EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Chemicals

QUESTIONS AND ANSWERS CONCERNING THE IMPLEMENTATION OF DIRECTIVE 2014/28/EU AND OF DIRECTIVE 2008/43/EC

Table of contents

1. INTRODUCTION

This document gathers some questions and answers concerning the interpretation of certain provisions of Directive 2014/28/EU and of Commission Directive 2008/43/EC.

The answers were discussed between the relevant Commission services and members and observers of the Group of Experts on Explosive, of the AdCo group on Explosives for Civil Uses, and/or with the Forum of Notified Bodies for Explosives. The document attempts to provide guidance to Member States' competent authorities, market surveillance authorities, notified bodies and economic operators.

The answers represent the opinion of the relevant 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 Union legislation.

This guidance document was last updated in October 2017. It will continue to be regularly updated and published on CIRCABC and on the dedicated webpage of DG GROW.

2. CE MARKING OF ON-SITE MIXED EXPLOSIVES

Question received from industry:

Paragraph 2.1 of the "Blue Guide on the implementation of EU product rules" establishes that it is the responsibility of the manufacturer to verify whether or not the product is within the scope of a given piece of Union harmonisation legislation.

In the scope of Directive 2014/28/EU (explosives for civil uses) there are no exclusions for the commercialised explosives manufactured directly in the end-users sites with a factory-truck; in the jargon of the sector this is the so-called "on site mixing".

Our interpretation is that Directive 2014/28/EU is applicable to commercialised explosives manufactured with a factory-truck if any of the "essential safety requirements" included in the annex II 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 notified bodies.

Therefore I would be grateful if you could confirm us if Directive 2014/28/EU is applicable to "on site manufactured explosives" or if our thinking of essential safety requirements applicability is correct.

If the answer is positive, our doubt in this case is how to affix the CE marking; in paragraph 4.5.1.4. of the "Blue 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 affix the CE marking on the truck like if it was the packaging or could we put the CE marking in any document?

Answer:

<u>Affixing of the CE marking</u>:

Pursuant to Articles 5(1) and 5(2) of the Directive if a company places an explosive on the market or uses it for its own purposes, this explosive has to comply with the essential safety requirements and has to be CE marked.

Article 4 of the Directive prescribes that "Member States shall take the necessary measures to ensure that explosives may be made available on the market only if they comply with the requirements of this Directive". This article, in combination with articles 5(1) and 5(2) of the Directive, leads to the conclusion that if a company places an explosive on the market, this explosive has to be CE marked.

Placing on the market is defined as "the first making available of an explosive on the Union market"; making available on the market is defined as "any supply of an explosive for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge".

According to the "Blue Guide", paragraph 2.3., products built for own use are, generally, not considered as being placed on the market. The "Blue Guide", however, also mentions that "some Union harmonisation legislation however covers products manufactured for own use in its scope (see for instance, the Directives on Machinery, Measuring Instruments, ATEX, Civil Explosives)". The Blue Guide also specifies that "when Union harmonisation legislation covers own use, this does not refer to the occasional manufacturing for own use by a private person in a non-commercial context".

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 delivers the explosives and/or pumps the explosive down the holes. 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 however considered to be **used for own purposes** by the explosives company in the provision of blasting services, rather than for the use of the mine or quarry operator. Therefore, also in this case, pursuant to Articles 5(1) and 5(2) of the Directive, the explosives must be CE marked.

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. As far as the CE marking is concerned, Article 23(5) of Directive 2014/28/EU states that "in cases of explosives manufactured for own use, explosives transported and delivered unpackaged or in Mobile Explosives Manufacturing Units (MEMUs) for their direct unloading into the blast-hole, and explosives manufactured at the blasting sites which are loaded immediately after being produced (in situ production), the CE marking shall be affixed to the accompanying documents".

