

Chemical substances in goods: ECHA Guidance Document on REACH

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On 26 May 2008 the European Chemical Agency (ECHA) adopted its Technical Guidance Document to the REACH rules relating to chemical substances in goods (articles). The Document focuses on communications and registration requirements placed on producers and importers of articles, and clarifies several key issues, including key definitions. This article briefly explains the REACH rules, analyses the main aspects of the ECHA Guidance Document, illustrates the risk of different interpretations across member states and gives practical advice on how to avoid compliance pitfalls and supply-chain failures.

Cristiana Spontoni and Chiara Galiffa, Squire, Sanders & Dempsey LLP

Millions of toys coated in toxic lead paint made in the Republic of China were recently recalled. The events that followed - including the suicide of a Chinese toys manufacturer - demonstrate the importance of complying with the rules on chemicals safety, not only for the chemicals industry but also for producers, importers and distributors of goods.

The REACH Regulation (REACH), which came into force on 1 June 2008, regulates chemical substances in goods ("articles") in the European Union (EU) (*Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, OJ 2006, L 396, pp. 1-849*). Under REACH, producers and importers of articles must comply with communication and registration requirements in relation to the chemicals contained in their articles (subject to certain conditions), and with any approved restrictions on the use of specific chemicals.

On 26 May 2008 the newly established European Chemical Agency (ECHA) published a Guidance Document to the REACH provisions on substances in articles (*see ECHA "Guidance on requirements for substances in articles", at http://reach.jrc.it/docs/guidance_document/articles_en.pdf*). The Guidance Document clarifies several key issues, including what or who qualifies as an article, manufacturer or importer under REACH.

Against this backdrop, this article:

- Explains the REACH rules on articles.
- Analyses the main aspects of the ECHA Guidance Document.
- Illustrates the risk of different interpretations across member states.
- Gives practical advice on how to avoid compliance pitfalls and supply-chain failures (*see checklist, "Ensuring compliance"*).

Reach rules on articles

Subject to certain conditions, producers and importers of articles must comply with four requirements:

- Registration of substances in articles.
- Notification to ECHA of substances in articles.
- Communication of information down the supply chain.
- Community-wide restrictions on the use of certain substances.

Registration

From 1 June 2008, an EU producer or importer must register any substance intended to be released from an article during “normal or reasonably foreseeable conditions of use” (*see below, “The ECHA Guidance Document, Definition of “intended release” and “normal or reasonably foreseeable conditions of use”*) if that substance is present in the article in quantities exceeding 1 tonne per producer or importer per year (*Article 7(1) REACH*).

Notification

If an article contains a substance included in a list of substances potentially subject to pre-market authorisation (the “candidate list”) (*see below*) the EU producer or importer of that article must notify the substance to ECHA if both the following conditions are met (*Article 7(2) REACH*):

- The substance is present in the article in quantities exceeding 1 tonne per producer or importer per year.
- The substance is present in the article above a concentration limit of 0.1% weight by weight (w/w).

It is possible to obtain an exemption from notification if either:

- The producer or importer can exclude human and environmental exposure to the substance during normal or foreseeable conditions of use of the article, including its disposal.
- The substance has already been registered for that use in accordance with Article 7(6) REACH.

All substances that meet the “Substances of Very High Concern” (SVHC) criteria must be authorised. These include substances which are:

- Classified under Directive 67/548/EEC (*Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 1967, 196, p. 1-98*) as carcinogenic, mutagenic or toxic for

reproduction (CMRs, categories 1 and 2).

- Persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).
- Scientifically proven to have a similar effect as those above (for example, endocrine disrupters).

ECHA in co-operation with a Committee of Member States' Competent Authorities must identify all substances potentially meeting the SVHC criteria by preparing a dossier under Annex XV REACH, and include them in a candidate list.

On 1 July 2008, ECHA published on its website a provisional list of 16 substances that may be included in the candidate list (see http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp). Interested stakeholders were given 45 days to submit comments, scientific observations or further information. A final decision on the first list is expected by the end of 2008. However, the candidate list will be constantly updated, therefore producers and importers of articles should carefully monitor all future inclusions. Unfortunately, the frequency of any future updates is still unclear, and will depend on the workload of member state authorities and the ECHA.

