations recommendations.
- Adaptations to technical progress of Annexes 2 and 3.
- The setting up of a register of European Union registration numbers for pyrotechnic articles that will make it easier to identify pyrotechnic articles and their manufacturer or the authorised representative in case of accidents through malfunctioning.
- Other measures needed for the efficient implementation of this Directive.

#### *Article 18*

##### **Committee**

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 99/468/EC shall be set at three months.

3. The committee shall adopt its rules of procedure.

#### *Article 19*

##### **Sanctions**

1. No later than [...] <sup>13</sup> of this Directive, Member States shall establish appropriate legal or administrative measures in order to deal with any infringement of this Directive and dissuasive, effective and proportionate sanctions for any such infringement.

Member States shall include measures allowing them to detain consignments of pyrotechnic articles that fail to comply with this Directive.

2. They shall immediately inform the Commission thereof.

#### *Article 20*

##### **Transposition**

1. Member States shall adopt and publish, by [...] <sup>14</sup> at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.
2. They shall apply those provisions by [...] <sup>15</sup> for fireworks and by [...] <sup>16</sup> for other pyrotechnic articles.
3. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
4. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.
5. National authorisations granted before the date indicated in paragraph 2 shall continue to be valid on the territory of the Member State having granted the authorisation until their expiry date or up to 10 years from the entry into force of the Directive, whichever is the shorter.
6. By way of derogation to the paragraph 5, national authorisations for automotive pyrotechnic articles granted before the date indicated in paragraph 2 shall continue to be valid until their expiry.

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<sup>13</sup> 18 months after the entry into force

<sup>14</sup> 18 months after publication of the Directive

<sup>15</sup> 24 months after publication of the Directive

<sup>16</sup> 5 years after the publication of the Directive

*Article 21*

**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*.

*Article 22*

**Addressees**

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## ANNEX I

### ESSENTIAL SAFETY REQUIREMENTS

- (1) Each pyrotechnic article must attain the performance characteristics specified by the manufacturer to the notified body in order to ensure maximum safety and reliability.
- (2) Each pyrotechnic article must be designed and manufactured in such a way that it can be disposed of safely by a suitable process with minimum effect on the environment.
- (3) Each pyrotechnic article must function correctly when used for its intended purpose.

The following information and properties - where applicable - must be considered or tested. Each pyrotechnic article should be tested under realistic conditions. If this is not possible in a laboratory, the tests must be carried out in the conditions in which the pyrotechnic article is to be used.

- (a) Design, construction and characteristic properties, including detailed chemical composition (mass and percentage of substances used) and dimensions.
- (b) The physical and chemical stability of the pyrotechnic article in all normal, foreseeable environmental conditions.
- (c) Sensitiveness to normal, foreseeable handling and transportation.
- (d) Compatibility of all components as regards their chemical stability.
- (e) Resistance of the pyrotechnic article 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.
- (f) Resistance to low and high temperatures, where the pyrotechnic article 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 pyrotechnic article as a whole.
- (g) Safety features intended to prevent untimely or inadvertent initiation or ignition.
- (h) Suitable instructions and, where necessary, markings in respect of safe handling, storage, use (including safety distances) and disposal in the official language or languages of the recipient Member State.
- (i) The ability of the pyrotechnic article, its wrapping or other components to withstand deterioration under normal, foreseeable storage conditions.
- (j) Specification of all devices and accessories needed and operating instructions for safe functioning of the pyrotechnic article.
- (k) During transportation and normal handling, unless specified by the manufacturer's instructions, the pyrotechnic articles should contain the pyrotechnic composition.

- (4) The various groups of pyrotechnic articles must at least also comply with the following requirements:

**A. Fireworks**

- a) The manufacturer shall assign fireworks to different categories according to Article 3 characterised by net explosive content, safety distances, sound level, or similar. The category shall be clearly indicated on the label.
- b) Fireworks may only contain construction materials which minimise risk to health, property and environment from debris.
- c) The method of ignition must be clearly visible or must be indicated by labelling or instructions.
- d) Fireworks shall not move in an erratic and unforeseeable manner.
- e) Fireworks of category 1, 2 and 3 must be protected against inadvertent ignition either by a protective cover, by the packaging, or by the construction of the article. Fireworks of category 4 must be protected against inadvertent ignition by methods specified by the manufacturer.

