NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT PACKAGE
(Implementation of the Goods Package)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles

(Recast)

(Text with EEA relevance)
EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

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

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

Directive 2007/23/EC of the European Parliament and of the Council on the placing on the market of pyrotechnic articles is an example of that Union harmonisation legislation, ensuring the free movement of pyrotechnic articles. It sets out essential safety requirements that pyrotechnic articles must comply with in order to be made available on the EU market. Manufacturers must demonstrate that a pyrotechnic article has been designed and manufactured in compliance with the essential safety requirements and affix the CE marking.

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

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

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

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the “New Legislative Framework” was adopted in 2008 as part of the goods package. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, Regulation (EC)
The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

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

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

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

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

For a number of other Union harmonisation directives, including Directive 2007/23/EC on the placing on the market of pyrotechnic articles no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance and notified bodies are nevertheless addressed in these sectors, and for the sake of consistency of the overall regulatory environment on products, it was decided to align these directives within a package to the provisions of the NLF Decision.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act\(^1\), which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

\(^1\) Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.
Furthermore it supports the Commission’s policy on Better Regulation and simplification of the regulatory environment.

2. **CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT**

**Consultation of interested parties**

The alignment of Directive 2007/23/EC on the placing on the market of pyrotechnic articles to the NLF Decision has been discussed with the national experts responsible for the implementation of this Directive in the pyrotechnics working group, the forum of notified bodies as well as in bilateral meetings with industry associations.

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


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

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

**Collection and use of expertise**

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

**Impact assessment**

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.
**Option 1 – No changes to the current situation**

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

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

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

**Option 3 – Alignment to NLF Decision by legislative measures**

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

Option 3 was found to be the preferred option because:

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

3. **MAIN ELEMENTS OF THE PROPOSAL**

3.1. **Horizontal definitions**

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

3.2. **Obligations of economic operators and traceability requirements**

The proposal clarifies the obligations of manufacturers and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that the pyrotechnic articles are correctly marked and accompanied by instructions and safety
information. They must keep a copy of the Declaration of conformity and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation. Distributors must verify that the pyrotechnic article bears the CE marking, the name of the manufacturer and of the importer, if relevant, and that it is accompanied by the required documentation and instructions.

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

**Enhanced traceability obligations** are introduced for all economic operators. Pyrotechnic articles have to bear the manufacturer’s name and address and a number allowing to identify and link the article to its technical documentation. When a pyrotechnic article is imported the importer’s name and address must also be on the pyrotechnic article. Furthermore every economic operator must be able to identify towards authorities the economic operator who has supplied him with a pyrotechnic article or to whom he has supplied a pyrotechnic article.

### 3.3. Harmonised standards

Compliance with harmonised standards provides a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation\(^2\) that sets out a horizontal legal framework for European standardisation. The proposal for the Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisations, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 2007/23/EC which cover the same aspects have been deleted in this proposal for reasons of legal certainty.

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

### 3.4. Conformity assessment and CE marking

Directive 2007/23/EC on the placing on the market of pyrotechnic articles has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their pyrotechnic articles comply with the essential safety requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision.

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

### 3.5. Notified Bodies

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

\(^2\) COM(2011) 315 final.
a notified body, the notification must comprise the documentation demonstrating how the competence of that body has been evaluated. Member States will have the possibility to object to a notification.

3.6. Market surveillance and the safeguard clause procedure

The proposal revises the existing safeguard clause procedure. It introduces a phase of information exchange between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant pyrotechnic article is found. A real safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or not – is only launched when another Member State objects to a measure taken against a pyrotechnic article. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

3.7. Sector specific issues

Some pyrotechnic articles, notably automotive pyrotechnic articles such as air bag gas generators, contain small amounts of commercial blasting agents and military explosives. Following the adoption of Directive 2007/23/EC it has become obvious that it will not be possible to replace these substances as additives in strictly combustive compositions, where they are used to enhance the energetic balance. Therefore it is proposed to modify the essential safety requirement (4).

3.8. Comitology and Delegated acts

The provisions on the operation of the Explosives Committee have been adapted to the new rules on delegated acts laid down in Article 290 of the Treaty on the Functioning of the EU and to the new provisions on implementing acts laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers3.

4. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

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

Subsidiarity principle

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 2007/23/EC on the placing on the market of pyrotechnic articles, namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of notified bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

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

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

Proportionality

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

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

Legislative technique used

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Directive 2007/23/EC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts4.

The changes made to the provisions of Directive 2007/23/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, notified bodies, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope of the Directive and the essential safety requirements, apart from the correction described under 3.7.

5. **Budgetary implications**

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

6. **Additional information**

Repeal of existing legislation

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The adoption of the proposal will lead to repeal of Directive 2007/23/EC on the placing on the market of pyrotechnic articles.

**European Economic Area**

The proposal concerns the EEA and should therefore be extended to the European Economic Area.
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2011/0358 (COD)  

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(Recast)  

(Text with EEA relevance)  

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  

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

Having regard to the proposal from the European Commission,  

After transmission of the draft legislative act to the national Parliaments,  

Having regard to the opinion of the European Economic and Social Committee,  

Acting in accordance with the ordinary legislative procedure,  

Whereas:  

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.


(4) The laws, regulations and administrative provisions in force in the Member States with regard to the placing/making available on the market of pyrotechnic articles are divergent, in particular as regards aspects such as safety and performance characteristics.

(5) The laws, regulations and administrative provisions of Member States, being liable to cause barriers to trade within the Community, should need to be harmonised in order to guarantee the free movement of pyrotechnic articles within the internal market whilst ensuring a high level of protection of human health and safety and the protection of consumers and professional end users.

(6) 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 excludes pyrotechnic articles from its scope and states that pyrotechnic articles require appropriate measures to ensure the protection of consumers and the safety of the public and that an additional directive is planned in this field.

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Safety during storage is governed by Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances which sets out safety requirements for establishments where explosives, including pyrotechnic substances, are present.

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. Those aspects should therefore not fall under the scope of this Directive.


According to the principles set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards a pyrotechnic article should comply with this Directive when the article is placed on the Community market for the first time. In view of religious, cultural and traditional festivities in the Member States, fireworks built by the manufacturer for his own use and which have been approved by a Member State for use on its territory should not be considered as having been made available on the market and should therefore not need to comply with this Directive.

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(11) 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. This Directive should apply without prejudice to national legislation on the licensing of manufacturers, distributors and importers by the Member States.

(12) Pyrotechnic articles should include fireworks, theatrical pyrotechnic articles and pyrotechnic articles for technical purposes, such as gas generators used in airbags or in seatbelt pretensioners.

(13) In order to ensure appropriately high levels of protection, pyrotechnic articles should be categorised primarily according to their level of hazard as regards their type of use, purpose or noise level.

(14) 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. With regard to pyrotechnic articles for vehicles, labelling requirements should take into account current practice and the fact that these articles are supplied exclusively to professional users.

(15) The use of pyrotechnic articles and, in particular, the use of fireworks, is subject to markedly divergent cultural customs and traditions in the respective Member States. It is therefore 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 reasons of public security or safety.
(16) Economic operators should be responsible for the compliance of pyrotechnic articles, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and to guarantee fair competition on the Union market.

(17) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market pyrotechnic articles which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.

(18) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.

Responsibility for ensuring that pyrotechnic articles comply with this Directive and in particular with those essential safety requirements should rest with the manufacturer. If the manufacturer is not established in the Community, the natural or legal person who imports a pyrotechnic article into the Community should ensure that the manufacturer has fulfilled his obligations under this Directive or should assume all obligations of the manufacturer.

(19) It is necessary to ensure that pyrotechnic articles from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those products. Provision should therefore be made for importers to make sure that the pyrotechnic articles they place on the market comply with the requirements of this Directive and that they do not place on the market pyrotechnic articles which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.