The candidate list mechanism has been strongly criticised by industry as likely to create a black list. It is feared that its effect in practice will be to scare the market away from the listed substances, irrespective of whether they will be eventually subject to authorisation.

Communication down the supply chain

If an article contains an SVHC substance in a concentration exceeding 0.1% w/w, the producer or importer must provide the article's recipients automatically, and consumers on request, with the information needed to ensure a safe use of the article (*Article 33 REACH*). Unlike the notification requirement, the obligation to communicate information down the supply chain applies regardless of the tonnage of the substance, even if the substance is present in the article in an amount below 1 tonne per producer or importer per year. The interpretation of the 0.1% w/w ratio has been the object of extensive debate (see below, "*Obligation to notify*").

Restrictions

The use of certain substances in articles may be restricted or banned from 1 June 2009 under the restriction procedure set out in Annex XVII REACH.

The ECHA Guidance Document

The ECHA Guidance Document clarifies some of the most important issues relating to the application of the REACH rules on substances in articles, including:

- Key definitions, such as the meaning of "article", and of "intended release" and "normal and reasonably foreseeable conditions of use".

- The registration procedure.
- Notification and communication requirements.

Definition of article

An article is defined as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition” (*Article 3(3) REACH*).

The first step in assessing whether an object is an article under REACH is to identify its function. Reference can be made to the manufacturer’s or supplier’s intention, as shown by the label text, any advertisements or user manuals, and the expectations of the person buying the article.

The next step is to identify the relevance of the object’s physical and chemical characteristics to its function. If the object’s shape, surface and design are more important for its function than its chemical composition, the object qualifies as an article. The definition of an article applies to the article “as produced or imported”. It is therefore irrelevant whether the article is subsequently assembled into a complex article. This means that, for example, both electronic chips and laptops may qualify as articles under REACH if produced or imported as such.

There are many borderline cases where the assessment exercise is likely to become fairly complicated. For example, suppliers and importers may face difficulties in establishing when chemical substances or preparations become articles during the processing of raw materials.

Besides looking at the function of the processed material, there are certain additional criteria which may help identifying when a substance or preparation becomes an article (transition point):

- If the substance already has certain functions that are independent of its further processing, this may be an indication that the transition point has already been reached.
- If the substance or preparation is sold or bought because of its shape, surface or design, it may already qualify as an article.

It may be helpful to analyse the various processing steps individually, to determine the point where the function of the material becomes more influenced by the article’s shape, surface or design than by its chemical composition.

Appendix 3 of the Guidance Document gives some practical examples in relation to metal, textile and paper processing:

- In the case of the processing of aluminium, the transition point is identified in between rolling ingots and sheets, extrusion ingots and extrusion profiles and aluminum alloy and alloy cast pieces.

- Man-made fibers can be considered articles.
- Dewatered paper, even if it does not yet have a specific shape, surface or design, can be considered an article.

There can also be uncertainty as to whether an object is an article or simply a container for a substance or preparation, for example in the case of a printer cartridge or a thermometer. The Guidance Document explains that, if the substance or preparation is removed or separated from the object or used independently from it, and the object is still able to perform its function, it is likely to qualify as a container of a substance rather than as an article incorporating such substance. Therefore, paint spray cans, printer cartridges and firecrackers are containers of substances, while thermometers or batteries qualify as articles.

Definition of “intended release” and “normal or reasonably foreseeable conditions of use”

One of the requirements for the application of the registration duty under Article 7(1) REACH is that “the substance [in the article] is intended to be released under normal or reasonably foreseeable conditions of use” (see above, “REACH rules on articles, Registration”). The Guidance Document specifies that “intended release” includes any release that is deliberately planned and has a special function for the article. By contrast, “not intended” are releases which:

- Occur during the removal of impurities from a finished or semi-finished article.
- Are an unavoidable side-effect of the functioning of the article.
- Are a consequence of undue use or accident (for example, a thermometer that drops and breaks).

Again, many borderline cases can arise in practice, such as that of adhesive tape. Here, the Guidance Document appears to have taken into consideration industry’s concerns. Only adhesive tapes that deliver substances onto a surface (for example thermally activated tapes or bonding films) have an “intended release”, while other tapes that do not deliver substances onto a surface do not.

