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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Resources Based, Manufacturing and Consumer Goods Industries
Chemicals Industry

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

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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 was last updated in February 2013 to include points 11 and 12. It will continue to 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.*

Questions by the Forum of Notified Bodies to the Commission

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.[1]

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

[1] 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.

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 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[2].

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[3].

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

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[2] 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.

[3] 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.

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.

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.

Questions added in 2012 and 2013

8. In accordance with Article 1(3) first indent, Directive 93/15/EEC does not apply to explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police. How should this exclusion be interpreted in the context of intra-EU transfers to differentiate between commercial and military explosives, for example in cases where a commercial company supplies an explosive to another company for further processing and/or incorporation into a finished product destined for military use?

It should be first underlined that the exclusion in Article 1(3) of the Directive refers to the 'intended use'. In that context a distinction needs to be drawn between immediate use and possible eventual use for military purposes. In particular, the eventual intended use may not always be evident so that in the example quoted above the first company may be unaware of the final use and may have no control over this or the finished product placed on the market or know the final consignee.

A basic starting point for determining whether the explosive falls within the exclusion in Article 1(3) would be whether or not the explosive falls within the Common Military List of the European Union (the latest version of which was adopted by the Council on 21 February 2011 (2011/C 86/01) (equipment covered by Council Common Position 2008/944/CFSP defining common rules governing the control of exports of military technology equipment)). In principle such explosives could be regarded as military explosives. However the possibility of possible dual use cannot be excluded and due regard should also be paid as to who the consignee is. If the immediate consignee is a commercial company, the rules of the Directive should apply up to the point that it becomes clear that the ultimate use is military.

If the explosive is not on the Common Military List it should be regarded as a commercial explosive and treated accordingly unless the consignee is the armed forces or the police. If the immediate consignee is a commercial company, even if the explosive is expected to be for military use, it should be regarded as falling under the Directive until the point that it becomes clear the final consignee is the military.

Since the distinction between civil and military explosives is not so clear for the purposes of the Directive, it is difficult to draw up further general guidance. Each specific case will need to be assessed individually taking into account the particular circumstances.

9. What is the status of shock tubes under the Directive?

Shock tubes are used to deliver the ignition impulse over intermediate or short distances through a plastic tube, while the tube itself stays fully intact and does not rupture. Due to the low exterior effects of shock tubes upon ignition they are often excluded from class

1 under Transport of Dangerous Goods Regulations since, when not attached to a detonator, they are non-hazardous. As such they cannot be used for a blasting purpose and do not show explosive properties and can be considered as similar to the lead wires of electric detonators.

It follows that shock tubes as such should not normally fall within the Directive's scope. When attached to the detonator to form a detonator assembly (as a non-electronic detonator, for example) they would however fall within the Directive's scope (for example the proper functioning between the shock-tube and the detonator cap would be part of the conformity assessment).

10. What is the procedure for attributing manufacturing site codes to non-EU manufacturing sites under Commission Directive 2008/43/EC, as amended by Directive 2012/4/EU?

Where manufacturing sites are located outside the EU, the procedures of Article 3(5) of Commission Directive 2008/43/EC should be followed. However, in cases where the overseas manufacturer is also established in the EU, he could contact the national authority of the Member State in which he is established or of first import and obtain a single code for the manufacturing site to be used for all imports into the EU. The manufacturer established in the EU would assume responsibility for compliance with the Directive for all those imports, including in particular the obligations of undertakings in relation to record-keeping.

In all other cases where the manufacturing site is located outside the EU, the importer of the explosives will have to obtain a code in accordance with the second subparagraph of Article 3(5) of the Directive.

To further reduce the administrative burdens, and also in cases where the overseas manufacturer is not established in the EU, the imports need not physically go through the location of the importer or of the EU legal entity of the manufacturer, but any point of entry, provided that they are handled in line with the single authorisation for simplified procedures (SASP)/centralised customs clearance used throughout the EU under customs legislation, whereby the import paperwork is submitted in one Member State, but the products can be shipped directly to another Member State or States (with the customs authorities there not requiring additional paperwork) (http://ec.europa.eu/taxation_customs/customs/procedural_aspects/general/centralised_clearance/index_en.htm).

