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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

"Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether)"

Final Environmental Draft of May 2004

CAS Number; 1163-19-5

EINECS Number: 214-604-9

Adopted by the SCHER
during the 4th plenary of 18 March 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

(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. GENERAL COMMENTS

The CSTEE has given opinions (19 June 2000 and 31 October 2002) on two earlier versions of the environmental part of the risk assessment report on DeBDE. The present document is an update including a number of results from monitoring and research activities regarding this substance. A large fraction of the new data is produced by industry as a result of the earlier versions of this risk assessment report.

DeBDE has very low vapour pressure and water solubility, and it is very persistent and lipophilic. The molecule is, however, so big that the uptake in organisms is low (or at least slow) and thus the bioaccumulation limited. The TGD, used for risk assessment of chemicals in the EU, was not developed for this type of substances and it is therefore not surprising that some of the results of its use are unreliable.

The SCHER thinks the update of the risk assessment is well done, but does not agree with the recommendation that further update of the assessment shall rely on mainly monitoring data and be revisited in three years time. The research activity in this area is very active and new results will appear frequently. These must be put into the assessment as soon as possible to see if further management of this compound is necessary. Special interest has to be focussed on degradation products (both nonpolar and polar), which are not covered by the planned monitoring. The results showing neurotoxic effects also need to be verified.

Emissions of DeBDE to the environment may constitute serious problems in the future. If formation of lower brominated, bioaccumulating substances take place this process can go on for a very long time and there are no possibilities to stop it. The previous scientific committee (CSTEE) said that the uncertainties in the fate of DeBDE warrant risk reduction measures. Today there is further evidence for degradation of this substance to potentially harmful compounds and SCHER also strongly recommends further risk reduction (conclusion iii[1]).

[1] *According to the Technical Guidance Document on Risk Assessment – European Communities 2003:*

Alternatives with properties similar to those of DeBDE should not be used until proven environmentally safe.

4. SPECIFIC COMMENTS

4.1. Exposure assessment

DeBDE is no longer produced in the EU, and industry has measured the emissions from different use sites indicating orders of magnitude lower values than those used in the previous assessment. The assessor carefully expects realistic worst cases to be somewhere between those levels.

The levels of DeBDE in fish seem to be low, but higher concentrations have been found in other species, especially predatory birds. A study on peregrine eggs from the UK indicates increasing levels of DeBDE over the period 1980-1995 (de Boer et al., 2004). All of 41 eggs from the same species collected at Greenland also contained DeBDE (Sörensen et al., 2004). The presence in animals far away from known sources also indicates that the compound may be transported in the environment over large distances, but it is difficult to exclude that at least part of this transport has taken place in consumer goods. Air transport was shown in measurements at a remote island in the Baltic where the concentrations of DeBDE was comparable to the total PCB levels, in rain the DeBDE was much higher than total PCB (ter Schure et al., 2004).

There are a number of reports on DeBDE in sewage sludge, and the compound is also found in areas where there is no known professional use of it. This indicates a diffuse, widespread emission that may continue as long as there are consumer goods containing DeBDE in use.

The assessor was not aware of any new information on levels of DeBDE in soil. Also here ongoing research will give extended knowledge and the compound is found in Swedish soil that has been treated with sewage sludge, and it is also present in earthworms in that soil (Ulla Sellström, personal communication).

A crucial question is if DeBDE is degraded to other persistent lipophilic substances in the environment. Several studies have shown photolytic conversion to lower brominated diphenyl ethers, especially in organic solvents, and low-brominated dibenzofurans have also been found. Under environmental conditions (in aqueous systems or on air borne particles) this process also takes place, but seems to be much slower. Several ongoing research projects are addressing this question and more knowledge can be expected soon.

Polybrominated dibenzo-*p*-dioxins and –furans were studied in common cormorant livers and eggs from Japan (Watanabe et al., 2004). Compounds from both groups containing four to seven bromine atoms were found, with pentabromodibenzofuran at the highest concentration, homologues also found in photolytic experiments with DeBDE.

- 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.

Metabolic degradation of DeBDE can also give lower brominated BDEs, especially under anaerobic conditions. In an ongoing research project (FIRE), DeBDE was found to be degraded to nona- and octabromodiphenyl ethers rather quickly in anaerobic sediment in the dark (Parsons et al., 2004). This degradation has also been found in sewage sludge (Gerecke et al., 2005). There is also increasing evidence that DeBDE is metabolised to lower brominated diphenyl ethers in fish. Juvenile carp given DeBDE in the feed contained no detectable amount of this compound, but several ethers containing five to eight bromines were found (Stapleton et al., 2004). None of the HpBDEs was identical to BDE 183, which is the major component of the technical octaBDE product.

4.2. Effect assessment

There was limited amount of new data on effects of DeBDE, but a study of developmental neurotoxicity in mouse indicates an effect at 2.22 mg/kg bw, a result that calls for further studies in this field.

4.3. Risk characterisation

The PEC/PNEC ratios were all below 1 in the previous risk assessment, and with the lower emissions anticipated in this report they are still lower. In the PBT assessment, DeBDE is found to be very persistent, but not bioaccumulating due to the low bioconcentration factor. The SCHER considers that the bioconcentration factor approach included in the TGD for assessing the bioaccumulation potential is not applicable to DeBDE and related substances. Additional toxicokinetic information including metabolism is required to classify the real bioaccumulation potential of DeBDE. It is, however, proven that other PBT compounds can be formed in the environment. It is also concluded that the data on DeBDE levels in predatory birds' eggs are inconclusive for the moment, but as pointed out above there are now more data verifying the first observations. The SCHER agrees that it must be difficult to extrapolate the neurotoxicity effects seen in mice to birds' eggs.

5. REFERENCES

CSTEE opinion on the results of the Environmental Risk Assessment of Decabromodiphenyl ether (CAS N° 1163-19-5) (EINECS N° 214-604-9) Opinion expressed at the 16th CSTEE plenary meeting, Brussels, 19th of June 2000
http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out67_en.htm

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6. LIST OF ABBREVIATIONS

CSTEE	Scientific Committee on Toxicology, Ecotoxicology and Environment
DeBDE	Decabromodiphenyl ether
FIRE	Flame retardants Integrated Risk assessment for Endocrine effects
PCB	Polychlorinated Biphenyls
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
TGD	Technical Guidance Document

7. ACKNOWLEDGEMENTS

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