



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Chemicals, Metals, Forest-based & Textile Industries  
**Chemicals**

**QUESTIONS AND ANSWERS  
CONCERNING THE IMPLEMENTATION OF DIRECTIVE  
93/15/EEC**

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## **Table of contents**

1. Introduction
2. CE marking of on-site mixed explosives
3. If one notified body has certified a product, can the manufacturer turn to another notified body to take care of conformity to type examination (module C) or quality audits (module D or E) for the same product?
4. Which notified body is responsible in case of a product not fulfilling the Directive after being put on the market, the notified body responsible for module B or the notified body responsible for the submodule?
5. Which notified body is responsible for allowing the manufacturer to CE-mark the product?
6. Can certificates [for the different modules] be withdrawn, if yes, at which occasions and how?
7. Do propellant cartridges for powder actuated fastening tools (PAT) fall under the Explosives Directive because their UN Number is not listed in Directive 2004/57/EC ?

## **1. INTRODUCTION**

This document gathers some questions and answers concerning the interpretation of Council Directive 93/15/EEC.

The answers were discussed between the Commission services and the representatives from the Member States in the Explosives Working group and/or the Forum of Explosives Notified Bodies. The document attempts to provide guidance to Member States, notified bodies and economic operators.

The answers represent the opinion of the Commission services but may not necessarily represent the opinion of the Commission. This guidance document does not constitute any formal commitment on behalf of the Commission. Only the European Court of Justice can give an authoritative interpretation of Community legislation.

This guidance document will be regularly updated and published on the website of the European Commission.

## 2. CE marking of on-site mixed explosives (question received from industry)

### *Text of the question:*

The point 2.1 of the "Guide to the implementation of Directives based on the new approach and the global approach" establishes that it is the responsibility of the manufacturer to verify whether or not the product is within the scope of a Directive.

In the scope of 93/15/EEC (Civil Explosives) there are no exclusions for the commercialised explosives manufactured directly in the end-users places with a factory-truck; in the jargon of the sector this is so-called "on site mixing".

Our interpretation is that Directive 93/15/EEC is applicable to commercialised explosives manufactured with a factory-truck if any of the "essential safety requirements" included in the annex 1 are applicable; once it was done, we found that many of the essential safety requirements are applicable. However, there are doubts in the sector and also doubts and different criteria between authorities and notify bodies.

Therefore I would be grateful if you could confirm us if the 93/15/EEC directive is applicable to "on site manufactured explosives" or if our thinking of essential safety requirements applicability is correct.

If the answer was positive, our doubts is this case is how to affix the CE mark; in 7.3 point of the "Guide..." we found a specific mention to the marking impossibility in explosives as an example, but there are no solutions for it. Could it be possible to fix the CE mark on the truck like it was the packaging or could we put the CE mark in any document?

If the answer was negative, we have then another doubt which is the applicability or not of the 92/59/ECC Directive on general product safety (See point 2.2.2 of the Guide to the implementation of new approach directive).

### **Answer:**

- Compliance with essential safety requirements:

Because of the specific nature of explosives, the Commission services recommend to apply the relevant general and specific essential safety requirements to all on-site mixed explosives, whether they are placed on the market or not.

- Affixing the CE marking:

Pursuant to Article 2.2 if a company places an explosive on the market, this explosive has to be CE marked.

Article 2.2 prescribes that "Member States shall take the necessary measures to ensure that explosives falling within the scope of this Directive may be placed on the market only if they comply with on the provisions of this Directive, are provided with the CE marking described in Article 7 and their conformity has been assessed in accordance with the procedures referred to in Annex II. Therefore, if a company places an explosive on the market, this explosive has to be CE marked.

Placing on the market is defined as “any first disposal against payment or free of charge of explosives covered by this Directive with a view to their distribution and/or use on the Community market.”

According to the “guide to the implementation of directives based on the new approach and the global approach”, products built for own use are, generally, not considered as being placed on the market.

We therefore suggest the following distinction

In general, the explosives **are placed on the market** and have to be CE marked if the quarry or mine company is responsible for most aspects of the blasting operations while the explosives manufacturer for example only pumps the explosive down the holes and initiates the blast. In such a situation, the explosives are for the use of the quarry operator and therefore have been placed on the market;

Explosives are not deemed to have been placed on the market if the explosives company carries out, and has full responsibility for, the blasting operations. In this case, the explosives are for the use of the explosives company in the provision of blasting services, rather than for the use of the mine or quarry operator (although the quarry operator receives the benefit). To use the industry expression the quarry operator buys 'rock on the floor [of the quarry]'.

