

The European Regulation Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals

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Abstract: The European regulation n°1907/2006 of 18 December 2006 – commonly referred to as “REACH” – states the mandatory registration and evaluation of chemical substances marketed, manufactured or imported in quantities of more than one ton per year on the European market. This obligation not only applies to chemical substances but also to articles which contain chemical substances when they must be considered as associations of articles and chemical substances according to REACH, meaning that their chemical composition determines their function to a greater degree than or the same degree as the special shape, surface or design they are given during production.

In its “Guidance on requirements for substances in articles” (RIP 3.8), the European Chemical Agency (ECHA) mentions fireworks as examples of such associations of articles and chemical substances. The professional experts of CEN/TC 212 who developed the European standards for fireworks under a mandate of the European Commission disagree firmly with this statement. As a consequence they decided to react with their own arguments.

The present paper gives an overview of the arguments of the professional experts of CEN/TC 212, and recalls their previous attempt to promote them at the level of the European Commission and the opening they were given by return that might lead to possible specific action of the European Commission “*including, in particular in the Guidance on requirements for substances in articles.*” In that perspective and following the same approach that was adopted for ammunition by the European Defence Agency, they decided to prepare a professional guidance document in which they would express clearly their position in contradiction with ECHA’s position. Such document is intended to be presented to the European Commission in order to obtain its support and, consequently, a modification of ECHA’s position.

A task group was created by CEN/TC 212 to do so before the end of 2015.

Introduction

The European regulation n°1907/2006 of 18 December 2006 – commonly referred to as “REACH” – states the mandatory registration and evaluation of chemical substances marketed, manufactured or imported in quantities of more than one tonne per year in the European Economic Area, and the obtaining of special authorizations for using substances of very high concern. It maintains the pre-existing system of restriction on use.

Although REACH is mostly intended for substances and mixtures of substances, it also extends to articles which contain chemical substances and

mixtures of substances when their chemical composition determines their function to a greater degree than or the same degree as the special shape, surface or design they are given during production. In that case, according to REACH, these articles are called “associations of article and substance”. In the opposite case, they are simply called “articles” and are not submitted to the requirements of REACH.

All manufacturers and importers must identify and manage the risks of the substances and/or associations of article and substance they market. For substances produced or imported in quantities over 1 tonne per year and per company, they must

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demonstrate the manner they do so in a registration dossier which must be submitted to the European Chemicals Agency (ECHA). ECHA checks that the registration dossier complies with the REACH regulation and must approve the manufacturers' test proposals and ensure that they are limited to what is strictly necessary and sufficient.

Such a process is quite complex and expensive. So, in the case of articles which contain chemical substances and mixtures of substances, it is of importance to check whether these articles are "articles" or "associations of article and substance". REACH gives some help to manufacturers and importers by considering that the function of a product is "determined by what its producer/supplier wants it to be used for and what the person acquiring it expects it to do". As a consequence, the first step is always to use such understanding of the function of an article to determine it. Such determination must be thoroughly carried out and clearly justified.

In its "Guidance on requirements for substances in articles" (RIP 3.8), ECHA provides complementary tools to complete such determination process and, for "borderline cases" – meaning cases for which the function of the article cannot reliably lead to a decision on whether the article is an "article" or an "association of article and substance" – flow charts and examples of application.

REACH and Fireworks

Among the examples given in the last version of its "Guidance on requirements for substances in articles" (RIP 3.8), ECHA mentions fireworks, considers they are articles that "explode and make colours" and, from such understanding of their function, concludes that they are associations of articles and substances.

A group of experts who developed European harmonized standards for fireworks under a mandate of the European Commission firmly expressed their disagreement with such a conclusion and then, at its plenary meeting of July 2nd, 2014 the technical committee of CEN (the European Standardization Committee) – CEN/TC 212 – in charge of the development of those standards decided to activate a task group to prepare a road map to promote its position regarding fireworks as articles according to REACH, instead of associations of articles and substances.