11. How should the term 'end-user' be understood for the purposes of Commission Directive 2008/43/EC?

Chapter 3 of the Directive relating to data collection and record-keeping provides that undertakings in the explosives sector collect and maintain data relating to each explosive in their possession or custody throughout the supply chain and life cycle until it is transferred to another undertaking or used.

The end-user would be the last undertaking to take possession or custody and to use the explosive, for example operating blasting on site. In certain cases this could be the sub-contracting company undertaking the blasting. In other words, those responsible for the last place of storage on a site prior to use should keep records from the time they take possession or custody of the explosive until it is used. It should not however normally be necessary for records to be kept on the individual person, such as the individual shot-firer, to whom the explosive is given to use.

The end-user would not necessarily be the undertaking authorised to carry out blasting on site. This would depend on whether they have possession/custody when the explosive is used. In cases where a subcontractor is operating all the blasting process, including the bringing out and taking back of explosives from storage, that undertaking would be perceived as the end-user and assume responsibility for compliance

12. Marking of various explosives in compliance with Directives 2008/43 and 2012/4/EU

There have been a number of questions regarding marking as follows.

A. Smallest Packaging Units and Marking small or oddly shaped explosives

Directive 2008/43 at Article 3(1) refers to marking all explosives and smallest packaging units (SPUs) yet Articles 5 to 11, which provide the detailed instructions for marking for specific types of explosives, only mention SPU in Article 6 on two-component explosives. Excepting two-component explosives, it is difficult to see the security benefit of marking the SPU in the case where the explosive itself can be fully or partially marked in accordance with 2008/43. Doing so will otherwise be an unnecessary burden on industry. Marking the SPUs for very small items as per the amendments to paragraph 3 of the Annex to the Directive introduced by Directive 2012/4 is however understandable as then the explosive item cannot be uniquely identified. This explains why subparagraph 2 onwards of paragraph 3 of the Annex specifically requires marking the SPUs for the articles concerned.

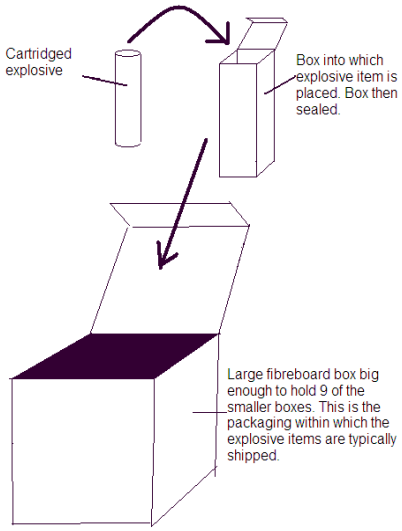
Against this background, while according to a strict interpretation Article 3(1) of Directive 2008/43 should be followed except where specified otherwise, as there is no definition of SPU in the Directives, the table below, in conjunction with the following diagrams (illustrating some examples of possible packaging), presents scenarios and interprets the Directives' requirements with regards to what needs to be marked with what and what constitutes a SPU, where present. This does not preclude marking the innermost packaging or the unit of packaging closest to the explosive, where appropriate, for example to meet the specific needs of users.

Scenario – refer to diagrams below	**Items big enough to fully mark – 2008/43 Article 4**	**Small items that can be partially marked – 2008/43 Annex Para 3**	**Marking in accordance with 2012/4/EU for small (8.5mm or less in diameter) or oddly shaped items that cannot even be partially marked in compliance with 2008/43 Annex Para 3**
Example 1 Cartridged explosives	Mark full unique identification on the cartridge and associated label on the case (outer box). No need to mark inner box.	Mark country ID letters, 3 digit site code and electronic readable ID on the cartridge and associated label on the case (outer box). No need to mark inner box.	Not included.
Example 2 Plain detonators	Mark full unique identification on the detonator and associated label on the case (outer box). No need to mark wrapper or inner box.	Mark country ID letters, 3 digit site code and electronic readable ID on the detonator and associated label on the case (outer box). No need to mark wrapper or inner box.	Mark detonator with country ID letters and 3 digit site code. Mark full unique identification and number of items on the smallest packaging unit (wrapper). Close the smallest packaging unit with a seal so that disappearances in the supply chain can be easily noticed. N.B.: In this case 'full unique