(20) The distributor makes a pyrotechnic article available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that his handling of the pyrotechnic articles does not adversely affect the compliance of the pyrotechnic article.

(21) Any economic operator who either places a pyrotechnic article on the market under his own name or trademark or modifies a pyrotechnic article in such a way that compliance with the requirements of this Directive may be affected should be
considered to be the manufacturer and should assume the obligations of the manufacturer.

(22) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the pyrotechnic article concerned.

(23) It is appropriate to establish essential safety requirements for pyrotechnic articles in order to protect consumers and to prevent accidents.

(24) Some pyrotechnic articles, notably automotive pyrotechnic articles such as air bag gas generators, contain small amounts of commercial blasting agents and military explosives. Following the adoption of Directive 2007/23/EC it has become obvious that it will not be possible to replace these substances as additives in strictly combustive compositions, where they are used to enhance the energetic balance. The essential safety requirement (4), which restricts the use of commercial blasting agents and military explosives, should therefore be modified.


14 OJ L [..], [..], p. [..]
Regulation (EU) No [...] [on European Standardisation] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy requirements of this Directive.

European harmonised standards are drawn up, adopted and modified by the Committee for European Standardization (CEN), the Committee for Electro-technical Standardization (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 cooperation between themselves, and the European Commission and the European Free Trade Association, 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 and of rules on Information Society services]. With regard to pyrotechnic articles for vehicles, the international orientation of the European vehicle supply industry should be reflected by taking into account the relevant international ISO standards.

In line with the ‘New Approach to technical harmonisation and standardisation’, pyrotechnic articles manufactured in compliance with harmonised standards should benefit from a presumption of conformity with the essential safety requirements provided for in this Directive.

In order to enable economic operators to demonstrate and the competent authorities to ensure that pyrotechnic articles made available on the market comply with the essential safety requirements, it is necessary to provide for conformity assessment procedures. Decision 768/2008 establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure intersectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.

(28) Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of a pyrotechnic article with the requirements of this Directive and of the relevant Union harmonisation legislation.

2007/23/EC recital 17

By Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives, the Council 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.

2007/23/EC recital 19

In order to be placed on the market, pyrotechnic articles should bear a CE marking indicating their conformity with the provisions of this Directive to enable them to move freely within the Community.

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(29) The CE marking, indicating the conformity of a pyrotechnic article, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

(30) Experience has shown that the criteria set out in Directive 2007/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(31) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(32) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an

essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(33) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(34) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the pyrotechnic articles to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(35) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(36) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(37) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(38) In order to ensure legal certainty, it is necessary to clarify that the rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to pyrotechnic articles. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(39) Groups of pyrotechnic articles that are similar in design, function or behaviour should be assessed by the notified bodies as product families.
According to the ‘New Approach to technical harmonisation and standardisation’, a safeguard clause procedure is necessary to allow the possibility for contesting the conformity of a pyrotechnic article or failures. Accordingly, Member States should take all appropriate measures to prohibit or restrict the placing on the market of products bearing a CE marking or to withdraw such products from the market if they endanger the health and safety of consumers when the products are used for their intended purpose. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

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

Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

It is in the interests of the manufacturer and the importer to supply safe pyrotechnic articles in order to avoid liability costs for defective products causing damage to individuals and private property. In this regard, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products\(^{18}\) complements this Directive, since that Directive imposes a strict liability regime on manufacturers and importers and ensures an adequate level of protection for consumers. Furthermore, that Directive provides that notified bodies should be adequately insured in respect of their professional activities, unless their liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.¹⁹

In particular, the Commission should be empowered to adopt Community measures concerning United Nations recommendations, the labelling requirements of pyrotechnic articles and adaptations to technical progress of Annexes II and III related to safety requirements and conformity assessment procedures. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement it by the addition of new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.²⁰

(44) In order to ensure uniform conditions for the implementation of this Directive implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission’s exercise of implementing powers.²⁰

(45) The examination procedure should be used for the adoption of the implementing acts in order to set up a traceability system and common criteria for collecting and updating of data on accidents related to pyrotechnic articles:

(46) In order to achieve the objectives of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of adopting Union measures concerning adapting this Directive to United Nations recommendations on the transport of dangerous goods, adaptations to technical progress of the conformity assessment modules in Annex I to this Directive and the labelling requirements of pyrotechnic articles. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(47) The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(48) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that these rules are implemented. The penalties provided for should be effective, proportionate and dissuasive.

(49) It is vital to provide for a transitional period to allow national laws in specified fields to be adapted gradually. Manufacturers and importers need to be given time to exercise any rights under national rules in force before the date of application of national rules transposing this Directive in order, for example, to sell their stocks of manufactured products. Furthermore, the specific transitional periods provided for for the application of this Directive would allow extra time for the adoption of harmonised standards and would ensure the speedy implementation of this Directive so as to enhance the protection of consumers.

(50) Since the objectives of this Directive, namely to ensure that pyrotechnic articles on the market fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States and can therefore 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 on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive set out in Annex III.

HAVE ADOPTED THIS DIRECTIVE:

Chapter 1

General provisions

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 level of protection of human health and public security and the protection and safety of consumers and taking into account the relevant aspects related to environmental protection.

2. This Directive establishes the essential safety requirements which pyrotechnic articles must fulfil with a view to their being placed on the market.

Article 2

Scope

This Directive shall apply to pyrotechnic articles as defined in Article 2(1) to (5).
This Directive shall not apply to:

(a) pyrotechnic articles intended for non-commercial use, in accordance with national law, by the armed forces, the police or fire departments;

(b) equipment falling within the scope of Directive 96/98/EC;

(c) pyrotechnic articles intended for use in the aerospace industry;


(e) explosives falling within the scope of Directive 93/15/EEC;

(f) ammunition, meaning projectiles and propelling charges and blank ammunition used in portable firearms, other guns and artillery;

(g) fireworks built by a manufacturer for his own use and which have been approved by a Member State for use on its territory.

Article 23 [Article R1 of Decision No 768/2008/EC]

Definitions

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

(1) ‘pyrotechnic article’ means any article containing explosive substances or an explosive mixture of substances designed to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions;

(2) ‘firework’ means a pyrotechnic article intended for entertainment purposes;

(3) ‘theatrical pyrotechnic articles’ means pyrotechnic articles designed for indoor or outdoor stage use, including film and television productions or similar use.
‘Pyrotechnic articles for vehicles’ means components of safety devices in vehicles which contain pyrotechnic substances used to activate these or other devices.

‘Ammunition’ means projectiles and propelling charges and blank ammunition used in portable firearms, other guns and artillery.

‘Person with specialist knowledge’ means a person authorised by a Member State to handle and/or use on its territory category 4 fireworks, category T2 theatrical pyrotechnic articles and/or category P2 other pyrotechnic articles as defined in Article 3.

‘Placing on the market’ means the first making available of a pyrotechnic article on the Community market of an individual product, with a view to its distribution and/or use, whether for payment or free of charge. Fireworks built by a manufacturer for his own use and which have been approved by a Member State for use on its territory are not to be considered as having been placed on the market.

‘Making available on the market’ means any supply of a pyrotechnic article for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

‘Manufacturer’ means a natural or legal person who designs and/or manufactures a pyrotechnic article, or who causes such an article to be designed and/or manufactured, with a view to placing it on the market and markets that pyrotechnic article under his own name or trademark.

‘Imposter’ means any natural or legal person established in the Community within the Union who places a pyrotechnic article originating from a third country available on the Community Union market for the first time in the course of his business.
‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a pyrotechnic article available on the market in the course of his business.