As far as the function of a product is "determined by what its producer/supplier wants it to be used for and what the person acquiring it expects it to do", the function of a firework is undeniably to generate an artistic visual and/or aural effect in the

air, on the ground, on the surface of water or underneath it, and during a given time.

The artistic visual effects are not only based on a varied set of colours, but also on the various luminous shapes which are traced either (1) by burning objects ("stars") and incandescent slag particles ejected from the fireworks or (2) by the flames and/or showers of sparks and hot gases projected from the fireworks. In the first case, combustion is initiated inside the firework casing and proceeds outside; in the second case, combustion remains strictly internal.

If colours are undoubtedly important, it is mainly the variety of luminous shapes and modulated sounds which makes fireworks shows attractive and answers the creative needs of firers. A fireworks show which was solely based on the use of coloured shells would be particularly monotonous, even with a high intensity of firing. Then, one must consider the fact that firers will first choose the fireworks for the shape and extension of the visual effects which will be traced in space and time in the air, above the ground or the surface of water.

Colours depends on the chemical formula of the pyrotechnic composition, but the shape and extension of the visual effects result from the specific design of the firework and/or the shape and surface of the pyrotechnic units (e.g. stars) contained in the firework.

Firstly, the shape (spherical, cylindrical, tubular, etc.) stars are given by their manufacturing process (rolling, pressing, casting, extrusion, etc.) allows these unitary effects to burn regularly with a stable colour and/or constant tracing tail. In the same manner, "crossette" effects are obtained by stars which are given a specific shape so that they burn and break abruptly after a few seconds into fragments which trace a cross-like figure in the air.

Without being compacted to these typical shapes, pyrotechnic compositions would exhibit a violent and erratic burning and even deflagrate in a great number of cases. Colours would quickly tend to turn white due to the high temperature of the flame which would inevitably be a consequence of the strong increase of the burning rate.

Secondly, it is the manner in which stars are arranged, clustered and/or disassociated inside the shells which leads to such varied shapes in the air as a dahlia, a peony, a ring, a heart, a cross, etc... or a combination of those.

Similarly, as concerns aural effects, a maroon only gives a report when its composition is kept within its casing during a sufficiently long time after ignition to reach deflagration and if its ignition charge is sufficiently powerful. A cracker only bangs when its composition is tightly confined by its

cardboard casing. If not, the composition of maroons and crackers will simply make a puff and a part of it will be dispersed without being ignited.

The design is even more important for pyrotechnic whistles where the burning composition generates no sound if it is not charged into a tube in such a specific manner that it is stimulated as an organ pipe. Similar dependence on design is observed for other aural effects like humming or crackling.

More generally, colours and sounds can be generated by means of a large variety of pyrotechnic compositions the chemical formulas of which may be very different. But none of them can burn in such a way that it gives its visual or aural effect if it is not used with an appropriate design of product.

It is in fact this appropriate design which makes a shell spread its stars in multiple trajectories to trace a flower, a ring, a rainfall, etc. in the air whatever the colour and then the chemical formula of the pyrotechnic composition, and which differentiates it from a fountain, a mine, a Bengal flame, a roman candle...

It is only its design which makes a fountain throw a shower of sparks as a water fountain or waterfall does, which a shell will never do. And happily a fountain does not explode when it is correctly manufactured!

It is again because of its design a roman candle generates a sequence of varied and possibly different effects or a mine throws a powerful narrow or fan-type jet of burning stars, etc...

To conclude, it is mainly the design of fireworks which assures the variety of effects and makes possible the high number of their artistic space-time combinations which characterize fireworks shows.

All the above arguments lead the experts of CEN/TC 212 to conclude that, **from the point of view of REACH, fireworks are – in their large majority – articles and not substances in special containers. This statement means they are given a specific shape, surface or design which determines their function to a greater degree than does their chemical composition.**

Generic types according to the European harmonized standards for fireworks

When they developed the European Standards for Consumer and Professional Fireworks, the experts of Working Groups 1 and 2 of CEN/TC 212 had to differentiate fireworks in *“sets of articles with a*

common, very general, design feature and/or with a common characteristic effect” to characterize their impact on public and users safety. They named these sets by the term *“generic types”* and deducted from the general essential safety requirements of the European Directives 2007/23/EC and 2013/29/EU specific requirements for such generic types.

