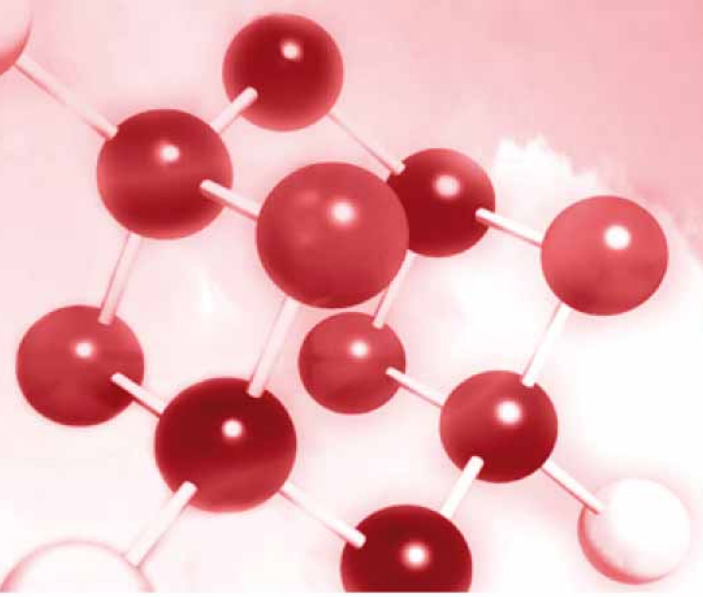

ECHA
http://echa.europa.eu

Guidance *Fact Sheet*

Ref.: ECHA-2011-GF-01-EN
Date: 06/06/2011
Language: English

Requirements for substances in articles

The European Chemicals Agency (ECHA) has issued a series of Fact Sheets which provide a structured overview of each REACH guidance document published by the Agency. These documents are available in the following 22 languages:

Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish

A Guidance Fact Sheet provides a short summary of the key aspects of the respective REACH Guidance Document including bibliographic information and other references.

If you have questions or comments in relation to this Fact Sheet please send them by e-mail to info@echa.europa.eu quoting the Fact Sheet reference, issue date and language version, shown above.

WHO SHOULD READ THE GUIDANCE DOCUMENT?

The Guidance on requirements for substances in articles is intended primarily for companies producing, importing and/or supplying articles within the European Economic Area (EEA), as well as for non-EEA companies producing and exporting articles to the EEA who have appointed an Only Representative to carry out the duties of their European customers.

WHAT IS THIS GUIDANCE ABOUT?

The Guidance document explains and illustrates the provisions of Regulation (EC) No 1907/2006 (REACH Regulation) that apply to substances in articles. It aims to assist companies in

- determining their role(s) in the supply chain, and particularly whether article importers and suppliers also have unexpectedly the role of importers and suppliers of substances; and
- deciding whether they consequently have to fulfil registration, notification and/or communication requirements related to substances in their articles.

In the REACH Regulation, an article means "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".

Suppliers of articles have lighter duties under the REACH Regulation compared to the manufacturers, importers and downstream users of substances. A correct and consistent decision as to **what is an article** under the REACH Regulation is therefore a key issue in the Guidance. Determining the function of an object, and to which extent this is determined by its chemical composition or its shape, surface or design are the bases for this decision. This decision can be difficult in certain cases, for example when dealing with semi-finished products or substances in special containers or on special carrier materials. The indicative questions given in the Guidance help to assess the article status of these particular products.

Another key question, to determine whether registration is required, is to what extent substances in articles **can be released** during service life, and whether or not this **release is intended**. If an article has an accessory function, which is achieved through the release of substances or mixtures then the release is to be regarded as intended. For these substances, registration is required if the total amount of the substance present in such articles exceeds 1 tonne per year per producer or importer.

In certain cases ECHA may decide that article producers or importers must submit a registration for any substance contained in an article if the amount of the substance exceeds 1 tonne per year. Such a decision is to be based on the suspicion that the substance is released from the article resulting in risks to human health or the environment.

The guidance also deals with the special case of substances of very high concern[1] (SVHCs). For SVHCs that are on the Candidate List and present in articles, notification to the Agency may be required if the following conditions are met:

- the substance is present in articles produced and/or imported above a concentration of 0.1% (w/w), and
- the total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per actor per year.

The threshold of 0.1% applies to the article as produced or imported. In practice, however, companies may already be collecting information not only on the whole article but also on parts thereof. Companies may, on a voluntary basis, prepare their notification to ECHA on this basis.
A notification of an SVHC in articles must be made to the Agency at the latest 6 months after it has been included in the Candidate List. This obligation applies starting from 1 June 2011, when substances included in the Candidate List by 1 December 2010 should be notified.

For SVHCs that are on the Candidate List and present in articles above a concentration of 0.1% (w/w), information requirements apply:

- the recipient of such an article must be informed of the presence of the substance in the article
- and provided with enough information to allow safe handling if relevant,

[1] Identification of substances meeting the criteria referred to in Article 57 and establishing a Candidate List of Substances of Very High Concern for Authorization (= Candidate List) takes place in line with the procedure as described in Article 59.