‘economic operators’ means the manufacturer, the importer and the distributor;

‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a pyrotechnic article;

‘harmonised standard’ means harmonised standards as defined in Article 2(1)c of Regulation EU No [.../...][on European Standardisation] adopted by a European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC and with which compliance is not compulsory;

‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

‘national accreditation body’ means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

‘conformity assessment’ means the process demonstrating whether the essential safety requirements relating to a pyrotechnic article have been fulfilled;

‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

‘recall’ means any measure aimed at achieving the return of a pyrotechnic article that has already been made available to the end user;

‘withdrawal’ means any measure aimed at preventing a pyrotechnic article in the supply chain from being made available on the market;

‘CE marking’ means a marking by which the manufacturer indicates that the pyrotechnic article is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.
Article 6
Free Movement

1. Member States shall not prohibit, restrict or hinder the placing \(\text{making available} \) on the market of pyrotechnic articles which satisfy the requirements of this Directive.

2. The provisions of this Directive shall not preclude measures taken by a Member State to prohibit or restrict the possession, use and/or the sale to the general public of category 2 and 3 fireworks, theatrical pyrotechnic articles and other pyrotechnic articles, which measures are justified on grounds of public order, security or safety, or environmental protection.

3. At trade fairs, exhibitions and demonstrations for the marketing of pyrotechnic articles, Member States shall not prevent the showing and use of pyrotechnic articles not in conformity with the provisions of this Directive, provided that a visible sign clearly indicates the name and date of the trade fair, exhibition or demonstration in question and the non-conformity and non-availability for sale of the articles until brought into conformity by the manufacturer, where such manufacturer is established within the Community Union, or by the importer. 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.

4. Member States shall not prevent the free movement and use of 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 non-availability for purposes other than research, development and testing.

Article 5
Placing \(\text{Making available} \) on the market

1. Member States shall take all appropriate measures to ensure that pyrotechnic articles may be placed \(\text{made available} \) on the market only if they satisfy the requirements of this Directive, bear a CE marking, and comply with the obligations relating to the conformity assessment.

2. Member States shall take all appropriate measures to ensure that pyrotechnic articles do not unduly bear a CE marking.
Article 63  
Categories of pyrotechnic articles  

1. Pyrotechnic articles shall be categorised by the manufacturer according to their type of use, or their purpose and level of hazard, including their noise level. The notified bodies referred to in Article 2110 shall confirm the categorisation as part of the conformity assessment procedures referred to in Article 179.

Categorisation shall be as follows:

(a) Fireworks:

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

   (ii) Category 2: fireworks which present a low hazard and low noise level and which are intended for outdoor use in confined areas;

   (iii) Category 3: fireworks which present a medium hazard, which are intended for outdoor use in large open areas and whose noise level is not harmful to human health;

   (iv) Category 4: fireworks which present a high hazard, which are intended for use only by persons with specialist knowledge (commonly known as fireworks for professional use) and whose noise level is not harmful to human health.

(b) Theatrical pyrotechnic articles:

   (i) Category T1: pyrotechnic articles for stage use which present a low hazard;

   (ii) Category T2: pyrotechnic articles for stage use which are intended for use only by persons with specialist knowledge.

(c) Other pyrotechnic articles:

   (i) Category P1: pyrotechnic articles other than fireworks and theatrical pyrotechnic articles which present a low hazard;
(ii) Category P2: pyrotechnic articles other than fireworks and theatrical pyrotechnic articles which are intended for handling or use only by persons with specialist knowledge.

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

\[2007/23/EC\] (adapted)

**Article 7**

**Age limits**

1. Pyrotechnic articles shall not be sold or otherwise made available on the market to consumers below the following age limits:

\[2007/23/EC\]

(a) **Fireworks:**

(i) Category 1: 12 years

(ii) Category 2: 16 years

(iii) Category 3: 18 years

\[2007/23/EC\] (adapted)

(b) Other pyrotechnic articles of category P1 and theatrical pyrotechnic articles of category T1: 18 years.

Category T1 and P1: 18 years.

2. Member States may increase the age limits set out in paragraph 1 where justified on grounds of public order, security or safety. Member States may also lower the age limits for persons vocationally trained or undergoing such training.

3. Manufacturers, importers and distributors shall not sell or otherwise make available on the market the following pyrotechnic articles except to persons with specialist knowledge:

\[2007/23/EC\]

(a) Fireworks of category 4
(b) pyrotechnic articles of category P2 and theatrical pyrotechnic articles of category T2.

Chapter 2

Obligations of economic operators

Article 4 [Article R2 of Decision No 768/2008/EC] Obligations of the manufacturer manufacturers importer and distributor

1. When placing their pyrotechnic articles on the market, manufacturers shall ensure that pyrotechnic articles placed on the market comply they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.

2. If the manufacturer is not established in the Community, the importer of the pyrotechnic articles shall ensure that the manufacturer has fulfilled his obligations under this Directive or assume these obligations himself. The importer may be held liable by authorities and bodies in the Community with regard to those obligations.

3. Distributors shall act with due care in accordance with applicable Community law. In particular they shall verify that the pyrotechnic article bears the required conformity marking(s) and is accompanied by the required documents.

4. Manufacturers of pyrotechnic articles shall:

   (a) submit the pyrotechnic article to a notified body as referred to in Article 10 which shall perform a conformity assessment in accordance with Article 9; and

   (b) affix a CE marking to, and label the pyrotechnic article in accordance with Article 11, and Article 12 or 13.

2. Manufacturers shall draw up the technical documentation referred to in Annex II and carry out the relevant conformity assessment procedure referred to in Article 16.
Where compliance of a pyrotechnic article with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least 10 years after the pyrotechnic article has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in pyrotechnic article design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a pyrotechnic article is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a pyrotechnic article, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of pyrotechnic articles made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pyrotechnic articles and pyrotechnic article recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their pyrotechnic articles are labelled in accordance with Article 9 or 10.

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

7. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the pyrotechnic article, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have placed on the market.
Article 29
Labelling of pyrotechnic articles other than pyrotechnic articles for vehicles

1. Manufacturers shall ensure that pyrotechnic articles other than pyrotechnic articles for vehicles are properly labelled visibly, legibly and indelibly in the official language(s) of the Member State in which the article is made available to the consumer.

2. The labelling of pyrotechnic articles shall include as a minimum the name and address of the manufacturer or, where the manufacturer is not established in the Community, the name of the manufacturer and the name and address of the importer, the name and type of the article, the registration number, the minimum age limits as indicated in Article 7(1) and (2), the relevant category and instructions for use, the year of production for category 3 and 4 fireworks and, where appropriate, a minimum safety distance. The labelling shall include the net explosive content (NEC) equivalent quantity (NEQ) of active explosive material.

3. In addition, fireworks shall also display the following minimum information:

(a) Category 1: where appropriate: ‘for outdoor use only’ and a minimum safety distance;

(b) Category 2: ‘for outdoor use only’ and, where appropriate, minimum safety distance(s);

(c) Category 3: ‘for outdoor use only’ and minimum safety distance(s);

(d) Category 4: ‘for use only by persons with specialist knowledge’ and minimum safety distance(s).
4. In addition, theatrical pyrotechnic articles shall contain also display the following minimum information:

(a) Category T1: where appropriate: ‘for outdoor use only’ and a minimum safety distance.

(b) Category T2: ‘for use only by persons with specialist knowledge’ and minimum safety distance(s).

5. If the pyrotechnic article does not provide sufficient space for the labelling requirements referred to in paragraphs 2, 3 and 4, the information shall be provided on the smallest piece of packaging.

6. The provisions of this Article shall not apply to pyrotechnic articles shown at trade fairs, exhibitions and demonstrations for the marketing of pyrotechnic articles, as referred to in Article 6(3), or manufactured for the purpose of research, development and testing, as referred to in Article 6(4).

**Article 10**

Labelling of pyrotechnic articles for vehicles

1. The labelling of pyrotechnic articles for vehicles shall include the name of the manufacturer or, where the manufacturer is not established in the Community, the name of the importer, the name and type of the article, the registration number and the safety instructions.