**B. Other pyrotechnic articles**

- a) Pyrotechnic articles must be designed in such a way as to minimise risk to health, property and environment during normal use.
- b) The method of ignition must be clearly visible or must be indicated by labelling or instructions.
- c) The pyrotechnic article must be designed in such a way as to minimise risk to health, property and environment from debris when initiated inadvertently.
- d) Where appropriate, the pyrotechnic article shall function properly until the 'use by' date specified by the manufacturer

**C. Ignition devices**

- a) Ignition devices must be capable of being reliably initiated and be of sufficient initiation capability under all normal, foreseeable conditions of use.
- b) Ignition devices must be protected against electrostatic discharge under normal, foreseeable conditions of storage and use.
- c) Electric igniters must be protected against electromagnetic fields under normal, foreseeable conditions of storage and use.
- d) The covering of fuses must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal, foreseeable mechanical stress.



- e) The parameters for the burning times of fuses must be provided with the article.
- f) The electrical characteristics (e.g. no-fire current, resistance, etc.) of electric igniters must be provided with the article.
- g) The wires of electric igniters must be of sufficient insulation and mechanical strength including the solidity of the link to the igniter, taking account of their intended use.

## ANNEX II

### CONFORMITY ASSESSMENT PROCEDURES

#### 1. MODULE B: EC 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.

2. The application for EC type-examination is lodged by the manufacturer with a notified body of his choice.

The application must include:

- the name and address of the manufacturer,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical 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.

3. The technical documents must enable the conformity of the appliance with the requirements of the Directive to be assessed. They must, as far as is relevant for such assessment, cover the design, manufacture and operation of the appliance and contain as far as is relevant for assessment:

- a general type-description,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of the drawings and diagrams and the operation of the product,
- a list of the harmonised standards referred to in Article 8, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of the Directive where the harmonised standards referred to in Article 8 have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

4. The notified body must:

4.1. examine the technical documents, verify that the type has been manufactured in conformity with those documents and identify the elements which have been designed in accordance with the relevant provisions of the harmonised standards referred to in Article 8 as

well as the components which have been designed without applying the relevant provisions of those harmonised standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the harmonised standards referred to in Article 8 have not been applied, the solutions adopted by the manufacturer meet the essential safety 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 harmonised standards, these have actually been applied;

4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.

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

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 is refused a type certificate, the notified body must provide detailed reasons for such refusal.

Provision must be made for an appeals procedure.

6. The applicant informs the notified body that holds the technical documents concerning the EC type-examination certificate of all modifications to the approved appliance 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 must 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 must be kept at the disposal of the other notified bodies.

9. The manufacturer must keep with the technical documents copies of EC type-examination certificates and their additions for a period of at least 10 years after the last date of manufacture of the product concerned.

Where the manufacturer is not 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: Conformity to type**

1. This module describes that part of the procedure whereby the manufacturer ensures and declares that the pyrotechnic articles concerned are in conformity with the type as described

in the EC type-examination certificate and satisfy the requirements of this Directive that apply to them. The manufacturer must affix the CE marking to each pyrotechnic article and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process assures the conformity of the manufactured product with the type as described in the EC type-examination certificate with the essential safety requirements of the Directive.

3. The manufacturer must keep a copy of the declaration of conformity for a period of at least 10 years after the last date of manufacture of the product concerned.

Where the manufacturer is not 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 and appropriate tests, defined in the applicable harmonised standard referred to in Article 8 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 number of that body during the manufacturing process.

### **3. MODULE D: Production quality assurance**

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the pyrotechnic articles concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. The manufacturer affixes the CE marking to each article and draws up a written declaration of conformity. The CE marking is accompanied by the identification number of the notified body responsible for the checks referred to in Section 4.

2. The manufacturer must operate an approved quality system for production, final product inspection and testing as specified in Section 3. He is subject to the checks referred to in Section 4.

#### **3. Quality system**

3.1. The manufacturer lodges an application for assessment of his quality system with a notified body of his choice, for the pyrotechnic articles concerned.

The application must include:

- all relevant information for the pyrotechnic article category envisaged,
- the documents concerning the quality system,
- the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.

3.2. The quality system must ensure conformity of pyrotechnic articles with the type as described in the EC type-examination certificate and with the requirements of this Directive that apply to them.

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

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pyrotechnic articles,
- 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 of monitoring the achievement of the required quality of pyrotechnic articles and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in section 3.2. It must presume conformity with those requirements in respect of quality systems that implement the relevant harmonised standard. The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure includes an inspection visit to the manufacturer's premises.