3. IF ONE NOTIFIED BODY HAS TYPE-CERTIFIED A PRODUCT (MODULE B), CAN THE MANUFACTURER TURN TO ANOTHER NOTIFIED BODY TO TAKE CARE OF THE COMPLEMENTARY CONFORMITY ASSESSMENT MODULE (MODULES C2, D, E OR F) FOR THE SAME PRODUCT?

Directive 2014/28/EU does not oblige the manufacturer to choose the same notified body that he had previously selected for the EU-type examination (module B) to carry out the subsequent conformity assessment (Module C2, D, E or F). Moreover, in paragraph 5.1.5. of the "Blue Guide" it is clearly stated that "the conformity assessment body involved under module B is not necessarily the same as the one involved in the module that is used together with module B".

4. WHICH NOTIFIED BODY IS RESPONSIBLE IN CASE OF A PRODUCT FOUND TO BE NOT IN CONFORMITY WITH THE DIRECTIVE AFTER HAVING BEEN PLACED ON THE MARKET: THE NOTIFIED BODY RESPONSIBLE FOR MODULE B OR THE NOTIFIED BODY RESPONSIBLE FOR THE MODULES C2, D, E OR F?

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 EU-type examination (Module B) 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 C2, 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 EU-type examination. However, this may also depend on the gravity or evidence of the mistake in a particular case (e.g. 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 III, Module B, point 8, second paragraph of the Directive according to which each notified body that carries out EU-type examination "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 such certificates and/or additions thereto which it has issued" or in Annex III, Module B, point 8, third paragraph of the Directive under which "the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto".

On the other hand, for example, in each of the modules C2, D, E or F the notified body must examine and verify – in the particular relevant way – whether the manufacturer has taken all measures ensuring the conformity of the manufactured explosives and whether these measures meet the requirements of Annex III of the Directive[1].

[1] In module C2 (point 3): 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 equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the explosive with the type described in the EU-type examination certificate and with the relevant requirements of this Directive. In module D (point 3.2., first subparagraph): The quality system shall ensure that the explosives are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them. In module E (point 3.2., first subparagraph): The quality system shall ensure compliance of the explosives with the type described in the EU-type examination certificate and with the applicable requirements of this Directive. In module F (point 3, first subparagraph): A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the explosives with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

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 control 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 C2, D, E or F (and whose identification number figures on the product together with the CE marking) that assumes responsibility[2].

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.

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 EU-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[3]. According to Annex III, point 8, second paragraph of the Directive relating to this module the notified body must communicate to the other notified bodies the relevant information concerning the EU-type examination certificates and additions issued and withdrawn.

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[2] In module C2 see point 3 third subparagraph, in module D point 5.1., in module E point 5.1. and in module F point 4.2. See also Annex part I. B (f) and (g) of Council Decision 93/465/EEC.

[3] The reference to the originally certified type relates to the case where earlier certified products do not meet the essential safety requirements anymore, because the latter have been updated (e.g. due to newly gained knowledge on safety issues).

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 unexpected 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 7, second subparagraph, each notified body must then give the other notified bodies the relevant information concerning the quality system approvals withdrawn.

In the case of module C2 the Directive foresees in point 3 of the text relating to this module examinations of products at random intervals, and tests on an adequate sample of the final product. It states that "where a sample does not conform to the acceptable quality level, the notified body shall take 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 ANNEX I OF DIRECTIVE 2014/28/EU?

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 (2014/28/EU) or the Pyrotechnics Directive (2013/29/EU).

Annex I of Directive 2014/28/EU lists a number of articles which are considered to be pyrotechnic articles or ammunition in order to exclude them from the scope of the Explosives Directive (2014/28/EU). Annex I of 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 2013/29/EU.

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 3(1) of Directive 2013/29/EU[4].

Propellant cartridges intended for cartridge operated fixing and marking tools have 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 (the references of which will be published in due course in the Official Journal of the EU) 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.

8. DISTINCTION BETWEEN CIVIL EXPLOSIVES AND MILITARY EXPLOSIVES IN THE CONTEXT OF INTRA-EU TRANSFERS

Text of the question:

In accordance with Article 1(2)(a), Directive 2014/28/EU 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?