The Guidance Document describes “normal conditions of use” as the conditions associated with the intended function of an article. These are normally documented in user manuals or instructions for use. The use of an article in a situation or manner that its supplier clearly advised against in writing cannot be interpreted as normal conditions of use.

Finally, “reasonably foreseeable conditions of use” include conditions of use that are not originally intended by the article producer or importer, but which can be anticipated as likely to occur, because of the form, shape or function of the article, for example highly probable accidents or other likely consequences of intensive use. Again, clear misuse and situations where the article producer or importer has excluded a specific use cannot be defined as reasonably foreseeable conditions.

Registration procedure

The Guidance Document includes advice for producers and importers on whether it is necessary to register chemicals in an article. It also includes formulas to calculate the maximum amount of articles that can be placed on the market without triggering the registration requirement, and to calculate the total amount of a substance contained in the articles.

Once a producer or importer concludes that the threshold volumes are exceeded, it must proceed to the identification of the substances on the basis of the information obtained by the suppliers.

Typically, the article producer or importer would need to submit dossiers similar to those submitted by producers and importers of substances. Further guidance on how to prepare a registration dossier can be found in the ECHA's Guidance Document to registration (see http://reach.jrc.it/docs/guidance_document/registration_en.htm).

Obligation to notify

An article supplier must notify and inform downstream users that its articles contain SVHC substances in a 0.1 w/w concentration.

The concentration ratio applies to the article "as produced or imported", and not to the homogeneous materials or parts of the article. This interpretation attracted criticism from several member states, which strongly opposed it while the Guidance Document was being drafted, and delayed the publication of the final version. Austria, Belgium, Denmark, France, Germany and Sweden expressed the view that the concentration ratio should not apply to a complex article as a whole, but to the individual articles, parts or materials which form a complex article. These member states argued that the ECHA's interpretation of the concentration ratio requirement would lead to diminished protection of human health and the environment, and to arbitrary discrimination. The dissenting positions are likely to result in significantly divergent enforcement patterns across the EU (see *below*).

As regards the information obligations, the Guidance Document clarifies that information must include the name of the SVHC in the article and any details necessary to guarantee safe use. The type of information to be supplied should be determined on the basis of how the article will be used and any potential risks connected with its intended use. Also, when supplying information, suppliers should consider the service life of the article, its disposal and any specific storage or transport conditions.

Different interpretations

The provisions of the REACH regulation are directly applicable in all 27 EU member states, and in general do not need national implementing provisions, although some national rules are necessary to regulate certain aspects, such as the regime of sanctions in the event of infringements. National rules cannot deviate from the REACH provisions, as regulations are the strongest legal instruments for the achievement of the EU single market.

However, it is likely that some of the REACH rules will not be applied uniformly and consistently in all

member states, because they lend themselves to different interpretations. Although the Commission guidance documents are designed to provide authoritative clarification, they are non-binding. Only the European Court of Justice (ECJ) has the final word on the interpretation of EU law. Since the ECJ has not yet ruled on the interpretation of a REACH provision, the risk of different interpretations continues, particularly in the early stages of application.

A good example of an area in which national interpretations may differ is the interpretation of the 0.1 w/w rule relating to substances in articles. Several member states have officially expressed their disagreement with the interpretation adopted in the Guidance Document (*see above, "Obligation to notify"*). It is possible that an ECJ judgment will be needed to achieve legal certainty in this area.

It is hoped that the European Commission, in its role of guardian of the EU Treaties, will monitor any divergence in national practices. Divergence would undermine the purpose of the REACH Regulation: that of ensuring a predictable set of rules that apply across the EU consistently and without discrimination.

Cristiana Spontoni is a European partner and Chiara Galiffa is an associate in the Brussels office of Squire, Sanders & Dempsey LLP.

Checklist: Ensuring compliance

It is essential for producers, importers and distributors of goods to evaluate and understand all the requirements that apply to them and their supply chain. In summary, immediate action should include the following:

- Maximise communication with your chemicals suppliers to ensure full understanding of the identity, classification and properties of the chemicals contained in your articles.
- Assess the information you provide to your customers. For example, review and revise your labels, instruction manuals, and other documents supplied with your articles.
- Monitor closely the "candidate list" inclusions.
- Assess the potential risks that could result from exposure to chemicals contained in your articles when used, transported, stored or disposed.
- Be aware of the potential for differing interpretations of the new rules from one EU country to another.

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