All the differences between generic types are based on design and performance characteristics, never on chemical formulations and peculiarities.

As authorized by the Directives 2007/23/EC and 2013/29/EU, they also considered the interest of grouping *“pyrotechnic articles that are similar in design, function or behaviour”* in product families which could be submitted together to type-examination and testing. Colours have only been considered as variants within a family, but not as a distinctive parameter influencing the safety approach required by the above-mentioned Directives.

All generic types of fireworks have then very different respective designs. These designs are unique for a given generic type; on the contrary, a given colour can be generated by various pyrotechnic compositions and their corresponding chemical formulas may differ significantly. This observation reinforces the conclusion according to which the design of fireworks is generally more important than their chemical composition.

Previous attempt to prove fireworks are articles according to REACH

In 2010, the European Commission started a public consultation regarding the review of the scope of REACH according to its Article 138, No. 6:

“By 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal.”

In the same year, a group of experts of CEN/TC 212 WG2 examined the possible overlaps between REACH and the European Directive 2007/23/EC and prepared a document to bring to light such overlaps. This document was accompanied by an annex which demonstrated thoroughly that most pyrotechnic articles – and, among them, fireworks – were articles according to REACH and should not be considered as packaged substances.

The document and its annex were sent together on November 30th, 2010 by CEN/TC 212 to the Head of

Unit "Chemicals and nanomaterials" of DG Environment D3, the Head of Unit "Chemicals – REACH" of DG Enterprise and Industry G1, the Head of Unit "Chemicals - Classification & Labelling, Specific Products, Competitiveness" of DG Enterprise and Industry G2 and the Executive Director of the European Chemicals Agency. At the same time, they were posted on the ReachScope web link that was opened to gather all the documents contributing to the review of the scope of REACH.

The answer of the European Commission came on March 22nd, 2013 with the following conclusions:

"The Commission has concluded that REACH functions well and delivers on all objectives that at present can be assessed.

Some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission will not propose any changes to the enacting terms of REACH.

There is a reference to pyrotechnic articles in the accompanying Commission Staff Working Document:

Pyrotechnic articles: The Commission services concluded that certain pyrotechnic articles, considered as mixtures under REACH, might be subject to a double regulatory burden, at least as far as communication of the information in the supply chain is concerned. In such a case both obligations under REACH and under the Pyrotechnic Articles Directive⁵ would apply at the same time. According to the current ECHA guidance on requirements for substances in articles, a majority of pyrotechnic articles should be regarded as packaged mixtures, whereas they are regarded as articles by the technical experts in the responsible CEN Technical Committee (TC 112) and also by some competent authorities of the Member States. The Commission services will investigate whether this issue requires specific action, including, in particular in the Guidance on requirements for substances in articles."

In parallel, ECHA only acknowledged receipt of the document and its annex, but never replied to it nor changed their guidance on requirements for substances in articles.

The European Commission has not yet started the investigation that is mentioned in the last sentence of its conclusions but, in a recent letter to the European Fireworks Association (EUFIAS), it has declared its intention to do so before the end of 2015 and to organize a meeting between some professional experts and ECHA in its presence. To prepare this meeting, it has asked for more information about the present situation of

fireworks versus REACH in the various Members States of the European Union and for a more detailed presentation of the arguments developed by the professional experts.

The experience of military ammunition

REACH is based on the principle that the downstream manufacturers, importers and users have an obligation to manufacture, to market and to use substances whose hazardous effects for human health or the environment are correctly controlled. According to REACH itself, the evaluation of these hazardous effects is therefore now the responsibility of the manufacturers and importers concerned (and not the States as under the previous system).

