EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENE DIPHENOL (TETRABROMOBISPHENOL-A) Environmental Part

CAS Number: 79-94-7
EINECS Number: 201-236-9

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

Opinion adopted by the SCHER during the 21st plenary of 15 January 2008

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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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

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

1. Does the SCHER find the conclusions of the targeted risk assessment appropriate?
2. If the SCHER finds any conclusion not appropriate, the SCHER is invited to elaborate on the reasons for this divergence of opinion.
3. If the SCHER finds any specific approaches or methods used to assess the risks inappropriate, the SCHER is invited to suggest possible alternative approaches or methods meeting the same objectives.

3. OPINION

3.1 General Comments

The environmental part of the risk assessment of tetrabromobisphenol-A is in general of good quality. It uses properly the available information and presents justifications for the assumptions and decisions adopted in the RAR.

In general, the assessment is conservative. The main inconsistencies observed in the RAR are the use of different assessment factors for the derivation of the PNECs for the freshwater and marine compartments, even when data from marine organisms are employed for the derivation of the PNEC freshwater. In addition as the final conclusions are still pending on the assessment of the transformation product bisphenol-A, SCHER considers that the conditional conclusions ii)[1] should not be included.

Regarding secondary poisoning, the description of the mammalian assays in the environmental part is too scarce for supporting the conclusion, and the RAR mentions that new data may become available. Thus SCHER will not comment on this part of the assessment and suggest revisiting this aspect in line with the assessment of the human health part.

[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.*

3.2 Specific Comments

3.2.1 Exposure assessment

Tetrabromobisphenol-A is an ionisable chemical at environmentally relevant pHs with pK_{a1} and pK_{a2} were assumed to be 7.5 and 8.5 respectively. As a consequence, its solubility in water increases with the pH while the Kow decreases. This aspect should be considered in the assessment.

Tetrabromobisphenol-A is not produced in the EU. The RAR presents a good rationale covering the estimated import of tetrabromobisphenol-A as a chemical, and suggest a total amount of 6,500 tonnes/year; in addition, significant amounts is imported into EU as partly finished products (e.g. masterbatch, epoxy resins), and in finished products and components the RAR estimations are 6,000 and 27,500 tonnes/year, respectively.

The primary use (ca. 90%) of tetrabromobisphenol-A is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins. It may also be used (ca. 10%) as an additive flame retardant, generally in conjunction with antimony oxide, for example in the manufacture of acrylonitrile-butadiene-styrene (ABS) resins.

Tetrabromobisphenol-A is also used in the manufacture of derivatives, such as tetrabromobisphenol-A bis(methyl ether), bis(bromopropyl ether), bis(allyl ether), bis(2-hydroxyethyl ether), brominated epoxy oligomer, and carbonate oligomers. The main use of these derivatives is as flame retardants. According to the RAR there is no production of these derivatives in the EU by industries represented by the main consortium.

There is some evidence that shows that, under certain pyrolysis conditions, the presence of tetrabromobisphenol-A can lead to the formation of small amounts of brominated dibenzo-p-dioxins and dibenzofurans; an Annex presents quantitative estimations.

Releases are presented using default TGD values and when available industry specific information. SCHER welcomes this approach which is expected to increase the transparency of the assessment, unfortunately, not all relevant site-specific information has been presented in the RAR.

Based on the results of biodegradation tests, tetrabromobisphenol-A is not readily biodegradable but can undergo primary biodegradation to form several products, including bisphenol-A. The potential for bioaccumulation is properly assessed in the RAR. A conservative fish BCF of 1,234 l/kg is used in the environmental risk assessment representing a worst case BCF based on total radioactivity. Due to extensively metabolism, the BCFs based on tetrabromobisphenol-A itself are well below this value (range 160-485 l/kg for fish and around 148-160 for marine invertebrates). Excretion of tetrabromobisphenol-A and metabolites from aquatic organisms and mammals is very rapid. No accumulation in lipid tissues has been observed in toxicokinetic studies with mammals.

The emission assessment is appropriated considering the limited amount of information available and should be considered as conservative. Regarding, the uncertainty mentioned in the RAR on the bioavailaibility of environmental exposures associated to wastes (3.1.0.3.3 Waste remaining in the environment), SCHER considers that exposure to organisms should be expected as a result of the fragmentation and liberation of particles from articles. This is partly verified by the high exposure to BFRs from indoor dust and also by the levels found in sludge; considering that the BFRs in dust samples are bioavailable (e.g. Wilford et al., 2005; Karlsson ET AL., 2007).

In general, the predicted values are also in reasonable good agreement with the measured data.

3.2.2 Effect assessment

There are studies covering freshwater and marine organisms available, and the RAR includes a specific assessment on the potential for endocrine disruption, concluding that this is of low relevance. In general SCHER agrees with the interpretation of the study results presented in the RAR, but disagrees with the use of different assessment factors for freshwater and marine systems when all available information has been combined and, in fact, the PNEC freshwater is based on the NOEC from a marine organisms.

Regarding the PNEC for soil, SCHER supports the use of the PNEC derived from toxicity tests and in fact does not see the need for considering the equilibrium partitioning method when toxicity tests covering the three taxonomic groups are available.

Regarding secondary poisoning, the description of the mammalian assays in the environmental part is too scarce for supporting the conclusion, and the RAR mentions that new data may become available. Thus the SCHER will not comment on this part of the assessment and suggest revisiting this aspect in line with the assessment of the human health part.

3.2.3 Risk characterisation

SCHER agrees with the proposed PEC/PNEC ratios for fresh- waters and sediments, sewage treatment processes and soil; but as conclusion ii) is still pending on the outcome of the Bisphenol-A assessment, the committee considers that it should be more appropriate to limit the conclusions to i) and iii) and do not include the conditional conclusion ii).

As mentioned above, the committee cannot comment on the risk for secondary poisoning as no enough toxicological information has been provided.

Regarding the marine risk assessment SCHER agrees that tetrabromobisphenol-A cannot be considered a PBT chemical. The committee disagrees with the proposed PEC/PNEC values based on different assessment factors than those employed for the freshwater compartment, however, the potential risk associated to the production of bisphenol-A should be considered and the committee suggests conclusion i) for this compartment.

4. LIST OF ABBREVIATIONS

ABS	Acrylonitrile-Butadiene-Styrene
BCF	Bio-Concentration Factor
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulating Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted no effect concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. REFERENCES

Wilford BH, Shoeib M, Harner T, Zhu J, Jones KC. Polybrominated diphenyl ethers in indoor dust in Ottawa, Canada: implications for sources and exposure. Environ Sci Technol. 2005 39(18):7027-35.

Karlsson M, Julander A, van Bavel B, Hardell L. Levels of brominated flame retardants in blood in relation to levels in household air and dust. Environ Int. 2007 33(1):62-9.