

**Implications of RAC opinion to re-classify BPA:**

**BPA based products manufactured under EU standards are safe, and continue to remain safe**

*On 12 March 2014, the ECHA's Risk Assessment Committee (RAC) adopted an opinion proposing to re-classify bisphenol A (BPA) as reprotoxic 1 B, i.e. 'presumed human reproductive toxicant', under the EU Regulation on the classification, labelling and packaging of substances and mixture (CLP). BPA is currently classified as reprotoxic 2, 'suspected human reproductive toxicant', under the CLP. The full RAC opinion is currently not available. The following provides an initial **explanation** of the implications of this decision.*

**BPA can continue to be used in food contact applications for consumers**

BPA complies with both the Framework Regulation for all food contact materials (EU No.1935/2004) and with the Regulation on plastics used as food contact materials((EU No 10/2011). **The 1B classification** – when it is enforced – **will not affect compliance with food legislation.**

Exposure to BPA is very low, and far below the safety levels set by the authorities.

- BPA is the chemical building block which is converted into the final material through chemical reaction processes: during the production of the plastic material, the BPA monomers firmly bind to each other, thus forming the polymer chain which then becomes the final material, e.g. polycarbonate or epoxy resin. Only technically unavoidable trace amounts of BPA remain in the polymer.
- BPA was thoroughly risk assessed by the European Food Safety Authority (EFSA), who calculated a maximum level of BPA that may be present in food. This level gives the limit at which the requirements of the Framework Regulation for all food contact materials and the Regulation on plastics used as food contact materials are met and takes into account a significant margin of safety.
- The **re-classification of BPA by the RAC is based on a hazard assessment**, i.e. on the intrinsic properties of the substance. **It is not a risk assessment**, which looks at the actual exposure to a substance. EFSA's assessment of BPA as a component of food contact materials has resulted in the establishment by the EU of a migration limit below which exposure to BPA is considered safe and renders the food contact material to be inert.
- Regulation on plastics used as food contact materials allows for many substances to be used for food contact applications despite the fact that they carry a hazard labeling. Therefore, a 1B classification of BPA will not affect its approved use for food contact applications.

**BPA not available to consumers, no consumer contact to BPA in mixtures**

BPA is a raw material used to produce other materials and it is not available to consumers. During professional uses, BPA is mainly used as an intermediate in the production of polymers, such as

polycarbonate and epoxy resin. These professional uses of BPA are several manufacturing steps away from the final article the consumer would be exposed to. Under REACH, an article is a product a consumer can buy and use. Cars, mobile phones, food cans, furniture, paint etc. are articles in this sense.

BPA may also be used in mixtures. The CLP regulation defines a mixture as “mixture or solution composed of two or more substances” which don’t react with each other. **There are no consumer uses of mixtures made with BPA.**

## **CLP sets hazard-related rules for labelling of substances classified as 1B but does not introduce bans on the substances**

CLP is the Regulation on classification, labelling and packaging of substances and mixtures. It aligns previous EU legislation on classification, labelling and packaging of chemicals to the GHS (Globally Harmonised System of Classification and Labelling of Chemicals). Its main objectives are to facilitate international trade in chemicals and to maintain the existing level of protection of human health and environment. The GHS is a United Nations system to identify hazardous chemicals and to inform users about these hazards through standard symbols and phrases on the packaging labels and through safety data sheets (SDS). The classification level defines the content of the warning label to be placed on the product to guide its safe use.

## **Professional uses of BPA already strictly risk-managed under REACH**

Handling of BPA during the production of polycarbonate and epoxy resin, processing of preparations or mixtures and their conversion into a final article are examples of professional uses. Maintenance work at home or on a car by a craftsmen company is also considered professional use. Product labels as defined by CLP are designed to inform the users about the intrinsic properties of a substance, about how to handle it safely, which personal safety protection to use, what to do in case of an accidental contact, etc. For BPA, stringent risk management procedures are already in place and included in the REACH dossier. Also with a 1B-classification, **a ban or substitution of BPA in these professional uses is neither foreseen nor necessary.**

*For further information please contact:*

Jasmin Bird  
Communications Manager  
PC/BPA-Group  
PlasticsEurope

Tel: +32 2 676 17 38  
Fax: +32 2 675 39 35  
Email: [jasmin.bird@plasticseurope.org](mailto:jasmin.bird@plasticseurope.org)  
Website: [www.bisphenol-a-europe.org](http://www.bisphenol-a-europe.org)