2. If the article does not provide sufficient space for the labelling requirements referred to in paragraph 1, the information shall be provided on the packaging.


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24 OJ L 136, 29.5.2007, p. 3.
**Article 11 [Article R4 of Decision No 768/2008/EC]**

**Obligations of importers**

1. Importers shall place only compliant pyrotechnic articles on the market.

2. Before placing a pyrotechnic article on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 16 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the pyrotechnic article bears the CE marking and that the manufacturer has complied with the labelling requirements set out in Article 9 or 10.

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

3. Importers shall indicate their name and the address at which they can be contacted on the pyrotechnic article or, where that is not possible, on its packaging or in a document accompanying the pyrotechnic article.

4. Importers shall ensure that the pyrotechnic article is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a pyrotechnic article is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by a pyrotechnic article, importers shall, to protect the health and safety of consumers, carry out sample testing of pyrotechnic articles made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pyrotechnic articles and pyrotechnic articles recalls, and shall keep distributors informed of such monitoring.

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

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

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a pyrotechnic article in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article 12 [Article R5 of Decision No 768/2008/EC]
Obligations of distributors

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

2. Before making a pyrotechnic article available on the market distributors shall verify that the pyrotechnic article bears the required CE marking, that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the pyrotechnic article is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 9 or 10 and 11(3).

Where a distributor considers or has reason to believe that a pyrotechnic article is not in conformity with the essential safety requirements set out in Annex I, he shall not make the pyrotechnic article available on the market until it has been brought into conformity. Furthermore, where the pyrotechnic article presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a pyrotechnic article is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that a pyrotechnic article which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the pyrotechnic article presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the pyrotechnic article available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a pyrotechnic article. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have made available on the market.
Article 13 [Article R6 of Decision No 768/2008/EC]
Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a pyrotechnic article on the market under his name or trademark or modifies a pyrotechnic article already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 14 [Article R7 of Decision No 768/2008/EC]
Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a pyrotechnic article;
(b) any economic operator to whom they have supplied a pyrotechnic article.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the pyrotechnic article and for a period of 10 years after they have supplied the pyrotechnic article.

Chapter 3
Conformity of the pyrotechnic article

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 or encourage the relevant international bodies to draw up or revise international standards.

2. The Commission shall publish in the Official Journal of the European Union the references of such harmonised standards.

3. Member States shall ensure that the harmonised standards published in the Official Journal of the European Union are acknowledged and adopted. Member States shall consider pyrotechnic articles falling within the scope of this Directive which comply with the relevant national standards transposing the harmonised standards published in the Official Journal of the European Union to be in conformity with the essential safety requirements set out in Annex I. Member States shall publish the references of the national standards transposing those harmonised standards.
When Member States adopt national transpositions of the harmonised standards they shall publish the reference numbers of those transpositions.

4. Where a Member State or the Commission considers that the harmonised standards referred to in paragraph 2 of this Article do not fully satisfy the essential safety requirements set out in Annex I, the Commission or the Member State concerned shall refer the matter to the Standing Committee set up by Directive 98/34/EC, giving its reasons. The Standing Committee shall deliver its opinion within six months of such referral. In the light of the Standing 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 15

**Presumption of conformity of pyrotechnic articles**

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

[Where a harmonised standard satisfies the requirements which it covers and which are set out in Article 24 or Annex I, the Commission shall publish the references of those standards in the *Official Journal of the European Union.*]

### Article 16

**Conformity assessment procedures**

For the assessment of conformity of pyrotechnic articles the manufacturer shall follow one of the following procedures:

1. the EC type-examination (Module B) procedure referred to in Annex II, Section 1, and, at the choice of the manufacturer, either one of the following procedures:
   1. the conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) procedure referred to in Annex II, Section 2.
(ii) the production conformity to type based on quality assurance of the production process (Module D) procedure referred to in Annex II, Section 2 or 3.

(iii) the conformity to type based on product quality assurance (Module E) procedure referred to in Annex II, Section 4;

(b) the conformity based on unit verification (Module G) procedure referred to in Annex II, Section 5;

(c) the conformity based on full product quality assurance procedure (Module H) referred to in Annex II, Section 6, insofar as it concerns fireworks of category 4.

Article 17 [Article R10 of Decision No 768/2008/EC]
EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall contain the elements specified in the relevant modules set out in Annex II to this Directive, shall have the model structure set out in Annex III to Decision No 768/2008/EC and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the pyrotechnic article is placed or made available.

3. Where a pyrotechnic article is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including the publication references.

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

Article 18 [Article R11 of Decision No 768/2008/EC]
General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
Obligation to affix 
Rules and conditions for affixing the CE marking and other markings

1. After having successfully completed the conformity assessment in accordance with Article 9, manufacturers shall visibly, legibly and indelibly affix the CE marking to the pyrotechnic articles themselves or, if this is not possible or not warranted on account of the nature of the pyrotechnic article, it shall be affixed, to an identification plate attached thereto or to the packaging, and to the accompanying documents. 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 Decision 93/465/EC.

2. No marking or inscription which may confuse third persons as to the meaning and form of the CE marking may be affixed to pyrotechnic articles. Any other marking may be affixed to pyrotechnic articles provided the visibility and legibility of the CE marking is not impaired.

3. Where pyrotechnic articles are subject to other Community legislation which covers other aspects of, and prescribes the affixing of, the CE marking, this marking shall indicate that those articles are also presumed to conform to the provisions of the other legislation which applies to them.

4. The CE marking shall be affixed before the pyrotechnic article is placed on the market.

5. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer.

6. The CE marking and, where applicable, the identification number referred to in paragraph 3 may be followed by a pictogram or any other mark indicating a special risk or use.
Chapter 4

Notification of conformity assessment bodies

Article 10 [Article R13 of Decision No 768/2008/EC]

Member States shall inform the Commission and the other Member States of the bodies authorised which they have appointed to carry out the conformity assessment procedures referred to in Article 9, together with the specific third-party conformity assessment tasks under this Directive which these bodies have been appointed to carry out and the identification numbers assigned to them by the Commission.

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 minimum criteria referred to in paragraph 3. It shall immediately inform the other Member States and the Commission thereof.

5. If the notification of a body is withdrawn, the attestations of conformity and the related documents provided by the body in question shall remain valid unless it is established that there is an imminent and direct risk to health and safety.

6. The Commission shall make available to the public on its website the withdrawal of the notification of the body in question.

Article 21 [Article R14 of Decision No 768/2008/EC]

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

**Article 22 [Article R15 of Decision No 768/2008/EC]**

**Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

**Article 23 [Article R16 of Decision No 768/2008/EC]**

**Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

**Article 24 [Article R17 of Decision No 768/2008/EC]**

**Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the pyrotechnic article it assesses.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of
pyrotechnic articles and/or explosive substances which they assess. This shall not preclude the use of pyrotechnic articles and/or explosive substances that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those pyrotechnic articles and/or explosive substances, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 16 and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
7. The personnel responsible for carrying out conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

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

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 16 or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

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

**Article 25 [Article R18 of Decision No 768/2008/EC]**

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.
Article 26 [Article R20 of Decision No 768/2008/EC]
Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 16.

Article 27 [Article R22 of Decision No 768/2008/EC]
Application for notification

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

2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

Article 28 [Article R23 of Decision No 768/2008/EC]
Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 27(2), the notifying authority shall provide the Commission and the other
Member States with documentary evidence which attests to the conformity assessment body’s competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used. Only such a body shall be considered a notified body for the purposes of this Directive.

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

Article 29 [Article R24 of Decision No 768/2008/EC] Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available on its website the list of the notified bodies notified under this Directive, including the and their identification numbers that have been allocated to them and the tasks activities for which they have been notified.

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

Article 30 [Article R25 of Decision No 768/2008/EC] Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take
appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 31 [Article R26 of Decision No 768/2008/EC]
Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 32 [Article R27 of Decision No 768/2008/EC]
Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Article 16.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

   In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the pyrotechnic article with the requirements of this Directive.

