



# AUTHORISATION UNDER REACH – INFORMATION ON BPA-BASED MATERIALS

REACH\*, the EU chemicals legislation, places duties on manufacturers, importers and users of chemical substances. The REACH Regulation is 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 <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation>.

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).

## CRITERIA FOR IDENTIFICATION AS AN SVHC

In order for a substance to be identified as SVHC, a so-called ‘Annex XV dossier’ has to be submitted to ECHA that provides the justification for the proposal. REACH defines substances, which may be subject to Authorisation, as:

- Carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B;
- 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.

## APPLYING THE SVHC CRITERIA TO BPA

The EU Risk Assessment of BPA clearly states that BPA 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 WHO/IPCS criteria, which were presented by the EU Commission in June 2016 as basis for the identification of Endocrine Disruptors. In its January 2015 opinion on BPA the EFSA expert panel concluded that “based on the WHO criteria, it is not possible to conclude that BPA is an endocrine disruptor”. This is due to the fact that BPA does not show any reproducible evidence of adverse effects through the endocrine system.

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



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.

In August 2016, a reclassification of BPA as reprotox 1B entered into force will apply from March 2018. Based on this 1B reprotoxic classification, the French authorities submitted to ECHA an Annex XV dossier for BPA, proposing the identification of BPA as a substance of very high concern (SVHC) under REACH. Following the ECHA Member State Committee (MSC) agreement to identify BPA as SVHC in December, Bisphenol A (BPA) has been included in the REACH Candidate List of Very High Concern as of 12 January 2017, based on its classification as reprotox 1B. Identification as an SVHC could be the entry point into a potential authorization under REACH at a later stage.

### INTERMEDIATES ARE NOT SUBJECT TO AUTHORISATION

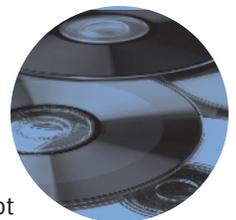
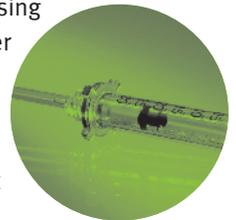
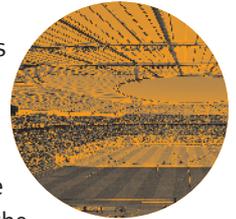
Intermediates are substances that are converted during chemical processing. Under REACH, Authorisation is not required for intermediates. BPA is predominantly used as an intermediate in the manufacture of polycarbonate plastic and epoxy resin. In fact, the overwhelming amount of all BPA produced is converted into such polymers. BPA, as an intermediate, is therefore exempt from Authorisation.

### SUBSTANCES ON THE “CANDIDATE LIST”

Substances identified under REACH as SVHC are collected on the so-called Candidate List. The first such Candidate List was published by ECHA in October 2008, it is since updated twice per year, usually in June and December.

The identification of a substance as SVHC and the inclusion in the Candidate List triggers communication and notification obligations for companies. These obligations refer not only to the listed substance on its own or in mixtures but also to its presence in articles, pursuant to Article 33 of REACH:

- Suppliers of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information to allow safe use of the article to their customers or upon request, to a consumer within 45 days of the receipt of the request. This information must contain as a minimum the name of the substance.
- Producers or importers of articles have to notify ECHA if their article contains a substance on the Candidate List. This obligation applies if the substance is present in those articles in quantities totalling over one tonne per producer or importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w). Of note, a notification is not required when the producer can exclude exposure of humans and the environment during the use and disposal of the article, or when the substance has already been registered for that use.



The predominant amount of all BPA produced is converted into polymeric materials such as polycarbonate and epoxy resin. BPA is firmly bound into the structure and only technically unavoidably trace levels of unreacted BPA may remain in the polymer matrix. Such levels are usually far below the levels that would trigger SVHC-related communication or notification obligations. Therefore, for the vast majority of BPA-based polymers, specifically polycarbonate and epoxy resins, no direct obligations are expected following the SVHC identification. Nevertheless it is the responsibility of each company in the value chain to evaluate, if their products (articles) fall under the communication and notification obligations of REACH, which are available under this link: <https://www.echa.europa.eu/candidate-list-obligations>.



More information on BPA is available at the following Web sites:

ECHA:

<https://echa.europa.eu/support/guidance>

<https://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern>

<https://echa.europa.eu/addressing-chemicals-of-concern/authorisation>

<https://www.echa.europa.eu/candidate-list-obligations>

EFSA:

<http://www.efsa.europa.eu/en/press/news/150121>

PlasticsEurope:

[www.bisphenol-a-europe.org](http://www.bisphenol-a-europe.org)

Or by contacting:

Jasmin Bird

Polycarbonate/Bisphenol-A

Group PlasticsEurope

Email:

[Jasmin.Bird.consultant@plasticseurope.org](mailto:Jasmin.Bird.consultant@plasticseurope.org)

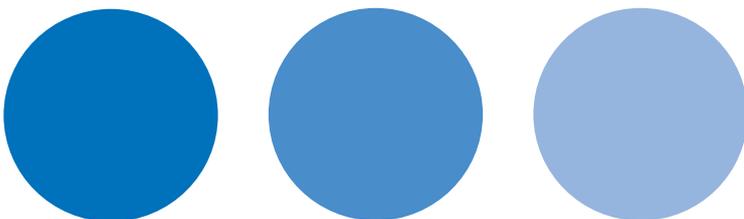
## FOOD CONTACT MATERIALS

EU food safety legislation covers materials and articles that are intended to come into contact with food. Food contact materials (FCMs) are regulated by the Framework Regulation for all food contact materials (EC No 1935/2004) and the use of BPA as monomer for plastic FCMs is explicitly permitted by the Regulation (EU No 10/2011). The SVHC-identification and inclusion in the Candidate List does not impact compliance of BPA-based food contact materials with the respective legislation. The European Risk Assessment concluded that BPA does not present a risk to consumers or the environment in its intended applications. The January 2015 EFSA opinion on BPA concluded: “EFSA’s comprehensive re-evaluation of bisphenol A (BPA) exposure and toxicity concludes that BPA poses no health risk to consumers of any age group (including unborn children, infants and adolescents) at current exposure levels. Exposure from the diet or from a combination of sources (diet, dust, cosmetics and thermal paper) is considerably under the safe level (the “tolerable daily intake” or TDI).”

## CONCLUSION

Substances on the Candidate List are subject to a prioritisation driven by ECHA. If BPA was prioritised among the substances on this list, it could ultimately mean that it may be subject to Authorisation under REACH at a later stage.

A substance can be identified as an SVHC and be included on the Candidate List – however, this implies neither a ban of the substance nor its automatic inclusion in Authorisation under REACH. Uses as intermediate, such as BPA for polycarbonate and epoxy resin, are exempt from Authorisation under REACH. Downstream users of BPA could therefore continue to use BPA-based materials such as polycarbonate plastic and epoxy resin with confidence.



The information contained in this communication is provided in good faith, to the best of our current knowledge, and for general information and use only. It does not constitute advice and should not be relied upon in making (or refraining from making) any decision. This content is provided “as is” and “as available”. Neither PlasticsEurope nor any contributor will be liable for loss or damages of any nature whatsoever resulting from the use of or reliance on this information.