

Polycarbonate/Bisphenol A group (PC/BPA)
Epoxy Resin Committee (ERC)

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Questions & Answers about BPA being added to REACH Candidate List

As of 12 January 2017, Bisphenol A (BPA) has been included in the REACH [Candidate List](#) of Substances of Very High Concern. This follows the ECHA Member State Committee (MSC) agreement to identify BPA as a Substance of Very High Concern (SVHC) under REACH, based on its harmonised classification as reprotox 1B.

This document is intended to provide further information to interested stakeholders and to answer questions about the processes and possible implications.

Why has BPA been added to the Candidate List?

Following the re-classification as reprotox 1B (which entered into force in August 2016), BPA formally meets the criteria for identification as a Substance of Very High Concern (SVHC) according to Article 57(c) of REACH. In February 2016, France notified its intention to ECHA to submit an Annex XV dossier proposing the identification of BPA as an SVHC based on the reprotox 1B classification. The dossier was submitted in August and was subject to a public consultation. In December 2016, ECHA's Member State Committee (MSC) agreed to identify BPA as SVHC, based on its harmonised classification as reprotox 1B, and to include it in the REACH Candidate List of Substances of Very High Concern for Authorisation.

Why did the new classification happen – is there new scientific data?

The re-classification of BPA from reprotoxic 2 (*suspected human reproductive toxicant*) to reprotoxic 1B (*presumed human reproductive toxicant*) was not based on new toxicological concerns. It was rather the result of the application of stricter criteria according to the current CLP Regulation rules. By the implementation of the criteria of Global Harmonized System (GHS) in CLP-regulation EC No 1272/2008, previous criteria and related guidance for CLP had changed.

Does the identification as an SVHC mean that the use of BPA is dangerous?

No, SVHC-identification does not determine whether the use of a substance is dangerous. It is important to note that the justification for SVHC identification is based on the intrinsic properties of the substance, not on use, real-life exposure and risk. The inclusion of BPA in the candidate list does not mean its uses are unsafe.

The identification as SVHCs is a formal *first* step which could ultimately lead to Authorisation requirements. The *second* step is to define whether SVHCs included in the Candidate List should be included in the Authorisation List. During prioritisation assessment of these substances, the uses and exposure are being considered.

Does the inclusion in the Candidate List mean that BPA or any of its current uses is now banned – or could eventually lead to such a ban?

The inclusion of a substance in the Candidate List in itself does not imply an immediate ban or restriction of any uses of the substance. It could however lead to Authorisation under REACH, should public authorities identify Authorisation as the best risk management measure.

ECHA regularly assesses the substances on the Candidate List in order to determine which ones should be prioritised for inclusion in the Authorisation List (Annex XIV of REACH). The prioritisation is based

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on information on the reason for inclusion on the Candidate List, the type of uses and the volumes of the substances on the EU market that fall within the scope of the Authorisation requirement.

Substances included in the Authorisation List are then subject to Authorisation: these substances cannot be placed on the market or used after a given date, unless an Authorisation is granted for their specific use, or when the use is exempted from Authorisation.

→ **With respect to BPA:**

Intermediate uses of a substance are exempt from Authorisation under REACH. In fact, **BPA is predominantly used as an intermediate to manufacture polycarbonate and epoxy resins** (polymeric materials). Therefore, even if BPA was prioritised to be included in the Authorisation List, these uses – and all uses of the resulting polymers - would not be subject to Authorisation.

What are the obligations resulting from inclusion in the Candidate List?

The identification of a substance as SVHC and the inclusion in the Candidate List triggers communication and notification obligations for companies¹. 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.

→ **With respect to BPA:**

It is important to note that the overwhelming amount of all BPA produced is converted into polymers such as polycarbonate and epoxy resins. Only technically unavoidable trace levels of unreacted BPA may remain in the polymer matrix, which 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 these communication and notification obligations of REACH.

¹ <https://www.echa.europa.eu/candidate-list-obligations>

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What would a potential later REACH-Authorisation of BPA mean for the industry?

BPA is predominantly used as an intermediate to manufacture polycarbonate and epoxy resin (polymeric materials). Intermediate uses are exempt from potential later Authorisation under REACH. Therefore, a potential later Authorisation should have no direct regulatory impact on BPA-based polymers like polycarbonate or epoxy resins.

Can BPA continue to be used in food contact applications for consumers?

Yes. Generally, 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).² The SVHC-identification and inclusion in the Candidate List does not impact compliance of BPA-based food contact materials with the respective legislation. *“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).”* <http://www.efsa.europa.eu/en/press/news/150121>

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² Despite this, in France a law is in place, suspending the use of BPA in food contact materials, which is in conflict with existing EU Food Contact Regulation.