3. Where a notified body finds that essential safety requirements set out in Annex I or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a pyrotechnic article no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 33
Appeal against decisions of notified bodies

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

Article 34 [Article R28 of Decision No 768/2008/EC]
Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35 [Article R29 of Decision No 768/2008/EC]
Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 36 [Article R30 of Decision No 768/2008/EC]
Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a forum of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that forum, directly or by means of designated representatives.
Chapter 5

Union market surveillance, control of products entering the Union market and safeguard procedures

Article 43

Union market surveillance and control of products entering the Union market

1. Member States shall take all appropriate measures to ensure that pyrotechnic articles 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 carry out regular inspections of pyrotechnic articles on entry into the Community and at storage and manufacturing sites.

3. Member States shall take appropriate measures to ensure that when pyrotechnic articles are transferred within the Community, the safety and public security and protection requirements of this Directive are met.

4. 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 a CE marking.

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

6. Member States shall inform the Commission annually about their market surveillance activities.

6. Where a Member State ascertains that a pyrotechnic article, bearing a CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose, is liable to endanger the health and safety of persons, it shall take all appropriate provisional measures to withdraw that article from the market, to prohibit its being placed on
the market or to restrict its free movement. The Member State shall inform the Commission and the other Member States thereof.

7. The Commission shall make available to the public on its website the names of articles that, pursuant to paragraph 6, have been withdrawn from the market, have been banned or are to be placed on the market subject to restriction.

Article 3815 [Article R31 of Decision No 768/2008/EC] Rapid information on products Procedure for dealing with pyrotechnic articles a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reasons to believe that a pyrotechnic article presents a serious risk to the health and/or safety of persons or to other aspects of public interest protection covered by this Directive, it shall inform the Commission and the other Member States thereof and they shall carry out an appropriate evaluation in relation to the pyrotechnic article concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities. It shall inform the Commission and the other Member States of the background for and the results of the evaluation.

Where, in the course of that evaluation, the market surveillance authorities find that the pyrotechnic article does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the pyrotechnic article into compliance with those requirements, to withdraw the pyrotechnic article from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the pyrotechnic articles concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the pyrotechnic articles being made available on their national market, to withdraw the pyrotechnic article from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant pyrotechnic article, the origin of the pyrotechnic article, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the pyrotechnic article to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this Directive;

(b) shortcomings in the harmonised standards referred to in Article 15 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the pyrotechnic article concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within 3 months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the pyrotechnic article concerned without delay.
Article 16

1. Where a Member State disagrees with the provisional measures taken by another Member State pursuant to Article 14(6), Where on completion of the procedure set out in Article 38(3) and (4), objections are raised against measures taken by a Member State, or where the Commission considers that such measures are contrary to Union legislation, the Commission shall consult, without delay, enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not all parties concerned, evaluate the measures and take a position as to whether or not the measures are justified. The Commission shall notify its position to the Member States and inform the interested parties.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the Commission considers that the national measures are considered justified, the other all Member States shall take the necessary measures to ensure that the non-compliant article is withdrawn from their national market and inform the Commission thereof accordingly. If the Commission considers that the national measures are not considered unjustified justified, the Member State concerned shall withdraw them the measure.

23. Where the national measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards referred to in Article 15 of this Directive, the Commission shall apply the procedure provided for in Article 8 of Regulation (EU) No [.....] [on European Standardisation] refer the matter to the Standing Committee set up by Directive 08/34/EC if the Member State at the origin of the measures maintains its position, and the Commission or that Member State shall initiate the procedure referred to in Article 8.
3. Where a pyrotechnic article does not conform but bears a CE marking, the competent Member State shall take appropriate action against whomever affixed the marking and shall inform the Commission thereof. The Commission shall inform the other Member States.

Article 40 [Article R33 of Decision No 768/2008/EC]
Compliant pyrotechnic articles which present a risk to health and safety

1. Where, having performed an evaluation under Article 38(1), a Member State finds that although a pyrotechnic article is in compliance with this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the pyrotechnic article concerned, when placed on the market, no longer presents that risk, to withdraw the pyrotechnic article from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the pyrotechnic articles concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the pyrotechnic article concerned, the origin and the supply chain of the pyrotechnic article, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 41 [Article R34 of Decision No 768/2008/EC]
Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Directive;
(b) the CE marking has not been affixed;
(c) the EU declaration of conformity has not been drawn up;
(d) the EU declaration of conformity has not been drawn up correctly;
(e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the pyrotechnic article being made available on the market or ensure that it is recalled or withdrawn from the market.

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2007/23/EC

Article 17

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 of 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 paragraph 1, the party concerned shall have an opportunity to put forward his views 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.
Chapter 6

Delegated and implementing powers

**Article 42**
Implementing measures

1. The following measures designed to amend non-essential elements of this Directive, inter alia by supplementing it by the addition of new non-essential elements, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(2) of this Directive. The Commission shall be empowered to adopt delegated acts in accordance with Article 46 concerning:

   (a) identification of pyrotechnic articles referred to in Article 3(1) on the basis of adaptations necessary to take account of any future amendments to United Nations recommendations on the transport of dangerous goods;

   (b) adaptations to technical progress of Annexes II and III;

   (c) adaptations of the labelling requirements set out in Articles 12 and 13.

**Article 43**
Exercise of the delegation

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

2. The delegation of power referred to in Article 42 shall be conferred for an indeterminate period of time from [insert a date - the date of entry into force of this Directive].

3. The delegation of powers referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or, if before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

**Article 44**  
**Implementing powers**

The Commission shall adopt implementing acts in order to set up the following:

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2. The following measures shall be adopted in accordance with the regulatory procedure referred to in Article 19(3)

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(a) the setting up of a traceability system, including a registration number and a register at Union level in order to identify types of pyrotechnic articles and their manufacturer;

(b) the setting up of common criteria for the regular collection and updating of data on accidents related to pyrotechnic articles.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(2).

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**Article 45**  
**Committee procedure**

1. The Commission shall be assisted by the Committee on Pyrotechnic Articles. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

幂. Where reference is made to this paragraph, Articles 5 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 1999/468/EC shall be set at three months.

Chapter 7
Transitional and final provisions

Article 20
Penalties

Member States shall lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and shall take all the measures necessary to ensure that they are implemented and enforced.

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

Member States shall also adopt the necessary measures allowing them to detain consignments of pyrotechnic articles that fail to comply with this Directive.
Member States shall notify those provisions to the European Commission by 3 July 2013 at the latest and shall notify it without delay of any subsequent amendment affecting them.

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**Article 47**  
**Transitional provisions**

1. Member States shall not impede the making available on the market of pyrotechnic articles which are in conformity with Directive 2007/23/EC and which were placed on the market before 4 July 2013.

2. National authorisations for fireworks of categories 1, 2 and 3 granted before 4 July 2010 shall continue to be valid on the territory of the Member State having granted the authorisation until their expiry date or until 4 July 2017, whichever is earlier.

3. National authorisations for other pyrotechnic articles, for fireworks of category 4 and for theatrical pyrotechnic articles granted before 4 July 2013 shall continue to be valid on the territory of the Member State having granted the authorisation until their expiry date or until 4 July 2017, whichever is earlier.

4. By way of derogation from paragraph 3, national authorisations for pyrotechnic articles for vehicles granted before 4 July 2013 shall continue to be valid until their expiry.

5. Certificates of conformity issued under Directive 2007/23/EC shall be valid under this Directive until 4 July 2020 unless they expire before that date.

