EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on hexabromocyclododecane Environmental Part

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

Opinion adopted by the SCHER during the 23rd plenary of 6 May 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).

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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.
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http://ec.europa.eu/health/ph_risk/risk_en.htm

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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 hexabromocyclododecane (HBCD) is very good and has been done using the methodology proposed in the Technical Guidance Document. The extensive descriptions of the studies used in the exposure assessment (220 pages) makes the document hard to read and much of it could have been annexed.

The compound is mainly used as a flame retardant for polystyrene and acrylic/latex for textile coatings. It exists as three diastereomers with somewhat different properties, but most effect studies are performed with the technical products so the assessment is focussed on that. It is presently only one producer in Europe and the annual production is estimated to 6000 tons. HBCD is a lipophilic compound with low water solubility and it is semivolatile.

A fundamental question, which is not addressed, is whether the HBCD is dissolved in the polymer or if it is present as particles in the matrix. The emission will probably be different from pure HBCD particles than from a polymer solution of the compound.

The predictions of environmental concentrations of HBCD based on EUSES are for several scenarios quite different from measured values. It would have been useful if the assessors had described possible reasons for that in order to give a basis for future improvements of the models.

A large number of activities involving HBCD are assessed and it seems that a substantial fraction of them are going on in the same region. It would be reasonable to look at the total impact on the environment in that region, even if that is not demanded by the TGD.

SCHER supports most of the conclusions of this risk assessment. A possible exception is the PBT classification as new data seems to indicate a rapid decrease in HBCD in porpoises along the UK coast after the production was ended in that country.

3.2 Specific Comments

3.2.1 Exposure assessment

The RAR includes an extensive exposure assessment mainly based on the EUSES model. It is not clear if the small HBCD particles added to the polymers are dissolved in the matrix or if they remain intact particles sitting in the matrix. If the latter is the case it would change several of the conclusions regarding the exposure. There are, however, rather many measurements of HBCD in the environment that can be used to validate some of the predicted levels. It is important to use every opportunity to do this in order to learn the limitations of the models being use, and collect experiences for their improvement.

In this assessment of HBCD the discrepancies between predicted and measured concentrations are for several matrices pretty large although there are rather many measurements available. The assessors prefer in most cases to use the predicted values which is not in accordance with the advice in the TGD. The continental PEC is even lower than the lowest background measurements. In the marine assessment a correction of the predicted values are done based on measured values.

Part of the information from industry seems optimistic, e.g. zero emission to water due to recycling of waste water.

There are many different sources to HBCD in the environment and PECs from each of them are individually compared with the PNEC. A large fraction of those sources seems to be concentrated in one area and it would probably be more relevant to add the emissions to predict a total PEC for that area.

The major sources of HBCD emissions to the environment will in the long run be from products in use, especially construction materials, and waste. The magnitude of these sources is still very difficult to estimate.

3.2.2 Effect assessment

The assessment of HBCD is complicated by the different forms the molecule can have. The main diastereomers are α-, β- and γ-HBCD and they have different water solubility. In most cases effect studies are performed with the technical mixture and up to 66 µg addition per litre all three forms are soluble but there the γ-HBDC becomes saturated. To reach the maximum solubility of the α-HBCD 610 µg of the technical mixture has to be added, and thus tests in this region will be done with different compositions of the agent. Above 610 µg/L the composition will be constant but different from the technical product. The ratio of the diastereomers will change in the environment and the effect of a certain total HBCD level may therefore be difficult to compare with the test results. However, with the present knowledge the assessment has to focus on the total HBCD levels.

Tests in the aquatic environment include long term tests on species at three different trophic levels and a NOEC for Daphnia of 3.1 µg/l has been used to derive a $PNEC_{water}$ of 0.31 µg/l. The available data also allow for a calculation of a PNEC for intermittent emissions, $PNEC_{STP}$ and $PNEC_{sediment}$ all according to the TGD.

Effects in the terrestrial environment have been studied with plants, earthworms and micro-organisms representing three trophic levels, and thus an assessment factor of 10 could be used, resulting in a $PNEC_{soil}$ of 5.9 mg/kg dry soil.

The uncertainties in the determination of the $PNEC_{oral}$ for non compartment effects are discussed and the provisional result will have to be reconsidered when results from the ongoing studies on mammalian toxicity are obtained. The bioaccumulation also needs to be taken into account in this assessment.

The assessment of the risk for the marine environment is also supported by SCHER, including the determination of the $PNEC_{intermittent}$ for this compartment.

3.2.3 Risk characterisation

A number of the activities including HBCD gives PEC/PNEC ratios above 1, and there is also a number giving slightly below 1 and thus add to the risk for effects in the environment if they are located together with other significant emitters of the substance.

SCHER agrees with the call for a valid earthworm BCF study, and supports the conclusions made in the risk characterisation for the different compartments, including the discussion on dilution of the intermittent emissions in the sewage sludge.

In the PBT assessment the B and T criteria are satisfied while the persistence is on the borderline. In one of two tests the criterion was fulfilled, but in another the degradation under aerobic conditions was faster than the threshold for the P classification. Based on measurements in sediment cores and the presence of the substances in remote areas the assessors classify it as PBT. However, recent analyses in the UK show rapidly decreasing levels of HBCD in porpoises after the production of HBCD in Aycliffe was ended in 2003 (unpublished data CEFAS, submitted for publication). This may indicate that the substance is not very persistent in the environment and that the PBT classification needs to be reconsidered following publication of Aycliffe data.

4. LIST OF ABBREVIATIONS

BCF	Bioconcentration factor
EUSES	European Union System for the Evaluation of Substances
HBCD	Hexabromocyclododecane
NOEC	No observed effect concentration
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
RAR	Risk assessment report
TGD	Technical Guidance Document