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Guidance Fact Sheet

REQUIREMENTS FOR SUBSTANCES IN ARTICLES

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Guidance on requirements for substances in articles

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

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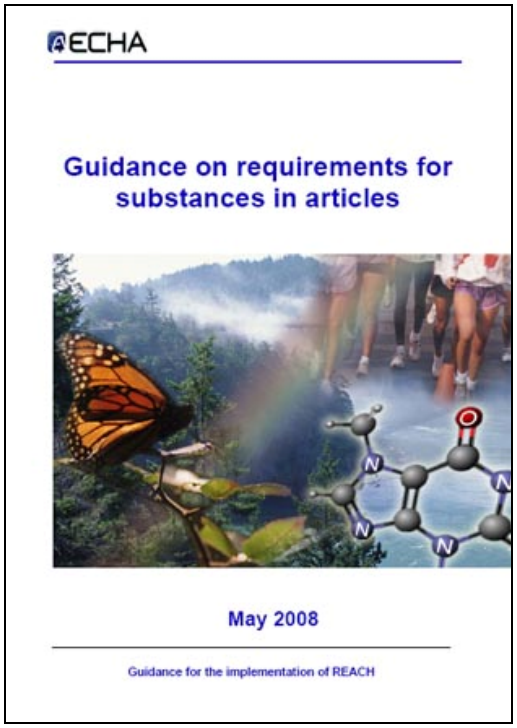

WHO SHOULD READ THE GUIDANCE DOCUMENT?

REACH distinguishes three types of products: substances as such, mixtures of substances (preparations) and articles. In REACH, 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".

While for example coatings, inks, adhesives or cleaners are preparations under REACH, products such as tyres, newspapers, compact disks or bottles are articles.

The *Guidance on requirements for substances in articles* is intended for companies located in the European Union who produce, import or distribute articles. Under particular circumstances these companies may have duties under REACH comparable to those of companies producing or importing chemicals.

The document is also a relevant source of information for those companies outside the European Union whose products are exported to the EU.

WHAT IS THIS GUIDANCE ABOUT?

The Guidance Document gives an overview of requirements for substances in articles. It aims to assist

- REACH actors in determining their role(s) whether they are manufacturers or importers of substances[1] and/or producers or importers of articles
- article suppliers[2] in deciding if they have to fulfil registration, notification and/or communication requirements related to substances in their articles.

Suppliers of articles have relatively lighter duties under REACH compared to the manufacturers, importers and downstream users of substances as such or in preparations. A correct and consistent decision as to **what is an article** under REACH is therefore a key issue in this guidance. Determining the function of an object, and to which extent this is determined by its chemical composition or its shape, surface and design are the bases for this decision. This decision can be difficult in so-called “borderline cases”. Two types of borderline cases are distinguished:

- the borderline in the sequence of processing natural or synthetic materials (substances) to final articles; in particular deciding whether a 'semi-finished product' is still a substance or already an article
- the borderline between substances/ preparations in special containers or on special carrier material compared to substances/preparations being (integral) parts of an article.

Another key question is to what extent substances in articles **can be released** during service life and waste life stages, and whether or not this **release is intended.** If an article has an accessory function, which is achieved through the release of substances or preparations 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.

The guidance also deals with the special case of substances of very high concern[3] (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 all articles produced or imported by one actor in an amount totalling over 1 tpa, and
- the substance is present in the articles above a concentration of 0.1% weight by weight (w/w). This threshold of

[1] On their own or in preparations

[2] producers, importers, distributors/retailers of articles as well as *only representatives* of non-EU companies

[3] 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.

0.1% applies to the article as produced or imported. It does not relate to the homogeneous materials or parts of an article, as it may in some other legislation[4].

If these criteria are met, the recipient of that article must be informed of the presence of the substance in the article and of suitable measures for safe handling if relevant. Such information should consider the entire life cycle of the article. What information is actually needed depends on a case-by-case assessment and is explained in the respective sections in this guidance. These requirements also apply to a consumer request in which case this information should be provided, free of charge, within 45 days of receipt of the request.

A notification of SVHC in articles shall be made to the Agency at the latest 6 months after it has been included in the 'candidate list' but only starting from 1 June 2011. 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 first list is expected in autumn 2008. The 'candidate list' will be updated continuously when substances have been identified as meeting the criteria of SVHCs.

The fact that neither registration, nor notification is required if the substance has already been registered for that use is also explained in the guidance. Chapter 9 of this guidance explains how to check whether the substance has been registered for that use. Further explanation can be found in Part D and Chapter 12 of the *Guidance on Information Requirements and Chemical safety Assessment*. Additionally, notification is not required if the producer or importer can exclude exposure of the substances to humans or the environment during normal or reasonable foreseeable conditions of use including disposal. How to carry out such assessment is further explained in Chapter 8.8 of this guidance and in the *Guidance on Information Requirements and Chemicals Safety Assessment* (Part D and Chapter 15 to 18).

The Agency may decide that an article producer or importer 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.

Further aspects are addressed in the Guidance on requirements for a substance in an article:

- Status of packaging under the REACH provisions
- Pre-registering substances in articles under REACH
- Chemical analysis as an option to identify and quantify substances in articles

The Appendices of the guidance provide further information and examples on how to fulfil your obligations with regard to substances in articles.

HOW TO READ THIS GUIDANCE?

The first two chapters give an overview of the requirements for substances in articles and how to use the guidance.

The framework (including workflows and decision trees) that assists in deciding whether an object is a substance or preparation or an article is given in chapter 3.

As explained in chapter 4, for article suppliers, communicating with the suppliers is the most important and efficient way to gather information on substances contained in their articles.

[4] Dissenting views, questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

If other approaches fail, conducting chemical analysis may thus be a 'last resort' for checking/fulfilling REACH obligations in relation to the identity and the content of substances in an article. This is explained in chapter 5.

The subsequent three chapters provide specific guidance and workflows for registration, notification and communication obligations with regard to substances in articles.

Appendices 1 to 3 list links to definitions and explanations to support the guidance, including illustration of the article definition with a number of typical borderline cases. Appendix 4 contains illustrative cases for checking if requirements regarding notification and communication of information on SVHCs may apply. Appendices 5 to 7 deal with information sources on the presence of substances in articles and existing restrictions.

KEY ASPECTS

Substances of Very High Concern

The notification and communication obligations apply to substances identified on the *Candidate List of Substances of Very High Concern for Authorisation*. The properties of these substances are defined in Article 57: carcinogenic, mutagenic or toxic to reproduction (CMRs category 1 and 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or for which there is evidence for similar concern. Details on the procedure to set up the "candidate list" are described in Article 59.

Intended release

The requirements in Article 7(1) relate to substances (as such or in preparations) that are intended to be released under normal or reasonably foreseeable conditions during the service life of the articles. 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.

Foreseeable conditions of use

Reasonably foreseeable conditions of use mean conditions of use that are not as originally intended by the article producer or importer (normal use) but which can be anticipated as likely to occur because of the form, shape or function of that article.

Normal conditions of use means the conditions associated with the intended function of an article. Normal conditions of use for articles used by industrial or professional users may differ significantly from conditions that are "normal" for consumers.

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.
REACH Guidance Fact Sheets and Frequently Asked Questions (FAQs) can be found in the REACH section of the ECHA website.

BIBLIOGRAPHIC INFORMATION OF THE GUIDANCE DOCUMENT

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

Version	1
Pages	118
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