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**Article 21**  
**Transposition**

1. Member States shall adopt and publish by 4 January 2010 or 3 July 2013, at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive Articles 3(8), 3(12), 3(13), 3(15) to (22), 4(1), 5, 8(2) to (7), 11 to 15, 17 to 28, 30 to 34, 36, 37(1), 38 to 41, 46, 47 and Annexes I and II. 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 4 July 2010 and the measures necessary to comply with the provisions of this Directive on other pyrotechnic articles, on fireworks of category 4 and on theatrical pyrotechnic articles from 4 July 2013.
for fireworks of categories 1, 2 and 3 and by 4 July 2013 for other pyrotechnic articles, for fireworks of category 4 and for theatrical 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. They shall also include a statement that references in existing laws, regulations and administrative provisions to the directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is formulated.

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 relevant 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 from paragraph 5, national authorisations for pyrotechnic articles for vehicles granted before the relevant date indicated in paragraph 2 shall continue to be valid until their expiry.

Article 49
Repeal

Directive 2007/23/EC is repealed with effect from 4 July 2013, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive set out in Annex III.

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

Article 2250
Entry into force

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.
Articles 1, 2, 3(1) to (7), 3(9) to (11), 3(14), 4(2) to (4), 6, 7, 8(1), 9, 10, 16, 29, 35, 37(2), 42 to 50 and Annexes III and IV shall apply from 4 July 2013.

Article 2351
Addressees

This Directive is addressed to the Member States.

Done at […],

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.

Each pyrotechnic article must 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.

The following information and properties — where applicable — must be considered or tested:

(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) Sensitivity to normal, foreseeable handling and transportation;

(d) Compatibility of all components as regards their chemical stability;

(e) Resistance of the pyrotechnic article to moisture where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by moisture;

(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;
The ability of the pyrotechnic article, its wrapping or other components to withstand deterioration under normal, foreseeable storage conditions;

specification of all devices and accessories needed and operating instructions for safe functioning of the pyrotechnic article.

During transportation and normal handling, unless specified by the manufacturer's instructions, the pyrotechnic articles should contain the pyrotechnic composition.

Pyrotechnic articles must not contain detonative explosives other than black powder and flash composition, except for articles of categories P1, P2, T2 and fireworks of category 4 meeting the following conditions:

(a) commercial blasting agents, except for black powder or flash composition; the detonative explosive cannot be easily extracted from the article;

(b) military explosives; for category P1, the article cannot function in a detonative manner, or cannot, in itself, initiate secondary explosives;

(c) for categories 4, T2 and P2, the article is designed and intended not to function in a detonative manner, or, if designed to detonate, it cannot in itself initiate secondary explosives.

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

A. FIREWORKS

The manufacturer must assign fireworks to different categories according to Article 6 characterised by net explosive content, safety distances, noise level, or similar. The category must be clearly indicated on the label.

(a) For category 1 fireworks, the following conditions must be met:

(i) the safety distance must be at least 1 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance,

(iii) category 1 must not comprise bangers, banger batteries, flash bangers and flash banger batteries.
(iv) throwdowns in category 1 must not contain more than 2.5 mg silver fulminate.

(b) For category 2 fireworks, the following conditions must be met:

(i) the safety distance must be at least 8 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance.

(c) For category 3 fireworks, the following conditions must be met:

(i) the safety distance must be at least 15 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance.

(2) Fireworks may only be constructed of materials which minimise risk to health, property and the environment from debris.

(3) The method of ignition must be clearly visible or must be indicated by labelling or instructions.

(4) Fireworks must not move in an erratic and unforeseeable manner.

(5) 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

(1) Pyrotechnic articles must be designed in such a way as to minimise risk to health, property and the environment during normal use.

(2) The method of ignition must be clearly visible or must be indicated by labelling or instructions.

(3) The pyrotechnic article must be designed in such a way as to minimise risk to health, property and the environment from debris when initiated inadvertently.

(4) Where appropriate, the pyrotechnic article must function properly until the ‘use by’ date specified by the manufacturer.
C. **IGNITION DEVICES**

1. Ignition devices must be capable of being reliably initiated and be of sufficient initiation capability under all normal, foreseeable conditions of use.

2. Ignition devices must be protected against electrostatic discharge under normal, foreseeable conditions of storage and use.

3. Electric igniters must be protected against electromagnetic fields under normal, foreseeable conditions of storage and use.

4. The covering of fuses must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal, foreseeable mechanical stress.

5. The parameters for the burning times of fuses must be provided with the article.

6. The electrical characteristics (e.g. no-fire current, resistance, etc.) of electric igniters must be provided with the article.

7. The wires of electric igniters must be sufficiently insulated and must be of sufficient mechanical strength, including the solidity of the link to the igniter, taking account of their intended use.
ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

Module B:

EU Type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that a sample, representative of the production envisaged, meets the relevant provisions of Directive 2007/23/EC (hereinafter referred to as this Directive). EU type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a pyrotechnic article and verifies and attests that the technical design of the pyrotechnic article meets the requirements of this Directive.

2. EU type examination shall be carried out as an examination of a specimen, representative of the production envisaged, of the complete product (production type).

The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.

The application must include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body.
(c) the technical documentation, as described in point 3. The technical documentation shall make it possible to assess the pyrotechnic article's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall contain, wherever applicable, at least the following elements:

- a general type description of the pyrotechnic article,
- conceptual design and manufacturing drawings and diagrams schemes of e.g. components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and diagrams schemes and the operation of the pyrotechnic article,
- a list of the harmonised standards referred to in Article 8 of this Directive and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards referred to in Article 8 of this Directive have not been applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.
(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body must shall:

4.1 (a) Examine the technical documents, documentation and supporting evidence to assess the adequacy of the technical design of the pyrotechnic article.

(b) 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 applicable provisions of the relevant harmonised standards referred to in Article 8 of this Directive and/or technical specifications, as well as the components elements which have been designed without applying the relevant provisions of those harmonised standards.

4.3 (b) perform or have performed the following examinations and necessary tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have been applied correctly, these have been applied correctly.

4.4 Carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical
specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive;

4.5 Agree with the applicant manufacturer on the location where the examinations and necessary tests are to be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

5.6 Where the type meets the relevant provisions requirements of this Directive the specific legislative instrument that apply to the pyrotechnic article concerned, the notified body must issue an EU type-examination certificate to the applicant manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the approved type. The certificate may have one or more annexes attached.

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

Where the manufacturer is refused a type certificate, The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.
Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU type examination certificate and shall inform the applicant accordingly, giving detailed reasons for such refusal.

Provision must be made for an appeals procedure.

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

The applicant shall inform the notified body that holds the technical documents concerning the EC type examination certificate of all modifications to the approved type that may affect the conformity of the pyrotechnic article with the essential safety requirements of this Directive or the prescribed conditions for use validity of the article. This certificate. Such modifications shall require additional approval must be given in the form of an addition to the original EU type-examination certificate.

Each notified body shall inform its notifying authorities concerning EC the EU type-examination certificates and additions issued or withdrawn. The other notified bodies may receive copies of the EC type-examination certificates and/or any additions thereto. The annexes to the certificates must be kept at the disposal of the other notified bodies. The manufacturer must keep with the technical documents copies of EC type examination certificates and any additions thereto for a period of at least 10 years after the last date of manufacture of the article concerned. Where the manufacturer is not established within the Community, the obligation to keep the technical documents which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of
certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

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

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

MODULE C2:

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

1. This module describes that part of the Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole 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 ensures the conformity of the manufactured product with the type as described in the EC type examination certificate and with the essential safety requirements of this 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 article 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 market.

4. A notified body chosen by the manufacturer must perform or cause to be performed examinations of the article at random intervals. A suitable sample of the finished articles, taken on the spot by the notified body, must be examined and appropriate tests, defined in the applicable harmonised standard referred to in Article 8 of this Directive or equivalent, carried out to check the conformity of the article with the requirements of this Directive. In the event of one or more samples of the articles examined not conforming, the notified body must take appropriate measures.

Under the responsibility of the notified body the manufacturer must affix the identification number of that body during the manufacturing process.

