



July, 2008

Subject: EFCTC position on REACH: Substances in articles

The obligations of producers and importers of articles containing substances are laid down in art 7 REACH.

Producers and importers of articles containing substances are downstream users – they do not manufacture the substance, but they use the substance in the article they manufacture or import. The primary responsibilities under REACH lies with the producer or importer of the substance. Consequently, art 7 REACH absolves any producer or importer of an article that contains one (or more) substance(s) of their obligations under article 7 if the substance has already been registered for that particular use (art 7 paragraph 6).

Already registered?

The first step producers and importers of articles containing substances should take is to check with their suppliers if these substances have been duly registered for the use in their articles.

Phase-in substances

For phase-in substances, the question arises whether or not producers and importers of articles containing these phase-in substances can rely on the phase-in status of the substances they use for the exemption under art 7 paragraph 6. Although this would seem reasonable enough, this is **not** the case. The European Chemicals Agency (ECHA) therefore recommends producers and importers of articles containing substances to pre-register these substances if they fulfill the criteria set in art 7 paragraph 1 (see below)¹.

When to register

Article 7 paragraph 1 requires any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

¹ http://echa.europa.eu/doc/reach/080611_REACH_ECHA_FAQ_2%202_Release_2.pdf, Question 8.4

- (a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year;
- (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

What is an article

The second step is to ensure that the product under consideration is an “article” under REACH. An “article” according to REACH is “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”. This is a very broad definition and covers nearly anything that is not a chemical substance (or a mixture of substances, or “preparation”). It ranges from very complex products (e.g. airplanes, motor vehicles, television sets) to relatively simple ones (cotton pads or pencils). There are obviously borderline cases, for example a drum containing a substance. The empty drum is clearly an article. But a drum filled with a substance with the clear goal of delivering the chemical is an accessory function. The manufacturer/importer of empty drums can consider his product as an article; the importer of a drum filled with a chemical substance is an importer of the substance, not an article containing a substance.

Know your substances

It would seem relatively simple to establish whether or not a substance in an article is produced or imported in quantities over one tonne, but unfortunately that is not always the case. For example, the composition of a chemical product (“mixture”) may change over time, and suppliers may not be willing to disclose the exact identity of their chemicals. There is no easy solution to this lack of information. It is important that down-stream users document their efforts in this respect in great detail.

Intended for Release?

It is equally challenging to assess if the substances used in an article are intended for release under normal foreseeable conditions of use. If the release of the chemical is a necessary feature for the product to fulfill its intended function, then it is clear that the substance is intended for release under normal foreseeable conditions of use. The non-legally binding guidance document of ECHA² formulates three good questions to determine whether or not the substance must be considered as intended for release:

- 1) *If the substance/preparation were to be removed or separated from the object or exchanged for a similar type of substance/preparation, would the object be unable to fulfill its intended purpose?*
- 2) *Is the main purpose of the object other than to deliver the substance/Preparation or its reaction products?*

² http://reach.jrc.it/docs/guidance_document/articles_en.pdf

3) *Is the object normally discarded with the substance/preparation at the end of useful life, i.e. at disposal?*

If the answer is “yes” to all three, then no release is intended under normally foreseeable conditions of use. If some answers are negative, then it does not automatically follow that release under normal foreseeable conditions of use is intended. Questions 1 and 3 are often the more difficult ones, especially in complex products. Most of these products are designed for servicing. Replacement of the substance during the useful life and removal at end of life of the product are standard procedures. That does not mean that the substance is intended for release, quite to the contrary: the servicing activities are intended to prevent release to the environment and to permit adequate disposal. For example, fluorinated refrigerant fluids must be recovered at end of life with a view to ensure reclamation and re-use or destruction. Clearly, these substances are not intended for release during normal foreseeable conditions of use.

Notification of Substances of Very High Concern

According to article 7, paragraph 2 manufacturers and importers of articles containing substances must submit a notification to ECHA if all of the following conditions are met:

- 1) The substance meets the criteria in Article 57 and is identified in accordance with Article 59 paragraph 1 (Substances of Very High Concern)³
- 2) The substance is present in those articles in quantities totaling over one tonne per producer or importer per year;
- 3) The substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

Substances of Very High Concern are substances that are classified as category 1 or 2 Carcinogenic, Mutagenic or Reprotoxic, or classified as persistent, bioaccumulative and toxic, or as very persistent and very bioaccumulative.

At present, no substance has yet been identified in accordance with art 59 REACH.

No notification is necessary if:

- 1) The substance has been registered for that use by the producer or importer of the substance, or
- 2) The producer or importer of the article can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or

³ Substances of Very High Concern are substances that are classified as category 1 or 2 Carcinogenic, Mutagenic or Reprotoxic, or classified as persistent, bioaccumulative and toxic, or as very persistent and very bioaccumulative, or “of equivalent concern”.

importer shall supply appropriate instructions to the recipient of the article.

The use of Substances of Very High Concern attracts obviously much interest, and we therefore recommend any downstream user to consult with their suppliers to ascertain if any of the substances meet the criteria.

Disclaimer: This information was prepared with the greatest care – any producer or importer of substances or articles containing substances must ensure compliance with REACH. The sole purpose of this document is to assist them in the assessment. EFCTC and its members decline any responsibility or liability associated with the completeness accuracy or use of this document