Conclusion

*The general and the relevant special* essential safety requirements should in all cases also apply to explosives manufactured on site which fall under the scope of the Explosives Directive. These explosives should also be CE marked except in the ‘own use’ case as explained above, where the CE mark is not required. As far as the CE mark is concerned, Article 7.1 of the Explosives Directive gives the possibility to affix the CE mark on an identification plate. A practicable solution could therefore be to attach a removable identification plate to the mixing truck. It is also possible *to carry the relevant documentation on the mixing truck.*

**3. If one notified body has certified a product, can the manufacturer turn to another notified body to take care of conformity to type examination (module C) or quality audits (module D or E) for the same product?**

The Directive 93/15/EEC does not oblige the manufacturer to choose the same notified body that he had previously selected for the EC type-examination (module B) to carry out the subsequent conformity to type (module C) or production quality assurance (module D). No link is established between the manufacturer's choice of a notified body referred to in module C (Annex II part 2 point 4 first subparagraph) or in module D (Annex II part 3 point 3.1 first subparagraph) and the choice referred to in module B (Annex II part 1 point 2 first subparagraph) and, therefore, the manufacturer is free in this respect.<sup>1</sup>

**4. If the answer [to the question above] is yes, which notified body is responsible in case of a product not fulfilling the Directive after being put on the market, the notified body responsible for module B or the notified body responsible for the submodule?**

It is the manufacturer who is responsible for having placed a non-conforming product on the market. The notified bodies, however, assume responsibility for the certificates that they issued to the manufacturer. The manufacturer may therefore invoke their professional responsibility under the conditions usually provided for in a contract between the manufacturer and the notified body or under the general terms of the respective contract law. In any case the responsibility has to be assessed and determined on a case-by-case basis, depending on where the actual fault (non-compliance) was found. In general, each notified body should be responsible only for that part of the work that it carried out. The notified body that performed EC type-examination should be responsible for the faults relating to the type, while the notified body which carries out the second phase of the conformity assessment procedure (module C, D, E or F) should be responsible for the faults linked to the production phase. In general, the notified body involved in the production phase should not be responsible for not having identified mistakes incurred during the EC type-examination. However, this may also depend on the gravity or evidence of the mistake in a particular case (eg in case of a serious and evident mistake both notified bodies involved might share the responsibility). When considering the responsibility in each particular case, attention must be also drawn to the fact whether the notified bodies complied with some other obligation laid down in the Directive, such as in Annex II part 1 point 7 of the Directive according to which each notified body that carries out EC type-examination "must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn" or in Annex II part 1 point 8 of the Directive under which "the other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies." On the other hand, for example, in each of the

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<sup>1</sup> The only limitation incumbent on the manufacture is that according to Annex II part 1 (Module B) point 2 second subparagraph second indent the manufacturer can't lodge more than one application for EC type-examination for the same product.

modules C, D, E or F the notified body must examine and verify – in the particular relevant way – the conformity of the product with the requirements of the Directive<sup>2</sup>.

**5. Which notified body is responsible for allowing the manufacturer to CE-mark the product?**

The affixing of the CE marking is also primarily the manufacturer's responsibility. However, when the CE marking appears on products with an identification number of a notified body, the notified body also assumes responsibility. The CE marking must be affixed at the end of the production phase. The CE marking shall only be followed by the identification number of the notified body if the notified body is involved in the production phase. Thus, the identification number of a notified body involved in conformity assessment according to module B does not follow the CE marking. It is therefore the notified body that carries out module C, D, E or F (and whose identification number figures on the product together with the CE marking) that assumes responsibility<sup>3</sup>.

**6. Can certificates [for the different modules] be withdrawn, if yes, at which occasions and how?**

There are several aspects that need to be taken into account when considering the validity and the possibility of withdrawing certificates:

- notified bodies are obliged to maintain themselves updated as far as the development of the state of the art is concerned;
- notified bodies allow manufacturers to make use of the certificates not only for the date when the certificate was issued;
- the manufacturer has the obligation to inform the notified body of all modifications where such changes may affect conformity with the essential requirements and where therefore a further approval is needed. This obligation is also part of the ongoing licence agreement between notified body and manufacturer;
- according to national civil law certification bodies usually have an obligation of due diligence vis-à-vis the validity of issued certificates.