3. MODULE D: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby a manufacturer who satisfies the obligations set out in point 2 ensures and declares that the pyrotechnic articles concerned are in conformity with the type as described in the EU type-examination certificate and satisfy the requirements of this Directive. 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 monitoring referred to in point 4.

2. Manufacturing

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

3. Product checks

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

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

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

4. Conformity marking and declaration of conformity

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

4.2 The manufacturer shall draw up a written declaration of conformity for the pyrotechnic article and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

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

**MODULE D**

Conformity to type based on quality assurance of the production process

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

2. ☑ Manufacturing ☐

   The manufacturer ☑ shall ☐ operate an approved quality system for production, final product inspection and testing ☑ of the pyrotechnic articles concerned ☐ as specified in point 3. He must ☑ and shall ☐ be subject to the monitoring referred to ☑ surveillance as specified ☐ in point 4.

3. ☐ Quality system
3.1 The manufacturer must shall lodge an application for assessment of his quality system with the notified body of his choice in relation to for the pyrotechnic articles concerned.

The application must shall include:

(a) the name and address of the manufacturer;
(b) a written declaration that the same application has not been lodged with any other notified body;
(c) all relevant information for the pyrotechnic article category envisaged;
(d) the documents concerning the quality system;
(e) the technical documentation of the approved type and a copy of the EC EU type-examination certificate.

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

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

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the product quality of the pyrotechnic articles;
(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out.
3.2 The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

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

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

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

The means of monitoring the achievement of the required product quality and the effective operation of the quality system.

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

3.5 The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the altered quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.
It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

4. Monitoring under the responsibility of the notified body

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

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

(a) the quality system documentation;
(b) the quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned.

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

4.4 Additionally, in addition, the notified body may pay unannounced unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests or have them carried out in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, tests have 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 article, keep at the disposal of the national authorities:

Conformity marking and declaration of conformity
5.1 The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EU type examination certificate and satisfies the applicable requirements of this Directive.

(a) the documents referred to in point 3.1 (b),

(b) documents relating to the updating referred to in second subparagraph of point 3.4,

(c) the decisions and reports of the notified body referred to in the fourth subparagraph of point 3.4, and in points 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning quality system approvals issued or withdrawn.

4. MODULE E: PRODUCT QUALITY ASSURANCE

1. This module describes the procedure whereby a manufacturer who satisfies the obligations set out in point 2 ensures and declares that the pyrotechnic articles are in conformity with the type as described in the EC type-examination certificate.

5.2 The manufacturer must affix the CE marking to each article and shall draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the monitoring referred to in point 4 each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.
6. The manufacturer shall, for a period ending at least 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

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

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

**Module E**

**Conformity to type based on product quality assurance**

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

2. Manufacturing

The manufacturer must shall operate an approved quality system for final production inspection and testing of the pyrotechnic articles concerned as specified in point 3. He must and shall be subject to the monitoring referred to surveillance as specified in point 4.

3. Quality system

3.1 The manufacturer must shall lodge an application for assessment of his quality system with the notified body of his choice for the assessment of the quality system in relation to his pyrotechnic articles concerned.

The application shall include the following information:
(a) the name and address of the manufacturer;

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

(c) all relevant information for the pyrotechnic product category envisaged;

(d) the documentation concerning the quality system documents;

(e) the technical documents pertaining to documentation of the approved type and a copy of the EU examination certificate.

3.2 Under the quality system, each pyrotechnic article must be examined and appropriate tests, as defined in the relevant harmonised standard(s) referred to in Article 8 of this Directive or equivalent, carried out in order to verify the conformity of the article with the relevant requirements of this Directive. The quality system shall ensure compliance of the pyrotechnic articles with the type described in the EU examination certificate and with the applicable requirements of this Directive.

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

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality.
(b) the examination and tests that will be carried out after manufacture;

(c) quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned;

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

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

It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

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

A duly substantiated assessment shall be notified to the manufacturer. The notification shall contain the results of the examination audit and the reasoned assessment decision.

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

3.5 The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
The notified body must assess the shall evaluate any proposed changes and decide whether the altered modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

A duly substantiated assessment shall notify the manufacturer of its decision. It must be notified to the manufacturer. It must contain the results conclusions of the examination and the reasoned assessment decision.

4. Monitoring Surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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 access for inspection purposes to the manufacturing , inspection, testing and storage premises sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation,

(b) the technical documents,

(c) the quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned.

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

4.4 Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

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

(a) the documents referred to in point 3.1.(b),

(b) documents relating to the updating referred to in the second subparagraph of point 3.4.
(c) the decisions and reports of the notified body referred to in the fourth subparagraph of point 3.4, and in points 4.3 and 4.4.

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

5. 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 point 2 conforms with the relevant requirements of this Directive.

5. Conformity marking and declaration of conformity

5.1 The manufacturer must affix the CE marking to the article and draw up a declaration of conformity. 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 of this Directive, or equivalent tests, to ensure this Directive, and, under the responsibility of the notified body referred to in point 3.1, the conformity of the article with the relevant requirements of this Directive. The notified body must affix, or cause to be affixed, its identification number to the approved pyrotechnic article and draw up a declaration of conformity concerning the tests carried out. The aim of the technical documents is to enable conformity with the requirements of this Directive to be assessed and the design, manufacture and operation of the pyrotechnic article to be understood.

5.2 The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

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

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

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

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

**MODULE G**

**Conformity based on unit verification**

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

2. **Technical documentation**

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

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**Where necessary for the assessment, the documents must contain:**

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(a) a general description of the type of pyrotechnic article;
(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits, etc.
(c) the descriptions and explanations necessary for the understanding of the conceptual design and manufacturing drawings, the schemes of components, sub-assemblies and circuits, and the operation of the pyrotechnic article;

(d) a list of the harmonised standards referred to in Article 8 of this Directive and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards referred to in Article 8 of this Directive have not been applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, and examinations carried out, etc.

(f) test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pyrotechnic article has been placed on the market.

3. Manufacturing

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

4. Verification

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

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

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

5. Conformity marking and declaration of conformity
5.1 The manufacturer shall affix the required conformity marking set out in the legislative instrument and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of this Directive.

5.2 The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

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

6. **MODULE H:**

**Conformity based on full quality assurance**

1. This module describes the procedure whereby the manufacturer who satisfies the obligations set out in points 2 and 5 ensures and declares on his sole responsibility that the pyrotechnic articles concerned meet the requirements of this Directive. The manufacturer or his importer 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 monitoring referred to in point 4.

2. **Manufacturing**

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

3. Quality system

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

The application must shall include:

(a) all relevant information for the pyrotechnic article category envisaged.
(a) the name and address of the manufacturer;

(b) the technical documentation for one model of each category of pyrotechnic articles intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the pyrotechnic article;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports;

(c) the documents concerning the quality system;

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

3.2 The quality system shall ensure the conformity compliance of the pyrotechnic articles article with the requirements of this Directive.

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

They must contain it shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product design and pyrotechnic article quality;

(b) the technical construction design specifications, including the standards applicable that will be applied and, if the standards referred to in Article 8 of this Directive have not been fully where the relevant harmonised standards and/or technical specifications will not be applied in full, the means of ensuring that will be used to ensure that the relevant basic essential safety requirements of this Directive will be met;

(c) techniques to control and assess the development results design verification techniques, processes and systematic actions that will be used to develop products belonging to when designing the pyrotechnic articles pertaining to the pyrotechnic article category in question covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, and the processes and systematic actions applied that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, and qualification reports of on the personnel concerned, etc.;

(g) the means of monitoring the achievement of the required design and product quality of the product and the effective operation of the quality system.

3.3 The notified body must shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It must shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding
specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

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

A duly substantiated assessment. The manufacturer shall be notified of the decision. The notification shall contain the results conclusion of the examination audit and the reasoned assessment decision.