Answer:

It should be first underlined that the exclusion in Article 1(2)(a) 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(2)(a) 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 potential 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. This is usually the case, when a written order can be linked to the explosives in question.

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.

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[4] The text was taken from meeting minutes of the Explosives WG of 12 October 2009.

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 candidates for exclusion from class 1 under Transport of Dangerous Goods Regulations (see e.g. section 2.2.1.1.8 in ADR[5]) 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.

However, a shock tube is an article containing explosives where the sound level during functioning can reach such values, that exclusion from class 1 under the legal framework of transport of dangerous goods is not accomplished.

Considering the construction of shock tubes and their relevance for safe blasting operations, shock tubes may be considered to 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 without doubt be subjected to the Directive's ESR (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 the Member State 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.

Some non-EU companies expressed concerns about the need to request different manufacturing site codes from different EU-countries for the same products from the same site, in cases where the same product is exported to several EU-countries. FEEM therefore proposed that an importer should be allowed to request one single code from the Member State where he is established, regardless of the country of import. However, the Commission notes that this proposal is difficult to reconcile with the wording and intention of the legislation. Accepting such proposal would generate a situation in which several different importers in different Member States could use the same overseas manufacturing site code, which could result in difficulties for competent authorities in tracing explosives imported from that non-EU manufacturing site and obtaining further information where necessary.

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[5] European Agreement Concerning the International Carriage of Dangerous Goods by Road, vol. 1, applicable as from 1 January 2017.

A manufacturing site code assigned to a non-EU company, is still linked somehow to the importer through which the products enter the EU. It is the importer who takes the responsibility of record keeping and who can be addressed as the starting point for tracing a lost explosive. This means the traceability of the imported explosives would be ensured only in cases where the non-EU manufacturer operates via a single EU importer. Therefore, FEEM's proposed approach with using a single manufacturing site code by a perhaps unknown variety of importers cannot be accepted.

To further reduce the administrative burden, 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, from the perspective of the traceability directive, 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 DIRECTIVE 2008/43/EC, AS AMENDED BY DIRECTIVE 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/EC 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/EC. 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/EU 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/EC 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/EC Article 4**	**Small items that can be partially marked – 2008/43/EC / 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/EC 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 an inner box, if present.	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 an inner box, if present.	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, where present.	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, where present.	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	Mark country ID letters, 3 digit site code and electronic readable ID on the booster and associated label on the case (outer box). No	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

Scenario – refer to diagrams below	Items big enough to fully mark – 2008/43/EC Article 4	Small items that can be partially marked – 2008/43/EC / 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/EC Annex Para 3
	wrapper or inner box where present.	need to mark wrapper or inner box, where present.	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/barcode). 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 or bags	Mark full unique identification on the drum or bag. 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 or bag and associated label on the case (box).	Not included.

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 of the associated label 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 2014/28/EU 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.

13. INTERPRETATION OF "USE FOR OWN PURPOSES" PURSUANT TO THE EXPLOSIVES DIRECTIVE

Question

On 24 November 2014, the Commission received from the competent authorities for explosives (hereinafter 'CAs') of BE, IE, SE and UK a request for clarification on the interpretation of Articles 5(1) and 5(2) of the new Explosives Directive. The purpose of the clarification request was to ensure that the new Explosives Directive would be correctly transposed into national legislation with regard to its scope.

In essence, BE, IE, SE and UK are asking the Commission to endorse two conclusions:

- First, that "use for own purposes" in Article 5(1) of the new Explosives Directive should be interpreted as referring only to

a) "blasting purposes by the manufacturer of those explosives;"

b) "providing a service such as blasting on the Union market; or"

c) "undertaking a similar commercial activity,"

while excluding

d) "using the explosives by manufacturers for research, trial, development, educational or experimental purposes;"

e) "using the explosives by manufacturers for the sole purpose of incorporation of the explosives into a formulation or article;"

f) "the disposal of defective products as part of manufacturing and production processes;" and

g) "extracting explosives from munitions or explosive articles where that explosive is disposed of by demolition or incineration and is not reused."