REACH introduces an unprecedented change in the way information is exchanged on the substances throughout the supply chain. Each actor must now reinforce the traceability of the substances he uses and ensure that its uses fall within the exposure scenarios taken into account by the suppliers.

It is then the responsibility of the manufacturers or importers to determine whether the public and the users of their products are exposed to the hazardous effects of the substances that are included in the products they place on the European market.

Having understood this main transfer of responsibilities from the States to the economic actors and to ensure that REACH is uniformly applied in the ammunition field (including rockets and missiles), the French defence manufacturers decided to write a **professional guide** in which they would give their evaluation of the possible chemical hazards linked to the substances included inside their products and show their common agreement on the status of the different types of ammunition regarding REACH.

Such a professional guide would be the reference document for the whole of the ammunition profession acting in a coherent and cohesive manner with respect to all third party requests. It might, if necessary, be presented as a supporting document during controls by the French Administration, as well as to insurance companies and customers who would request it.

A group of experts coming from the French defence industry started discussions in October 2008, in the presence of representatives of the French Ministry of Defence, and published their guide in November 2009. A second edition appeared necessary to include new types of ammunition and follow some significant modifications of the ECHA "Guidance on

requirements for substances in articles" (RIP 3.8); it was published in April 2013.

The professional guide starts from the function of every type of ammunition and shows that the function of most of them is determined by their specific shape, surface or design to a greater degree than does their chemical composition. According to REACH, such products are articles and not associations of article and substance.

Some few articles that intentionally reject chemical substances without transformation were identified and treated as borderline cases according to the flowcharts of the ECHA "Guidance on requirements for substances in articles". Indeed, such articles were considered as associations of articles and substances according to REACH. Doing so, the professional guide of the French Defence Industries shows that their conclusions were not based on preconceived opinions, but fair and thorough analysis of the function of every type of ammunition as expected by the Armies acquiring it.

The French Ministry of Defence has accepted this professional guide and promoted it within the European Defence Agency (EDA). Its translation in English was circulated to the Defence Industries and Ministries of the other European countries and they decided at a very large majority (and unanimously by the community of industrialists) to make it their reference guide for ammunition, whatever ECHA may think of it. EDA's position was eventually supported by the European Commission.

Why not follow the same approach for fireworks?

Work proposal

The Task Group "REACH and fireworks" which CEN/TC 212 activated on July 2nd, 2014, and EUFIAS have decided to combine their efforts to **write a European professional guide for fireworks** by analogy with the above example of military ammunition.

Such a professional guide should be supported by all national and European associations of manufacturers and importers as well as notified bodies. These associations and notified bodies are then invited to participate in the writing of that guide either directly during specific meetings or by reviewing its successive drafts, making comments, modifications and additions (where appropriate).

The generic types that are defined by the European harmonized standards for consumer and professional fireworks will serve as a basis for the technical analysis of functions versus shape, volume, design and chemical composition. It is foreseeable with a high confidence level that such analysis will show that the functions of most generic

types are more determined by the three first characteristics than the fourth one.

This guide will also include specific application of the flow charts of the ECHA "Guidance on requirements for substances in articles" to each generic type of fireworks, in order to confirm the conclusion that is suggested by its function regarding its status as "article" or "association of article and substance" and then to prevent any critic for not having considered fireworks as "borderline cases".

After completion, this professional guide will be sent to the European Commission so that it decides to give mandate to CEN/TC 212 and ECHA for "specific action, including, in particular in the Guidance on requirements for substances in articles". The Task Group "REACH and fireworks" of CEN/TC 212 and EUFIAS already informed the European Commission that such a professional guide will be part of the documents which will be submitted to discussion at the meeting to be planned by the European Commission by the end of 2015

A first meeting will be planned in Paris at the beginning of September 2015 to review a first draft of the professional guide for fireworks. Any European who is interested in taking part in this meeting is invited to send his/her application to the convener of the Task Group at the following e-mail address pthebault@pyroconsultant.com

Notes and references

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