EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
**C7 - Risk assessment**

# SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

# SCHER

## Opinion on

# "Risk Assessment Report on Tetrabromopbisphenol-A

# Human Health Part"

## CAS N°: 79-94-7

## EINECS N°: 201-236-9

**Adopted by the SCHER during the 7th plenary meeting of 23 September 2005**

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## 1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

## 2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

(1) Does the SCHER agree with the conclusions of the Risk Assessment Report?

(2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

## 3. OPINION

The health part of the document is of acceptable quality, it is comprehensive and the exposure and effects assessment follows the Technical Guidance Document. The RAR covers most of the studies relevant for exposure and hazard assessment of tetrabromobisphenol A, a list of several more recent publications on the toxicology of tetrabromobisphenol A is attached below.

For exposure assessment, the RAR uses several realistic scenarios for occupational settings. Due to limited data availability, air concentrations measured in a small pilot experiment and some monitoring data from industry are used. In the developed scenarios, a potential for high exposure to tetrabromobisphenol A is only present during the addition of tetrabromobisphenol A to batches of polymer; exposures during the other scenarios is estimated to be very low. Regarding indirect exposure, the exposure assessment is based on a total diet survey where concentrations of tetrabromobisphenol A were below the limit of detection in all of the 121 food and drink categories examined. Based on these data, very low indirect exposures are predicted. The modelling of indirect exposure is only performed for undissociated tetrabromobisphenol A. With a $pK_a$ of 7.5, the compound may be dissociated in basic soils. This will result in a different distribution and model output.

The toxicology of tetrabromobisphenol A is described in detail in the RAR and all conclusions are supported by the toxicology data. The potential of tetrabromobisphenol A for acute, chronic, and reproductive toxicity is low and no effects considered as adverse were observed in a 90 day oral study and in a recent guideline compliant two generation study in rats up to a dose of 1 000 mg/kg. Tetrabromobisphenol A is not irritating to the eyes and the skin, is not a sensitizer and is not genotoxic. Effects on the endocrine systems are not observed in vivo and this endpoint is therefore not considered as relevant for hazard and risk assessment. The SCHER also agrees with the conclusion that there are no concerns for the carcinogenicity of tetrabromobisphenol A and

supports conclusions ii)[1] for all exposure scenarios since the Margin of Safety (MOS) are very large.

The very low potential for toxicity in mammals is most likely the result of the very limited systemic bioavailability of tetrabromobisphenol A due to an efficient first-pass metabolism. Bioaccumulation of structurally similar polybrominated diphenyl ethers has been observed. However, due to low systemic biovailability and efficient conjugation of the phenolic groups in tetrabromobisphenol A, bioaccumulation of this compound is not considered to be of concern.

To improve the readability of the document, a table on the calculated MOS for the different exposure scenarios may be helpful. The reference to the WWF-study should be omitted since no information on experimental procedures and quality control is available in the document or from the cited website, limit of detection was variable and limit of quantisation is not given.

## 4. REFERENCES

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Reistad, T., Mariussen, E., and Fonnum, F. (2005). The effect of a brominated flame retardant, tetrabromobisphenol-A, on free radical formation in human neutrophil granulocytes: the involvement of the MAP kinase pathway and protein kinase C. *Toxicol Sci* **83**, 89-100.

## 5. ACKNOWLEDGEMENTS

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[1] *According to the Technical Guidance Document on Risk Assessment – European Communities 2003:*
*- conclusion i): There is a need for further information and/or testing;*
*- conclusion ii): There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;*
*- conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.*