- Second, that the conformity assessment and CE-marking requirements provided for by Article 5(2) of the new Explosives Directive apply only to explosives subject to Article 5(1), i.e. those listed above under paragraph 5(a)-(c) above.

Analysis

1.1. Relevant provisions

The relevant provisions in the new Explosives Directive read as follows:

Article 5 (*Obligations of manufacturers*)

"1. When placing their explosives on the market or when using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annex III and have the relevant conformity assessment procedure referred to in Article 20 carried out.

Where compliance of an explosive with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking."

Manufacturer is defined in Article 2(9) of the new Explosives Directive as "*any natural or legal person who manufactures an explosive or has an explosive designed or manufactured, and markets that explosive under his name or trade mark or uses it for his own purposes*".

Use is not defined in the Directive.

1.2. Limitation of Article 5(1) to "blasting"

As indicated in paragraph 5(a)-(b) above, it is essentially suggested to limit the application of "use for own purposes" in Article 5(1) of the new Explosives Directive to blasting, either for the manufacturer' own purposes, or for the purpose of providing a blasting service. That would exclude use for R&D, trials, education or experiments. It would also exclude incorporation into a formulation or article, disposal during production, and extraction for disposal.

The new Explosives Directive contains no recital to explain why it covers products used by the manufacturer. There is also no trace of any debate on this issue in the Council and the Parliament. This apparent absence of justification or discussion – despite the facts that "use" is not commonly regulated in product harmonisation Directives, and that Directive 93/15/EC (hereinafter the 'old Explosives Directive') contained no provision on use – can be taken as an indication that "use for own purposes" in the new Explosives Directive was intended to cover situations which are *in practice* already assimilated with placing on the market at the time of application of the old Explosives Directive.

Therefore, it is relevant to consider the Q&A relating to the application of the old Explosives Directive published by Commission staff (Annex IV to this note). The first question (Section 2 of the Q&A) relates to cases where explosives are manufactured directly at the site of the end-users, referred to as 'on-site mixing'.

In its answer in the Q&A, the Commission staff "recommends" that the essential safety requirements be applied to *all* explosives mixed on-site, regardless whether or not they have been placed on the market. The difference between those two situations is then illustrated as follows:

a) Placing on the market: The explosives manufacturer merely pumps the explosive down the hole and initiates the blast, but the quarry or mining company is responsible for most aspects of the blasting operation.

b) Use by the manufacturer: The explosives manufacturer carries out and has full responsibility for the blasting operation, and the quarry or mining company merely buys 'rock on the floor'.

It can be assumed, that the intention of introducing "use for own purposes" in the new Explosives Directive was to cover the situation referred to above under b), hence converting the Commission staff "recommendation" into a legal obligation for Member States. In other words, the intention would have been to cover only explosives used by the manufacturer *for*

purposes relating directly to their blasting effect, like allowing the extraction of material from a mine or quarry.

On the other hand, there appears to have been no intention to extend the scope of EU regulation to explosives used by the manufacturer in a manner *that does not necessarily include blasting*, and *the purpose of which is in any event not directly relating to any blasting effect*. Such purposes would include incorporation into a formulation or article, disposal or extraction for disposal, R&D, trials, education and experiments.

This interpretation is supported by a number of additional arguments, some of which have been advanced by the MSs in question:

First, R&D and trials are necessary for product development. A new product cannot be subject to essential requirements before it has been fully developed.

Second, researchers in the context of, *e.g.*, fight against home-made explosive devices, may need to manufacture and test own explosives. Subjecting those test products to essential requirements would be meaningless and counterproductive.

Third, neither disposal, nor extraction for disposal, corresponds with the general understanding of the expression "use for own purposes".

