

Questions & Answers about REACH and BPA

Introduction

REACH, the new EU chemicals legislation, places new duties on manufacturers, importers and users of chemical substances. In this document the Polycarbonate/Bisphenol A industry group of PlasticsEurope answers questions about Bisphenol A (BPA) and REACH. Detailed information about BPA and the Authorisation scheme under REACH is available in the separate fact sheet “Authorisation under REACH: Information on BPA-based materials”.

What is REACH?

REACH stands for “Registration, Evaluation, Authorisation and Restriction of Chemicals”. REACH became part of European law on 1 June 2007. It replaced several pieces of old legislation and introduces new requirements. The REACH regulation came into operation in each EU Member State at the same time and in the same way. However, EU Member States are free to set up national enforcement processes according to their own laws and systems.

What is an article?

Although many people use the word “product” in a general way, it is not used in REACH. The expression used in REACH is “article”, which is defined as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”. Examples of articles made from BPA-based materials such as polycarbonate and epoxy resin include CDs, transparent roofs, safety helmets, automotive parts, housings for electronic equipment, windmill blades and epoxy coated articles such as lined cans.



Who is a downstream user?

Downstream users are users of a chemical substance, either on its own or as preparation, in the course of their industrial or professional activities. Downstream users of BPA typically include manufacturers of BPA-based polymers (e.g. polycarbonate or epoxy resin), formulators of BPA-containing chemical mixtures or preparations and producers of BPA-based reaction products. Distributors and retailers are not regarded as downstream users under REACH. Their role is limited to being recipients of a substance, preparation or article and to placing those on the market.



What are the basics of Registration of BPA?

REACH requires manufacturers and importers to act as registrants. For a substance manufactured or imported in a quantity ≥ 1 tonne/year they must compile a Technical Dossier on the physicochemical, human health and environmental properties of that substance. For a substance manufactured or imported in a quantity ≥ 10 tonnes/year, like BPA, a Chemical Safety Assessment must be carried out and documented in a Chemical Safety Report (CSR). Each registrant must submit a Registration dossier including the Technical Dossier and the CSR, where it is required, to the European Chemicals Agency (ECHA). The deadline for Registration depends on the tonnage manufactured or imported. For BPA it is 1 December 2010. The leading manufacturers of BPA have joined to prepare a consistent registration dossier for BPA and have launched the BPA REACH consortium. The secretariat of the BPA REACH consortium can be contacted at consortium@reachcentrum.eu.

What are the duties of downstream users of BPA and BPA-based polymers in the Registration process?

The main obligations in the REACH Registration process fall upon the registrants of BPA. It is they who must demonstrate the safety of BPA and BPA-based materials for human health and the environment. As part of the Chemical Safety Assessment, REACH requires downstream users to inform the registrants about the way they use BPA. Users should provide sufficient information to allow the registrants to prepare a realistic exposure scenario for each specific use of BPA. This will enable the registrant to include the use in the CSR as an “identified” use and assure continued supply. The registrant is not obliged to include in the CSR a use of BPA that he considers he cannot support. For uses of BPA not covered by the CSR, downstream users must prepare their own Chemical Safety Assessment and CSR.



Is it true that polymers are exempt from Registration?

Yes, polymers are exempt from Registration, but the building blocks from which they are made, the monomers, are not. In the case of polycarbonate and epoxy resin BPA is the monomer from which they are manufactured.

Does a producer or importer of an article have to register BPA?

It will be necessary for the producer or importer of an article to register the use of BPA in that article only if BPA is intended to be released during normal and reasonably foreseeable conditions of use, and if some additional conditions are met. We know of no article that is intended to release BPA during use. Therefore, it is highly unlikely that any producer or importer of articles made from BPA-based materials will have an obligation to register BPA.

When does a producer or importer of an article have to notify a substance?

Notification in the context of REACH means the requirement to inform ECHA of the presence and use of a substance in an article. Notification of a substance in an article by the producer or importer of that article is required if all of the following criteria apply:

- The substance has been identified as a substance of very high concern (SVHC)
- The substance has been included in the Candidate List for Authorisation
- The substance is present in that article at a concentration exceeding 0.1% by weight
- The total amount of the substance present in that article exceeds one tonne per producer or importer per year
- The substance has not yet been registered for that specific use

Notification to ECHA shall be made at the latest six months after the substance has been included on the Candidate List, but only starting from 1 June 2011. However, there is no obligation to notify if the producer or importer of the article can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use and disposal. BPA does not fall under any of the criteria listed above. Producers or importers of articles made from BPA-based materials like polycarbonate and epoxy resin are not expected to have an obligation to notify the ECHA about BPA.



When does the “information obligation under Art. 33” apply to a supplier of an article?

The obligations apply to articles that contain above 0.1% by weight of a substance which is on the Candidate List. The supplier of such an article must “sufficiently inform” the recipient about the substance to enable the safe use of the article. As a minimum requirement, the name of the substance must be given. On request of a consumer, the supplier of the article must give the same information to the consumer within 45 days of receipt of that request. This information obligation does not apply to suppliers of articles made from polycarbonate or epoxy resin because BPA is not an SVHC and is not listed. Even if BPA were to be listed, it would still be exempt from information obligations: During the chemical process of polymerisation the intermediate BPA reacts and is firmly bound into the structure of the polymeric material. Technically unavoidable trace levels of free BPA in polycarbonate or epoxy resin articles are there for generally far below the threshold of 0.1%.

How can I find out about the status of BPA registration?

There is an active information flow from manufacturers and importers to downstream users about the status and progress of the Registration process. On 1 January 2009, ECHA published the list of all pre-registered substances together with the first Registration deadline.



Where can I get more information on BPA and REACH and its effects on my business?

For questions related to BPA which are not covered in our published information documents, please contact the PC/BPA industry group of PlasticsEurope. For more general queries about REACH, your own trade association will give you guidance or will refer you to the numerous websites operated by ECHA, national authorities and industry organisations.

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