

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

June 26, 2017

Questions & Answers about BPA being identified as SVHC due to alleged endocrine disrupting properties for human health

On June 16, 2017, the ECHA Member State Committee (MSC) unanimously agreed to identify BPA as a Substance of Very High Concern (SVHC) under REACH due to alleged endocrine disrupting (ED) properties for human health (HH). Since January 2017, Bisphenol A (BPA) has already been included in the REACH [Candidate List](#) of Substances of Very High Concern for Authorisation based on its classification as reproductive 1B substance

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

BPA is already on the Candidate List for Authorisation. What would a second listing mean?

Based on its classification as category 1B reproductive toxicant under the Globally Harmonized System of Classification and Labelling (GHS), BPA was identified as SVHC which led to inclusion in the REACH Candidate List of substances of very high concern for Authorisation by ECHA as of January 12, 2017. After the recent MSC decision it is expected that the Candidate List entry for BPA will be updated to also include the identification based on endocrine disrupting properties for human health by end of June this year. The obligations triggered by listing on the Candidate List are not affected by the second identification as SVHC. In practical terms, it makes no difference whether a substance is listed once or several times – the obligations related to a listing on the Candidate List are the same. *(For more details about the obligations please see page 2.)*

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. SVHC identification is a hazard-based approach. That means it is based solely on the intrinsic properties of a substance, without considering its actual use, real-life exposure and respective potential risk. The inclusion of BPA in the Candidate List as such therefore does not mean its uses are unsafe. The identification as SVHCs is the formal first step which could ultimately lead to Authorisation requirements under REACH.

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).¹ In order to assess the safety of substances used to manufacture food contact materials, the European Food Safety Authority (EFSA) carries out safety evaluations and risk assessments. In its most recent comprehensive scientific opinion on the safety of BPA (published January 2015), the authority concludes: *“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*

¹ 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.

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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>
The SVHC-identification and inclusion in the Candidate List does not impact compliance of BPA-based food contact materials with the respective legislation.

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?

In the context of REACH, the inclusion of a substance in the Candidate List in itself does not imply an immediate ban or a restriction of any uses of the substance. It could however lead to Authorisation under REACH.

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 on information on the reason(s) for inclusion on the Candidate List, the type of uses and the volumes of the substances on the EU market that would 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.

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 of BPA should have no direct regulatory impact on BPA-based polymers like polycarbonate or epoxy resins.

Non-intermediate uses of a substance, such as e.g. additive uses of BPA, are not exempt from REACH Authorisation. Such uses would therefore have to comply with the obligations under REACH 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 companies². 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

² <https://www.echa.europa.eu/candidate-list-obligations>

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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.

Is BPA an “endocrine disrupter”?

The PC/BPA Group provided comprehensive comments opposing the French proposal for the second SVHC identification. These comments are based on the legal interpretation of the REACH Regulation for identifying BPA under Article 57(f) and on the non-conclusive scientific evidence and the weakness in the scientific argumentation brought forward by the French authorities in the dossier. The decision of the MSC is in contrast with the industry’s own thorough assessment of the scientific data on BPA. It is also not consistent with the recent assessment of the European Food Safety Authority (EFSA), published in 2015. EFSA evaluated BPA against the widely accepted WHO definition of endocrine disrupters and *“concluded that scientific knowledge of how BPA behaves in humans was still unclear and there was no single explanation for how BPA potentially affects humans. Therefore, based on the WHO criteria, it was not considered possible to conclude that BPA is an endocrine disruptor.”* <http://www.efsa.europa.eu/en/topics/topic/bisphenol?activeTab=5>

WHO defines an endocrine disrupter as follows:

“An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations.”

During the ongoing process at the European Commission to define the criteria for identifying endocrine disruptors, the EU has also proposed to follow these WHO principles.

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