Fourth, a manufacturer's incorporation of an explosive into a formulation will result either

a) in a product which in itself is not an explosive (e.g. a medicine), in which case no explosion will take place, and application of the essential requirements for explosives is hence meaningless, or

b) in a product which in itself is an explosive, in which case the essential requirements will in any event apply to that final product.

Finally, manufacturers are in any event required to hold a license pursuant to Article 16 of the new Explosives Directive. This requirement applies regardless whether the explosives are placed on the market or used for own purposes. In consequence, even if a manufacturer using his product for other purposes than the explosion it causes does not need to ensure compliance with essential requirements, he will still need to be a responsible operator in accordance with Article 17 of that Directive.

It can therefore be concluded that **"use for own purposes" in Article 5(1) of the new Explosives Directive only covers the manufacturer's use for own purposes relating directly to the blasting effect of the explosives**, and not the manufacturer's use for *other* purposes, such as R&D, trials, education, experiments, incorporation into a formulation or article, disposal or extraction for disposal.

1.3. Exclusion from Article 5(1) of non-commercial purposes

Regarding the proposed exclusion from Article 5(1) of non-commercial purposes (paragraph 5(c) above), it is noted that the definition of a manufacturer does not distinguish between commercial and non-commercial purposes, and that it encompasses natural persons.

However, the obligations of manufacturers are described under Chapter 2 of the Directive, which has the heading "Obligations of economic operators".

It can therefore be concluded that "use for own purposes" in **Article 5(1) of the new Explosives Directive only covers economic operators**, be they legal or natural persons, and hence excludes own use by natural persons for non-commercial purposes.

1.4. Limitation of conformity assessment and CE-marking requirements only to explosives subject to Article 5(1)

Finally, the CAs concerned have suggested an interpretation by which the conformity assessment and CE-marking requirements pursuant to Article 5(2) apply *only* to explosives subject to Article 5(1).

The competent Commission Unit agrees that the conformity assessment and CE-marking requirements pursuant to Article 5(2) of the new Explosives Directive cannot apply to explosives which are excluded from the essential requirements, *i.e.* to explosives excluded from Article 5(1).

It can therefore be concluded that **the conformity assessment and CE-marking requirements pursuant to Article 5(2) of the new Explosives Directive do *not* apply to explosives excluded from Article 5(1)**.

Conclusions

In the view of the Commission Unit responsible for explosives,

a) "use for own purposes" in Article 5(1) of Directive 2014/28/EU (hereinafter the 'new Explosives Directive') should be interpreted as only covering the manufacturer's use for own purposes relating directly to the blasting effect of the explosives, and not the manufacturer's use for other purposes such as R&D, trials, education, experiments, incorporation into a formulation or article, disposal or extraction for disposal;

b) "use for own purposes" in Article 5(1) of the new Explosives Directive should be interpreted as covering only economic operators, and hence excluding own use by natural persons for non-commercial purposes; and

c) the conformity assessment and CE-marking requirements pursuant to Article 5(2) of the new Explosives Directive should be interpreted as not applying to explosives excluded from Article 5(1).

14. DATE OF APPLICATION OF RULES ON EXPLOSIVES TRACEABILITY

Pursuant to Article 15(1) of Directive 2008/43/EC (hereinafter the "Explosives Traceability Directive"), Member States shall apply the Directive's provisions on data collection and record keeping (hereinafter the "traceability rules") as of 5 April 2015.

It has been suggested by certain competent authorities that the traceability rules are not fully applicable to explosives that were placed on the market before 5 April 2013 and are hence not duly marked in accordance with the Explosives Traceability Directive. Under this interpretation, Member States could still allow storage or use of such explosives without requiring traceability.

In DG GROW/D.2's reading of Articles 13 and 14 of the Explosives Traceability Directive, the traceability obligations appear to become applicable for all undertakings in the explosives sector, including licenced or authorised users, as of 5 April 2015. Furthermore, the traceability obligations appear to become applicable to all explosives as of 5 April 2015,

without any differentiation between explosives manufactured or imported before and after 5 April 2013 (when the unique identification marking became mandatory).

