

**Statement regarding the relevance of the new
European Chemical Legislation (REACH)
for the import of articles into the EU**

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The application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is based on the properties of substances.

The general obligation to register and information requirements are regulated in Title II, chapter 1. In article 5, the following is stated:

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

This means that also producers and importers of articles can be affected, which has been made clear already in the first motives listed at the beginning of the regulation's text:

(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation..., and later on:

(16) This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in preparations and in articles.....

(29) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on substances which are intended to be released from articles and have not been registered for that use. In the case of substances of very high concern which are present in articles above tonnage and concentration thresholds, where exposure to the substance cannot be excluded and where the substance has not been registered by any person for this use, the Agency should be notified. The Agency should also be empowered to request that a registration be submitted if it has grounds for suspecting that the release of a substance from the article may present a risk to human health or the environment and the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year. The Agency should consider the need for a proposal for a restriction where it considers that the use of such substances in articles poses a risk to human health or the environment that is not adequately controlled.

The requirements for substances in articles are defined and explained in Article 7 (Registration and notification of substances in articles; see the complete text in the Annex).

For importers of articles into the EU the following applies:

1. Registration:

Importers are only responsible for the registration of substances in their articles if both of the following conditions are met:

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

Examples for the second point are flavors in candles or detergents in cleaning cloths which are intentionally released.

Obviously, this applies only to a limited number of articles.

However, the Agency may take decisions requiring producers or importers of articles to submit a registration for any substance in those articles, if all the following conditions are met:

- the substance is present in those articles in quantities totalling over one tonne per producer or importer per year; and
- the Agency has grounds for suspecting that:
- the substance is released from the articles, and
- the release of the substance from the articles presents a risk to human health or the environment;

Examples for this case could be dyestuffs in textiles, additives in plastics (flame retardants, plasticizer) from which it is already known that they might be released and that they possibly have hazardous properties.

2. Notification

If in the articles such substances are present which require an authorisation (i.e. if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) as a substance of very high concern (SVHC), i.e. cancerogene substances, mutagenic substances, substances toxic to reproduction and others), the following applies:

Any producer or importer of articles shall notify the Agency if both the following conditions are met:

- the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

The information requirements for such a notification are listed in the Annex (Article 7, (4)).

However, this duty shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

Conclusion for importers of articles to the EU:

Under the above mentioned circumstances importers of articles may be responsible for the registration of substances in their articles. If substances which are subject to authorization are present in those articles, the importer will have to notify the Agency.

⇒ according to article 33 of the REACH regulation, the supplier of the article has to inform importers about any SVHCs present in the article in concentrations > 0.1 % (w/w).

Additionally, he has to provide adequate information regarding the safe handling of the article

The same duty applies to the importer, if his clients or even consumers would ask him about dangerous substances in his articles.

Conclusion:

If no substances are intentionally released from the article, no registration is necessary. If the article does not contain SVHCs in concentrations > 0.1% (w/w), no notification is necessary, too.

Annex:

Some important articles of the REACH regulation:

Article 7

Registration and notification of substances in articles

1. 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:

- (a) the substance is present in those articles in quantities totalling 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.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- (b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. The information to be notified shall include the following:

- (a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
- (b) the registration number(s) referred to in Article 20(1), if available;
- (c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
- (d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
- (e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
- (f) the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the Agency has grounds for suspecting that:

(i) the substance is released from the articles, and

(ii) the release of the substance from the articles presents a risk to human health or the environment;

(c) the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7. From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).

8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3).

Information in the supply chain:

Article 33

Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Authorization:

Article 57
Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

- (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
- (b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
- (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
- (f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.