This obligation applies even in cases, where the total quantity of substance in the produced / imported articles is below 1 tonne per year. Such information should consider the entire life cycle of the article. The same information requirements exist also in cases of consumer requests in which case this information should be provided, free of charge, within 45 days of receipt of the request.

Information on substances on the Candidate List contained in articles is to be forwarded to the recipients of an article directly after a substance has been included in that list. The Candidate List is available on the ECHA website and will normally be updated twice a year (in January and June) when substances have been identified as meeting the criteria to be considered as SVHC.

Further aspects addressed in the Guidance on requirements for substances in articles are:

- Status of packaging under the provisions of the REACH Regulation
- Possible exemptions from obligations related to substances in articles
- Chemical analysis as an option to identify and quantify substances in articles

WHAT IS THE STRUCTURE OF THE GUIDANCE DOCUMENT?

The first chapter explains for which actors in the supply chain the Guidance document can be of relevance and what they can expect from reading it. It also clarifies which related topics are not covered by the Guidance document and which other documents should be consulted instead for further information.

The second chapter focuses on the concept of articles under the REACH Regulation. It explains the different elements of the definition of an article given in the REACH Regulation and how to interpret it correctly. A flowchart and indicative questions help the reader to assess whether a particular object can be regarded as an article under the REACH Regulation or not.

The obligations related to substances in articles are explained in chapters three and four. For this the concepts of “substances intended to be released” and “substances of very high concern” are introduced and the reader is assisted in checking whether the substances in an article fall into these categories. Example calculations illustrate how to determine if a substance intended to be released or a substance of very high concern reaches the tonnage and concentration in the article that trigger obligations under the REACH Regulation.

Where the information available on substances in articles is not sufficient to conclude whether any obligations need to be fulfilled or not, further information is required. Chapter five describes ways to obtain such information e.g. by means of communicating in the supply chain or through chemical analyses.

Obligations to register or notify substances in articles, as described in chapters three and four, do not apply in certain cases. Chapter six explains under what conditions an article producer or importer is covered by such an exemption and gives some advice on how this can be checked.

Appendix one of the Guidance document provides examples of borderline cases where it is not straightforward to decide whether the article definition applies to an object as a whole, or the object is a combination of an article (functioning as a container or a carrier material) and a substance/mixture; the latter case leading to additional legal requirements.

In Appendix two four different supply chains are analysed with a view to determine the step after which a material that is being processed becomes an article (and stops being a substance or mixture).

The case studies described in Appendix three illustrate scenarios in which producers and importers of articles identify which obligations specified in the REACH Regulation they have to fulfil with regard to substances in their articles.

The last four Appendices include compilations of public information sources on substances in articles, of sampling and analysis methods, of legislation other than the REACH Regulation restricting the use of substances in articles, as

well as a short overview of relevant parts of the REACH Regulation.

KEY ASPECTS

Substances of Very High Concern

The notification and communication obligations apply to substances identified as SVHC and placed on the *Candidate List*. The criteria on the basis of which these substances are identified substances are defined in Article 57 of the REACH Regulation. To meet the criteria and be identified as a SVHC the substance has to be: carcinogenic, mutagenic or toxic to reproduction (CMR category 1 and 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or a substance for which there is evidence for similar concern. The procedure according to which a substance is identified as a SVHC and put on the Candidate List is specified in Article 59.

Intended release

The registration requirements in Article 7(1) of the REACH Regulation relate to substances (as such or in mixtures) that are intended to be released under normal or reasonably foreseeable conditions of use during the service life of the articles and where the quantity of the substance exceeds one ton per year. Both conditions, intended release and normal or reasonably foreseeable conditions of use, must be met before registration requirements under Article 7(1) can be triggered.

Normal and reasonably foreseeable conditions of use

“Normal conditions of use” means the conditions associated with the main function of an article. They are frequently documented in the form of user manuals or instructions for use. Normal conditions of use for articles used by industrial or professional users may differ significantly from conditions that are “normal” for consumers.

“Reasonably foreseeable conditions of use” means conditions of use that can be anticipated as likely to occur because of the function and appearance of the article (even though they are not normal conditions of use).

LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006.

REACH Guidance website is a single point of access to general and detailed technical guidance on REACH.

Guidance in a nutshell documents are aimed at managers and decision-makers and explain the main elements of the full Guidance documents in simple terms.

ECHA website pages on substances in articles include general information, useful links and questions and answers on notification of substances in articles.

ECHA database of Frequently Asked Questions contains questions and answers on specific aspects of REACH.

BIBLIOGRAPHIC INFORMATION OF THE GUIDANCE DOCUMENT

The **Guidance on requirements for substances in articles** can be downloaded from the ECHA website.

Version 2
Pages 85
Date 2011