

Ms R Gross Project Manager Sustainable Products and Material Flows Division Öko-Institut e.V. Postfach 50 02 40 79028 Freiburg Germany

14 March 2008

## RoHS Additional Substances Study - Bisphenol A

## Dear Ms Gross

I am writing to you on behalf of the members of the Polycarbonate / Bisphenol A Group of Plastics Europe, representing the European producers of Bisphenol A (BPA), to express our concerns that BPA is among the substances to be studied in the report prepared by yourselves for DG Environment of the European Commission. BPA is the chemical intermediate from which polycarbonate and epoxy resins are made. It is converted into these plastics by chemical reaction.

In earlier correspondence you asked stakeholders to provide additional information and to comment upon the selection of high priority substances. You ask if there are risk / exposure assessments available for the listed substances. In the case of BPA, the Existing Substances Risk assessment report of 2003 has recently been updated. The final reports for both human health and environment, which have been agreed by the Member States in the Technical Committee for New and Existing Substances (TC NES), are available for review in your study.

The conclusions of these assessments which are relevant to your report are, in summary:

- There is <u>no risk to health of consumers</u> from the normal handling and use of articles made from BPA-based polymers, such as polycarbonate and epoxy resins;
- BPA is not an endocrine disrupter according to the Weybridge definition;
- Valid chronic studies with environmental species do not show endocrine-mediated effects at environmentally relevant concentrations;
- BPA is readily biodegradable and not persistent or bioaccumulative;
- Half-life in surface water is about 1.5 days;
- BPA is not a PBT or vPvB substance;
- There is an extensive data set of high quality ecotoxicological studies of effects of BPA on environmental species of major systematic groups;
- The updated RAR sets out concentrations of BPA in surface water derived both from EUSES modelling and from the data contained in approximately 80 scientific publications containing monitoring data from 11 EU countries together with Switzerland and Norway. The risk characterisation shows no concern for surface waters.
- Indeed, the risk characterisation in the updated RAR shows <u>no concern for any environmental compartment</u> arising from BPA releases from manufacturing plants or from emissions to the environment from polycarbonates and epoxy resins;
- There is no risk of secondary poisoning arising from the aquatic compartment.

It has been established that risk assessments carried out under the European Union's Existing Substances Regulation are required to use best available science. They are reviewed and agreed by TC NES, the most senior technical committee for risk assessment of the EU, consisting of expert delegates from the Member States, and further reviewed by the Scientific Committee for Health and Environmental Risks, effectively the highest scientific quality assurance committee of the Union. Therefore, EU risk assessments, where they exist, should in our opinion be the primary source of information.

You say in earlier correspondence that you wish to refine the list of substances by taking all available information into account. In these circumstances, and having regard to the short timescales involved in the completion of your report, we urgently request a meeting between representatives of our group and yourselves in which we will explain in detail the points set out above, with the objective of removing BPA from the listed substances.

I will contact you early next week with a view to arranging urgently a meeting to discuss these matters.

Yours sincerely

Dr Michael Burcher Regulatory Affairs Manager Polycarbonate/Bisphenol A Group Plastics *Europe* 

Secretary Tel: +32 (0) 2 676 1738 Office Tel: +44 (0) 1245 356366 Office Fax: +44 (0) 1245 356399 Mobile: +44 (0) 7802 177762

E-mail: michael.burcher@plasticseurope.org