The decision is notified to the manufacturer. The notification must contain the conclusions of the examination and the duly substantiated assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer must keep the notified body that has approved the quality system informed of any proposed change in the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in section 3.2 or whether reassessment is required.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

4. Monitoring under the responsibility of the notified body

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

4.2 The manufacturer must allow the notified body access for inspection purposes to the manufacturing, inspection, testing and storage premises and provide it with all necessary information, in particular:

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

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

4.4. Additionally the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the product, keep at the disposal of the national authorities:

- the document referred to in the second indent of section 3.1,
- the updating referred to in second paragraph of section 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of section 3.4, and in sections 4.3 and 4.4.

6. Each notified body must 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 Section 2 ensures and declares that the pyrotechnic articles are in conformity with the type as described in the EC type-examination certificate. The manufacturer must affix the CE marking to each article and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the checks referred to in Section 4.

2. The manufacturer must operate an approved quality system for final pyrotechnic article inspection and testing as specified in Section 3. He must be subject to the checks referred to in Section 4.

#### **3. Quality system**

3.1. The manufacturer lodges an application with a notified body of his choice for the assessment of the quality system for his pyrotechnic articles.

The application must include:

- all relevant information for the pyrotechnic category envisaged,
- the quality system's documentation,
- the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.

3.2. Under the quality system, each pyrotechnic article is examined and appropriate tests as defined in the relevant harmonised standard(s) referred to in Article 8 or equivalent tests are carried out in order to verify its conformity with the relevant requirements of the Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must enable the quality programmes, plans, manuals and records to be interpreted in a uniform manner.

It must in particular contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
- the examination and tests that will be carried out after manufacture,
- the means of monitoring 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 must assess the quality system to determine whether it satisfies the requirements referred to in section 3.2. It must presume conformity with these requirements in respect of quality systems that implement the relevant harmonised standard.

The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure must include an inspection visit to the manufacturer's premises.

The manufacturer must be notified of the decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer must keep the notified body which has approved the quality system informed of any proposed change in the quality system. The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in section 3.2 or whether a reassessment is required. It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

#### 4. Monitoring under the responsibility of the notified body

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

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage premises and provide it with all necessary information, in particular:

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

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

4.4. Additionally, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must for a period of at least 10 years after the last date of manufacture of the product keep at the disposal of the national authorities:

- the documents referred to in the second indent of section 3.1,
- the changes referred to in the second paragraph of section 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of section 3.4, and in sections 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

## **5. MODULE F: Product verification**

1. This module describes the procedure whereby a manufacturer checks and attests that the pyrotechnic articles subject to the provisions of section 3 are in conformity with the type as described in the EC type-examination certificate and satisfy the relevant requirements of the Directive.

2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the pyrotechnic articles with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them. He shall affix the CE marking to each pyrotechnic article and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the pyrotechnic article with the relevant requirements of the Directive by examination and testing of every article as specified in section 4.

The manufacturer shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last pyrotechnic article has been manufactured.



#### 4. Verification by examination and testing of every pyrotechnic article

4.1. All pyrotechnic articles shall be individually examined and appropriate tests as set out in the relevant harmonised standard(s) referred to in Article 8 or equivalent tests shall be carried out in order to verify their conformity with the relevant type and requirements of the Directive.

4.2. The notified body shall affix, or cause to be affixed, its identification number to each approved pyrotechnic article and draw up a written certificate of conformity relating to the tests carried out.

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

#### 6. MODULE G: Unit verification

1. This module describes the procedure whereby the manufacturer ensures and declares that the pyrotechnic article which has been issued with the certificate referred to in Section 2 conforms to the relevant requirements of the Directive. The manufacturer must affix the CE marking to the article and draw up a declaration of conformity.

2. The notified body must examine the pyrotechnic article and carry out the appropriate tests as set out in the relevant harmonised standard(s) referred to in Article 8, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

The notified body must affix, or cause to be affixed, its identification number on the approved pyrotechnic article and draw up a certificate of conformity concerning the tests carried out.

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

The documents must contain, in so far as is necessary for the 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 pyrotechnic article,
- a list of the harmonised standards referred to in Article 8, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of the Directive where the harmonised standards referred to in Article 8 have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

### ANNEX III

#### **MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE BODIES RESPONSIBLE OF CONFORMITY ASSESSMENTS**

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of pyrotechnic articles which they inspect, nor the authorised representative of any of these parties. They shall not become either involved directly or as authorised representatives in the design, construction, marketing or maintenance of such articles. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.
4. The staff responsible for inspection shall have:
  - sound technical and professional training,
  - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
  - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall take out civil liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

ANNEX IV

**CONFORMITY MARKING**

The CE conformity marking shall 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.