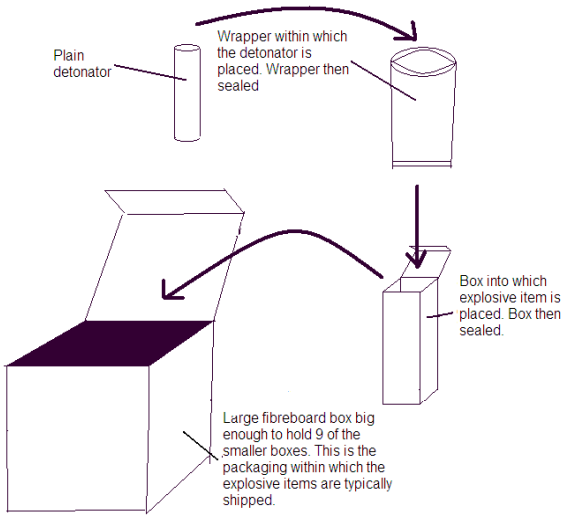
			identification' refers to the smallest packaging unit, not the individual detonator.
Example 3 Boosters	Mark full unique identification on the booster and associated label on the case (outer box). No need to mark wrapper or inner box.	Mark country ID letters, 3 digit site code and electronic readable ID on the booster and associated label on the case (outer box). No need to mark wrapper or inner box.	Mark booster with country ID letters and 3 digit site code. Mark full unique identification and number of items on the smallest packaging unit (inner box). Close the smallest packaging unit with a seal so that disappearances in the supply chain can be easily noticed. N.B.: In this case 'full unique identification' refers to the smallest packaging unit, not the individual booster.
Example 4 Detonating cord	Mark full unique identification on the spool/bobbin/reel and on the cord every 5 metres. Associated label on case (box) if used.	Mark country ID letters, 3 digit site code and electronic readable ID on the spool/bobbin/reel .On the cord repeat every 5 metres the minimum human readable part (no logistics information, no matrix/bar code).Associated label on case (box) if used.	Mark full unique identification on the spool/bobbin/reel and the smallest packaging unit (box).
Example 5 Explosives in drums	Mark full unique identification on the drum. No need to mark case (box). If several drums go into one box, the box should have an associated label.	Mark country ID letters, 3 digit site code and electronic readable ID on the drum and associated label on the case (box).	Not included.

