

Articles Regulated Under REACH

Articles manufactured in, and imported to, the European Union require consideration under REACH for the substances they contain. Under REACH, **an article is an object with a specially produced shape, surface, or design, which is more important to the object's normal function than the chemicals that it contains** (Article 3(3)). REACH did not change the current EU chemical regulatory approach to substances in articles, and will not impact article-related Directives 2002/95/EC (RoHS), 2002/96/EC (WEEE), and 2000/53/EC (ELV).

Industry's Required Reporting to the European Chemicals Agency for Articles (REACH Article 7)

Registration for substances in articles: Producers and importers must register substances (including pre-registration for phase-in substances) in articles meeting three criteria:

1. Are **intended to release the substance** under normal and foreseeable conditions of use;
2. Contain **more than 1 tonne of the substance per calendar year** for all articles of all types that are intended to release that substance per producer or importer; and
3. Have a **use for which the substance has not yet been registered.**

Intended release is a release required by the object's function (i.e., marking pen), or that gives added value (i.e., perfumed bookmark), but excludes impurities from semi-finished or finished articles (i.e., oils washed from metal parts), release during use or maintenance (i.e., dye rinsed from clothing), and of substances formed in chemical reactions (i.e., a fire).

Normal conditions of use are associated with intended use functions, and are deducible by common sense or from object's instructions, but exclude types of use explicitly excluded from instructions, or covered by cautions and warnings on the label or in instructions.

Foreseeable conditions of use are outside producer's intended use that may be foreseen due to form, shape, or function of the article, and include: very likely accidents (i.e., breakage of fragile material), extremely intensive use, different exposure pathways, and children's access to the article. Excluded from foreseeable use are: misuse, uses advised against by warning labels or item design, and use the producer or importer clearly and noticeably excluded.

Notification for substances in articles: Producers and importers of an article containing a substance must provide notification to the Agency if the following five criteria are met:

1. Substance **concentration exceeds 0.1 percent by weight** in the article;
2. Substance is on list of **substance of very high concern (SVHC)** in REACH Annex XIV.
3. Total **SVHC exceeds 1 tonne per calendar year** for all articles per producer or importer;
4. **Exposure to humans and environment cannot be excluded** by importer or producer during normal or reasonably foreseeable conditions of use and disposal of the article; and
5. Article has a **use for which the SVHC has not yet been registered.**

Excluded exposure applies to each use, or user group. Human exclusion cannot apply to articles in contact with the human body (i.e., clothing, shoes). Articles with no releases may be excluded, but exclusion should consider substance's properties (i.e., vapor pressure, water solubility) and use conditions (i.e., abrasion, temperature, ventilation). Exposure information and studies must be considered. [See Annex 7 of the Draft Technical Guidance on Articles.]

Deadlines for registration are the same as for other substances. **Deadlines for notification** for SVHC in articles will occur after 1 June 2011, and will be set at six months after the date that the specific substance is placed on the candidate list of SVHCs in Annex XIV of REACH.

Notification for substances in articles must include (Article 7(3)):

- Identity of the importer or producer (including: registrant(s) name, address, phone, fax, e-mail address, contact person, and location of registrant's own production sites);
- Registration number of the substance (if established);
- Substance identity (including: name, IUPAC name, other names, EINECS or ELINCS numbers, CAS name and number, other identity codes, molecular and structural formula information, isometric information and optical activity, molecular weight, composition, degree of purity (%), nature of impurities (isomers and byproducts, and % of main impurities), and nature and magnitude of additives (i.e., stabilising agents, inhibitors));
- Classification of the substance and hazard label, as provided by the Agency;
- Brief description of the use(s) of the substance(s) in the article, and of the article; and
- Tonnage range that the substance in the article(s) falls into under REACH.

Other Industry Requirements for Articles Under REACH:

Participation in Substance Information Exchange Forum (SIEF): Importers of articles will be required to join the on-line SIEF for the phase-in substances contained in their articles (Article 29). Producers of articles will have the option to join the SIEFs, since they are not the manufacturers of the substances contained in the articles.

Provide information on substances in articles to users: Producers and importers of articles containing SVHCs at a concentration above 0.1 percent must provide recipients of the articles with sufficient information to allow safe use (e.g., limit risk) (Article 33). The name of the substance(s) is the minimum information, and other information needed may include: exposure controls and personal protection; first aid measures, fire fighting measures; handling and storage; transportation; and disposal considerations. Similar information must be provided to a consumer within 45 days of receipt of a request.

Documentation: Although REACH does not set any specific documentation requirements for articles, the technical guidance on articles recommends that documentation be maintained, including information from suppliers, analytical results, summaries of registration and notification assessments, and any industry association's assessments of the articles.

Reference on Articles under REACH:

- Draft Technical Guidance Document on Requirements for Substances in Articles (RIP 3.8) [Draft of 26 May 2006 – revisions planned, especially to appendices].
http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.8_ARTICLES/RIP_3.8_Final_report_Draft_TGD_May_2006.pdf