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

3.5 The manufacturer shall keep the notified body that has approved the quality system constantly informed of any proposed update of intended change to the quality system.

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

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

4. EC monitoring. Surveillance under the responsibility of the notified body.

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

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

(a) the quality system documentation.
(b) the quality records required as provided for by the design part of the quality system for the development field such as the results of analyses, calculations, and tests, etc.;

(c) the quality records required as provided for by the manufacturing part of the quality system for the manufacturing field such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned, etc.

4.3 The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report to ensure the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

4.4 Additionally, the notified body may pay unannounced unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out pyrotechnic articles tests or have them carried out to verify that in order to check the proper functioning of the quality system is functioning correctly. The notified body must. It shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. Conformity marking and declaration of conformity

5.1 The manufacturer shall affix the required conformity marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1., the latter's identification number to each individual pyrotechnic article that satisfies the applicable requirements of this Directive.

5.2 The manufacturer shall draw up a written declaration of conformity for each pyrotechnic article model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article model for which it has been drawn up.

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

56. The manufacturer shall, for a period ending at least 10 years after the last date of manufacture of the article product has been placed on the market, keep at the disposal of the national authorities:
(a) the technical documents documentation referred to in point 3.1(b);

(b) the documents documentation relating to the updating concerning the quality system referred to in second subparagraph of point 3.41;

(c) the change referred to in point 3.5, as approved;

(d) (c) the decisions and reports of the notified body referred to in the fourth subparagraph of points 3.45, and in points 4.3 and 4.4.

Each notified body must give the other notified bodies the relevant information concerning shall inform its notifying authorities of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

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

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

1. The body, its director and the staff responsible for carrying out the verification tests must not be the designer, manufacturer, supplier, installer or importer of pyrotechnic articles which they inspect, nor the authorised representative of any of these parties. They must not become involved either directly or as authorised representative in the design, construction, marketing, maintenance or importation 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 must carry out the verification tests with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. The body must 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 must also have access to the equipment required for special verification.

4. The staff responsible for inspection must have:
   (a) sound technical and professional training,
   (b) satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
   (c) the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.

6. The body must 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 must 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.
The CE conformity marking must 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.
## ANNEX III

List of time-limits for transposition into national law and application

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<thead>
<tr>
<th>Directive</th>
<th>Time-limit for transposition</th>
<th>Date of application</th>
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<td>4 January 2010</td>
<td>4 July 2010 (fireworks of categories 1, 2 and 3)</td>
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### ANNEX IV

**CORRELATION TABLE**

<table>
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<tbody>
<tr>
<td>Article 1(1)</td>
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<tr>
<td>Article 1(2)</td>
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<td>Article 1(3)</td>
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<td>Article 1(4)(a)</td>
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<td>Article 1(4)(e)</td>
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<td>Article 1(4)(f)</td>
<td>Article 2(2)(f) and Article 3(5)</td>
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<td>Article 2(1)</td>
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<td>Article 2(2) 1st sentence</td>
<td>Article 3(7)</td>
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<td>Article 2(2) 2nd sentence</td>
<td>Article 2(2)(g)</td>
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<td>Article 2(3)</td>
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<td>Article 3(13)</td>
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<td>Article 3(15) to (22)</td>
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<td>Article 3(1)</td>
<td>Article 6(1)</td>
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<td>Article 3(2)</td>
<td>Article 6(2)</td>
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<tr>
<td>Article 4 (title)</td>
<td>Articles 8, 11, 12 (titles)</td>
</tr>
<tr>
<td>Article 4(1)</td>
<td>Article 8(1)</td>
</tr>
<tr>
<td>Article 4(2), 1st subparagraph</td>
<td>Article 11(1) to (4) and Article 13</td>
</tr>
<tr>
<td>Article 4(2), 2nd subparagraph</td>
<td>Article 13</td>
</tr>
<tr>
<td>Article 4(3)</td>
<td>Article 12 (1) and Article 12(2) 1st subparagraph</td>
</tr>
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<td>-</td>
<td>Article 12(2) 2nd subparagraph</td>
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<td>Article 12(5)</td>
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<tr>
<td>Article 4(4)(a)</td>
<td>Article 8(2) 1st subparagraph</td>
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<tr>
<td>Article 4(4)(b)</td>
<td>Article 8(2) 2nd subparagraph and Article 8(5)</td>
</tr>
<tr>
<td>-</td>
<td>Article 8(3) to (7)</td>
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<td>-</td>
<td>Article 14</td>
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<tr>
<td>Article 5(1)</td>
<td>Article 5</td>
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<td>Article 7(1)</td>
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<td>Article 8(1)</td>
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<tr>
<td>Article 8(2)</td>
<td>Article 15, 2nd subparagraph</td>
</tr>
<tr>
<td>Article 8(3), first sentence</td>
<td>-</td>
</tr>
<tr>
<td>Article 8(3), second sentence</td>
<td>Article 15</td>
</tr>
<tr>
<td>Article 8(3), third sentence</td>
<td>-</td>
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<tr>
<td>Article 8(4)</td>
<td>-</td>
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<tr>
<td>Article 9</td>
<td>Article 16</td>
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<td>Article 17</td>
</tr>
<tr>
<td>Article 10(1)</td>
<td>Articles 20 and 29(1)</td>
</tr>
<tr>
<td>Article 10(2)</td>
<td>Article 29(2)</td>
</tr>
<tr>
<td>Article 10(3)</td>
<td>Articles 24 and 25</td>
</tr>
<tr>
<td>Article 10(4)</td>
<td>Article 30(1)</td>
</tr>
<tr>
<td>Article 10(5)</td>
<td>Article 30(2)</td>
</tr>
<tr>
<td>Article 10(6)</td>
<td>-</td>
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<td>-</td>
<td>Articles 21 and 23</td>
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<td>Articles 26 to 28</td>
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<td>Articles 31 to 36</td>
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<td>Article 11(1)</td>
<td>Article 19(1)</td>
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<tr>
<td>Article 11(2)</td>
<td>Article 18</td>
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<td>Article 11(3)</td>
<td>Article 18</td>
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<td>Article 10(1)</td>
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<td>Article 14(1)</td>
<td>Article 37(1)</td>
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<tr>
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<td>Article 37(1)</td>
</tr>
<tr>
<td>Article 15</td>
<td>Article 38(1), 1st subparagraph</td>
</tr>
<tr>
<td>-</td>
<td>Article 38(1), 2nd, 3rd, 4th subparagraphs</td>
</tr>
<tr>
<td>-</td>
<td>Article 38(2) to (8)</td>
</tr>
<tr>
<td>Article 16(1)</td>
<td>Article 39(1), 1st subparagraph</td>
</tr>
<tr>
<td>Article 16(2)</td>
<td>Article 39(2) and (3)</td>
</tr>
<tr>
<td>Article 16(3)</td>
<td>Article 41(1)(a)</td>
</tr>
<tr>
<td>-</td>
<td>Article 39(1), 2nd subparagraph</td>
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<tr>
<td>-</td>
<td>Article 40</td>
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<td>Article 41</td>
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<td>Article 17(2)</td>
<td>Article 37(1)</td>
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<tr>
<td>Article 18(1)</td>
<td>Article 42</td>
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<td>Article 18(2)</td>
<td>Article 44</td>
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<td>Article 19(1)</td>
<td>Article 45(1)</td>
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<td>Article 19(2)</td>
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<td>Article 19(3), 1st subparagraph</td>
<td>Article 45(2)</td>
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<td>Article 19(3), 2nd subparagraph</td>
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<tr>
<td>Article 20</td>
<td>Article 46</td>
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<td>Article 21(1)</td>
<td>Article 48(1)</td>
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<td>Article 21(2), first sentence</td>
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<td>Article 47(4)</td>
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<td>Article 24</td>
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