Guidance on Marking in Accordance with Directives 2008/43 and 2012/4

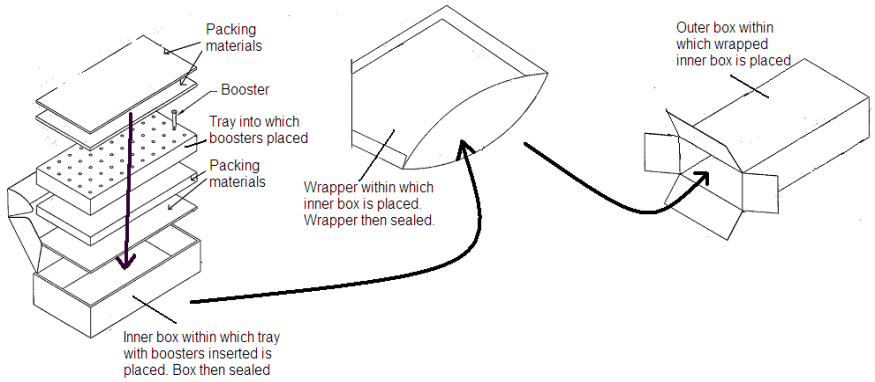
Example 1 Cartridged Explosives



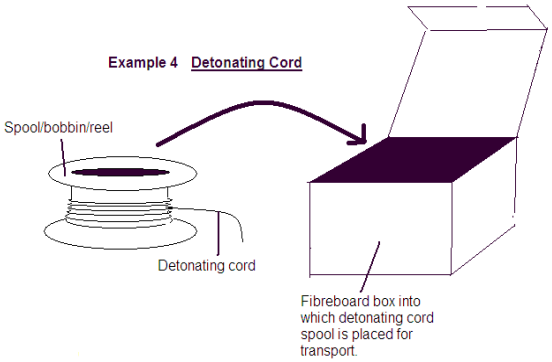
Example 2 Plain Detonators



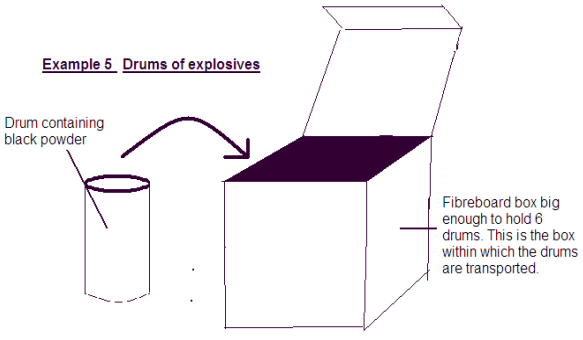
Example 3 Boosters



Example 4 Detonating Cord



Example 5 Drums of explosives



B. Associated Labels

What should be on an "associated label"? If a box contains 50 primers does the associated label have to state the unique identifications for all 50 or can the label simply state something like "Contains 50 primers"?

There is no need that the label contains all numbers of the items in the box. The matrix/bar code should suffice. The related information is available in the systems / database of the producer / distributor and is transferred to the buyer via XML file. If police stopped a truck and wanted to check a specific item number in connection with the box, they should be able to scan the box themselves or obtain information on the number and unique identifications of the items in the box from the manufacturer or distributor. There should be no need to print all item numbers on the box or the delivery documents.

C. Labelling of SPUs

In the case of example 3 – Primers above, the SPU – the inner box - contains 50 items. If the primers are less than 8.5 mm in diameter and therefore the SPU needs to be labelled, do all 50 unique identifications have to be marked on the SPU (inner box in the example)?

No

D. Manufacturer's Name on Unique Identification

Does the manufacturer's name need to be in full or can it be abbreviated (eg RHEMCO instead of Rhinoceros and Hippopotamus Explosives Manufacturing Co) to assist the marking of smaller items? This has benefits and in any event the Member State will be able to identify the manufacturer from their records using the 3 digit site code.

This is a matter for the competent authorities in the Member State issuing the code to judge on a case-by-case basis. If the abbreviated name is a commonly known and recognisable trade name, this should be acceptable; if the abbreviation makes it impossible to identify the manufacturer it would not be advisable.

E. Marking of an explosive article incorporating other explosive articles

In the offshore oil and gas industry, companies manufacture jet-perforating guns (JPG) that consist of a number of shaped charges, detonating cord and detonator manufactured by a third party. These items will be marked in accordance with the Directive however when they are incorporated into the JPG (essentially a long pipe with holes cut in it for the shaped charges) none of their Ids will be visible. Our view is that a single new Identification is marked on the finished JPG and relevant records are kept to detail the incorporation of the smaller items within the JPG. Is this a correct interpretation?

On the assumption that the provisions of the second subparagraph of Article 3(1) of the Directive do not provide an exemption (taking into account also the obligations of Article 4 to which that refers), which would seem the case here, in principle that would be a correct interpretation. The finished JPG would fall within the definition of explosive under Directive 93/115/EEC and would need to be marked to enable a full tracing record.

If the JPG is created 'on-site', marking the JPG as a separate item may not be necessary provided it is not transported elsewhere.