

Authorisation under REACH

Information on BPA-based materials

REACH*, the new EU chemicals legislation, places new duties on manufacturers, importers and users of chemical substances.

The REACH Regulation was implemented by EU Member States and applies to almost all chemical substances. Under REACH, “substances of very high concern” (SVHCs) may be subject to Authorisation in order to ensure that the risks from these substances are properly controlled. For a comprehensive explanation of the authorisation process, please refer to the website of the European Chemicals Agency (ECHA) at http://guidance.echa.europa.eu/authorisation_en.htm.

In this document, the Polycarbonate/Bisphenol A industry group of PlasticsEurope examines Authorisation under REACH and provides supplementary information on the manufacturing and marketing of articles made from materials based on Bisphenol A (BPA).

BPA does not fall within the criteria of an SVHC

BPA does not meet the criteria of an SVHC under REACH. REACH defines these substances, which may be subject to Authorisation, as:

- Carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2**;
- Persistent, bio accumulative and toxic (PBT);
- Very persistent and very bio accumulative (vPvB);
- Showing scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern, such as substances with endocrine disrupting properties.

BPA does not fit any of these criteria. Specifically:

- BPA is not classified as a CMR category 1 or 2 according to the EU's Classification and Labelling Directive (2001/59/EC)**;
- The EU Risk Assessment of BPA (an updated risk assessment was published in 2008) states clearly that it is neither persistent nor bio accumulative. Therefore, BPA is neither a PBT nor a vPvB substance.
- BPA is not an endocrine disruptor according to the criteria in the EU REACH guidance and as defined by internationally-accepted definitions for endocrine disruption (such as the Weybridge definition). This is due to the fact that BPA does not show any reproducible evidence of adverse effects through the endocrine system.

More broadly, the EU Risk Assessment of BPA has concluded that BPA presents no risk to consumers or the environment in its intended applications. The responsible authorities for consumer safety worldwide support this conclusion.

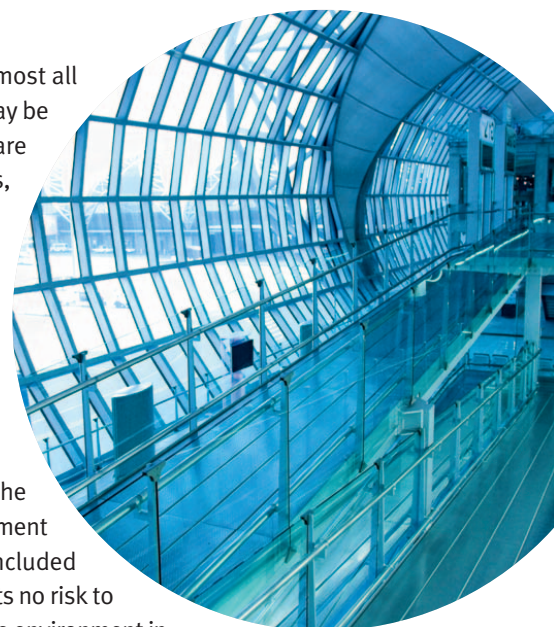
Intermediates are not subject to Authorisation

Under REACH, Authorisation is not required for “intermediates”; that is substances that are converted during chemical processing.

BPA is predominantly used as an intermediate in the manufacture of polycarbonate plastic and epoxy resin. In fact, more than 99% of all BPA is converted into such polymers. BPA, as an intermediate, is therefore exempt from Authorisation.

* REACH: Registration, evaluation, authorisation and restriction of Chemicals (<http://echa.europa.eu/>)

** during the transfer from the existing classification into the new "Global Harmonised System" (GHS) these classifications will be adapted by December 1st, 2010.

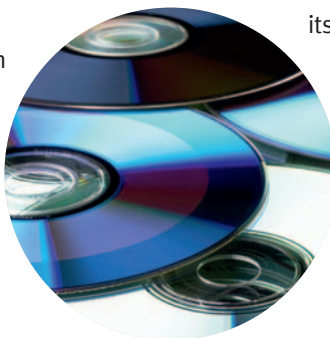


BPA is not on the “Candidate List”

The first step in the Authorisation process is the compilation of a “Candidate List” of SVHCs. The first such Candidate List was published by ECHA in October 2008, two updates appeared since (January and March 2010).

As BPA did not meet the criteria of an SVHC, it also does not meet the criteria for being placed on the Candidate List for authorisation.

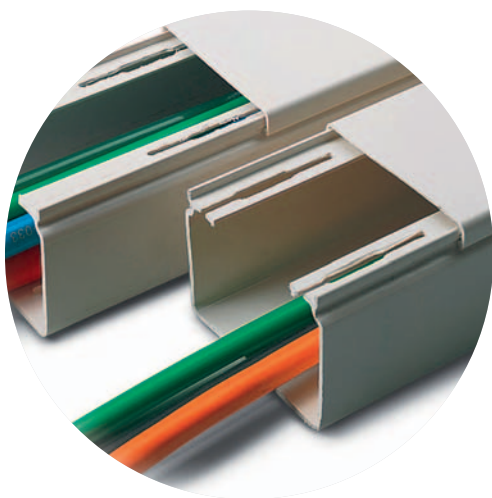
Furthermore, given that BPA has not been included on the Candidate List for Authorisation (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp), the information obligations according to Article 33 of REACH do not apply to suppliers of articles made from polycarbonate plastic or epoxy resin.



Food Contact Materials

Existing EU food safety legislation already covers substances that are intended to come into contact with food. The European Food Safety Authority (EFSA) has positively listed BPA for approved use in food contact applications in the EU. Only substances confirmed to be safe are included on this positive list for food contact use.

This existing legislation is respected by REACH. Therefore, there is no additional requirement under REACH to consider potential risks to human health for the use of substances in food contact materials.



Conclusion

The European Risk Assessment concluded that BPA does not present a risk to consumers or the environment in its intended applications.

Based on available scientific data, the existing regulatory assessments and the provisions of the REACH regulation itself, BPA, does not fulfil the criteria of an SVHC and is neither eligible for Authorisation nor the Candidate List. Furthermore, as an intermediate, it is exempted from authorisation.

Downstream users of BPA should therefore continue to use BPA-based materials such as polycarbonate plastic and epoxy resin with confidence.



Contact

Jasmin Bird
 Manager Communications
 PC/BPA-Group PlasticsEurope
 Tel: +32 2 676 1738
jasmin.bird@plasticseurope.org
www.bisphenol-a-europe.org