15. THE CASE WHEN A QUARRY OR MINE MIXES ITS OWN EXPLOSIVE ON SITE FOR BLASTING ON ITS OWN SITE: DOES IT FALL UNDER THE DEFINITION OF A MANUFACTURER USING AN EXPLOSIVE FOR OWN PURPOSES?

One Member State raised the issue of whether a quarry or mine mixing their own ammonium nitrate and fuel oil to produce on site ANFO for blasting at its own quarry or mine, would be required to have its mix conformity assessed. The Member State suggested that this activity should not fall under the scope of the definition of "use for own purposes", as this case does not involve a placing on the market nor the provision of a professional service by the company manufacturing the explosive on site.

Basically, the Member State suggested making a distinction between

1. on the one hand explosives mixed on-site by a manufacturer in the quarry or mine of *another* economic operator, and

2. on the other hand explosives mixed on-site by a manufacturer in *his or her own* quarry or mine.

and considering that conformity pursuant to article 5 of the directive is required only in scenario 1.

In the view of GROW/D.2, this is a rather counterintuitive reading of the concept of use "for their own purposes". If scenario 1) qualifies as use for own purposes, scenario 2 appears to do so *a fortiori*.

The justification of the distinction is based on the argument that scenario 2 involves neither provision of a service, nor any sale of an explosive. In GROW/D.2's view, there is no justification for limiting that argument to on-site mixing, or to ANFO. The consequence would be that any explosives manufactured by users without any intention to provide a service to someone else would be exempted from the scope of the directive. In the opinion of GROW/D.2, that would deprive the provisions on own use of large parts of their purpose. Therefore, the proposed interpretation cannot be supported.

16. HOW SHALL THE WORDING "PRODUCT, TYPE, BATCH OR SERIAL NUMBER" IN THE EXAMPLE FOR THE DECLARATION OF CONFORMITY (SEE ANNEX IV OF THE DIRECTIVE 2014/28/EU) BE INTERPRETED IN THE CASE OF EXPLOSIVES?

The example for the declaration of conformity as given in Annex IV of the Directive has occasionally given rise to discussion, specifically how item no. 1 reading "*No ... (product, type, batch or serial number)*" and item no. 4 reading "*Object of the declaration (identification of product allowing traceability)*" shall be understood, also in view of the traceability requirements for economic operators set out in Article 15.

Interpretation does not seem to be straight forward, since "product number" and "batch number" would normally be used in different contexts and for a differing range of explosives: while the product number would normally refer to the product as a type and in a general manner, for example in the meaning of an article number of the manufacturer, the batch number on the other hand, would refer to a much more limited range of products, manufactured during a single day or from a defined amount of raw materials.

The contents of the declaration of conformity must be seen in relation to its function, which is that “the manufacturer assumes responsibility for the compliance of the product” as it is stated in the Blue Guide in section 4.4 and in the Directive in Article 21(4). The manufacturer therefore assumes the responsibility for **all** products, which are identified by the information given in the declaration of conformity. For example, in the case where the explosive presents a risk, the manufacturer is obliged to either bring **all** those explosives into conformity, or to withdraw/recall them, whichever is appropriate.

The standard EN ISO/IEC 17050-1 provides general criteria for the declaration of conformity. The standard clearly states, that for a series production of identical products the individual serial numbers of every single product are not meant here, but that the name of the product or a “model number” shall be given.

The wording under item no 4 using the term “traceability” must be understood here as the traceability in production, which is basically any relevant information supplementary to the identification number of a product[6].

In conclusion, it is up to the manufacturer to decide how best to identify that a given product is covered by a certain declaration through reference to a unique product, a type, a batch or a serial of products.

[6] 2016/C 272/01 Commission Notice – The "Blue Guide" on the implementation of EU products rules 2016, p. 58. According to the Blue Guide, the identification number does not need to be unique to each product. It could refer to a product, batch, type or serial number (this is left to the discretion of the manufacturer).