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<sup>2</sup> In module C (point 4): A notified body chosen by the manufacturer must perform or have performed examinations of the product at random intervals. A suitable sample of the finished products, taken on the spot by the notified body, is examined and appropriate tests, defined in the applicable standard or standards referred to in Article 4 or equivalent tests are carried out to check the conformity of the product with the requirements of the corresponding Directive. In module D (point 3.2. first subparagraph): The quality system must ensure conformity of explosives with the type as described in the EC type-examination certificate and with the requirements of this Directive that apply to them. In module E (point 3.2. first subparagraph): Under the quality system, each explosive is examined and appropriate tests as defined in the relevant standard(s) referred to in Article 4 or equivalent tests are carried out in order to verify its conformity with the relevant requirements of the Directive. In module F (point 3 first subparagraph): The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the explosive with the relevant requirements of the Directive by examination and testing of every explosive as specified in 4.

<sup>3</sup> In module C see point 4 second subparagraph, in module D point 1 last sentence, in module E point 1 last sentence and in module F point 4.2. See also Annex part I. B (f) and (g) of Council Decision 93/465/EEC.

On the basis of those aspects it can be concluded that though certificates are issued to the manufacturer at a given moment, notified bodies cannot deny their responsibility in time for those certificates. It is therefore necessary for the notified bodies to have the possibility to withdraw the certificate.

In the case of module B it is not correct to simply state that an EC type-examination certificate states compliance of a test sample with essential requirements only at a certain point of time and does not imply future compliance. On the contrary the notified bodies must inform the manufacturer that the certificate may not continue to be used because the originally certified type does no longer meet the provisions of the directive. According to point 7 of the text of the Directive relating to this module the notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.

In the case of module D the Directive foresees in point 4.3 of the text relating to this module periodic audits carried out by the notified body and in point 4.4 unannounced visits to the manufacturer to make sure that the manufacturer maintains and applies the quality system and that the quality system is functioning correctly. In case of shortcomings when no corrective measures are taken by the manufacturer the certificate should be withdrawn. According to point 6 each notified body must then give the other notified bodies the relevant information concerning the quality system approvals withdrawn.

In the case of module C the Directive foresees in point 4 of the text relating to this module examinations of products at random intervals. It states that “in the event of one or more samples of the products examined not conforming, the notified body must take the appropriate measures”. Such measures may include suspension of the notified body’s approval until the product is made compliant with the requirements of the Directive or withdrawal of such approval (including the withdrawal of the identification number of the notified body affixed on the product).

In all cases it needs to be stressed that when a notified body finds that requirements of the Directive have not been met or are no longer met, it has to restrict, suspend or withdraw certificates, approvals or other relevant conformity assessment results, taking into account the principle of proportionality and the risk involved, unless compliance is ensured through the implementation of appropriate corrective measures.

**7. Do propellant cartridges for powder actuated fastening tools (PAT) fall under the Explosives Directive because their UN Number is not listed in Directive 2004/57/EC ?**

Contrary to the Machinery Directive previously in force, the scope of Directive 2006/42/EC of 17 May 2006 on machinery now also includes cartridge operated fixing and marking tools, which in the future have to be CE marked in conformity with the requirements of the Machinery Directive. Directive 2006/42/EC also includes the following derogation: "Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive."

It has been assumed that after the date stated above, propellant cartridges for fixing and marking tools will no longer be regarded as ammunition, and the question has arisen if in the future they will fall under the Explosives Directive (93/15/EEC) or the Pyrotechnics Directive (2007/23/EC).

Commission Directive 2004/57/EC lists a number of articles which are considered to be pyrotechnic articles or ammunition in order to exclude them from the application of the Explosives Directive (93/15/EEC). The Directive does not contain an exhaustive list of **all** existing pyrotechnic articles nor does it define what pyrotechnic articles are.

The only text within European legislation that defines Pyrotechnic articles and sets rules applying to these articles is Directive 2007/23/EC.

Having looked at the properties of propellant cartridges, the following line seems technically adequate:

*Propellant cartridges having a net explosive content (NEC) of less than 10 g intended for powder actuated fastening tools fall under the definition of a pyrotechnic article contained in Article 2.1 of Directive 2007/23/EC. .*

Propellant cartridges intended for cartridge operated fixing and marking tools have currently been included in the work programme of CEN TC 212, where harmonised standards for pyrotechnic articles are developed. Propellant cartridges meeting the future harmonised standard (which will be published in due course in the Official Journal) can then be considered pyrotechnic articles, while other propellant cartridges, typically with an NEC of 10 g or more, have to be considered to fall under the Explosives Directive.