



Scientific Committee on Health and Environmental Risks

SCHER

DRAFT OPINION ON

"CHEMICALS AND THE WATER FRAMEWORK DIRECTIVE: DRAFT ENVIRONMENTAL QUALITY STANDARDS"

Hexabromocyclododecane (HBCDD)

SCHER adopted this opinion at its 12<sup>th</sup> plenary on 30 March 2011

#### 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 Safety (SCCS), 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 (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

#### SCHER

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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## 1. BACKGROUND

Article 16 of the Water Framework Directive (WFD, 2000/60/EC) requires the Commission to identify priority substances among those presenting significant risk to or via the aquatic environment, and to set EU Environmental Quality Standards (EQSs) for those substances in water, sediment and/or biota. In 2001 a first list of 33 priority substances was adopted (Decision 2455/2001) and in 2008 the EQSs for those substances were established (Directive 2008/105/EC or EQS Directive, EQSD). The WFD Article 16 requires the Commission to review periodically the list of priority substances. Article 8 of the EQSD requires the Commission to finalise its next review by January 2011, accompanying its conclusion, where appropriate, with proposals to identify new priority substances and to set EQSs for them in water, sediment and/or biota. The Commission is now aiming to present its proposals to Council and the Parliament by June 2011.

The Commission has been working on the abovementioned review since 2006, with the support of the Working Group E (WG E) on Priority Substances under the Water Framework Directive Common Implementation Strategy. The WG E is chaired by DG Environment and consists of experts from Member States, EFTA countries, candidate countries and more than 25 European umbrella organisations representing a wide range of interests (industry, agriculture, water, environment, etc.). A shortlist of 19 possible new priority substances was identified in June 2010. Experts nominated by WG E Members (and operating as the Sub-Group on Review of Priority Substances) have been deriving EQS for these substances and have produced draft EQS for most of them. In some cases, a consensus has been reached, but in some others there is disagreement about one or other component of the draft dossier. Revised EQS for a number of existing priority substances are currently also being finalised.

The EQS derivation has been carried out in accordance with the draft Technical Guidance on EQS reviewed recently by the SCHER. DG Environment and the rapporteurs of the Expert Group that developed the TGD have been considering the SCHER Opinion and a response is provided separately.

## 2. TERMS OF REFERENCE

### 2.1 General requests to SCHER

DG Environment now seeks the opinion of the SCHER on the draft EQS for the proposed priority substances and the revised EQS for a number of existing priority substances. The SCHER is asked to provide an opinion for each substance. We ask that the SCHER focus on:

- 1. whether the EQS have been correctly and appropriately derived, in the light of the available information<sup>1</sup> and the TGD-EQS;**
- 2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

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<sup>1</sup> The SCHER is asked to base its opinion on the technical dossier and the accompanying documents presented by DG Environment, on the assumption that the dossier is sufficiently complete and the data cited therein are correct.

Where there is disagreement between experts of WG E or there are other unresolved issues, we ask that the SCHER consider **additional points**.

## 2.2 Specific requests on HBCDD

The SCHER is asked to consider **the two generic questions in the request**. There are no additional points.

## 3. OPINION

### 3.1. Responses to the general requests

#### 1. whether the EQS have been correctly and appropriately derived, in the light of the available information and the TGD-EQS;

Hexabromocyclododecane (HBCDD) is a flame retardant produced in large volumes that is used for impregnating textiles and polymers applied in building constructions, e.g., building insulation. HBCDD has been nominated as a POP recently (Tema Nord 2008). The dossier is largely based on the risk assessment report (RAR) made by the EC (2008) and includes a table of estimated environmental emissions, an overview of physicochemical parameters important for environmental distribution, and a list of concentrations in the environment (both predicted and reported in the literature). In addition experimental acute and chronic ecotoxicity data as well as mammalian and avian toxicity data from the literature are presented for evaluation of secondary poisoning risks. Finally human health is evaluated based on fish consumption and mammalian toxicity data.

Although the Predicted Environmental Concentrations presented in the dossier do not serve in the derivation of the EQSs themselves, SCHER wonders why direct releases of HBCDD to soil were not considered a relevant route of emissions for the derivation of PECs. The applications in textiles and building constructions imply that significant amounts of HBCDD can be expected to be in landfills and are likely to lead to direct emissions into soils.

The dossier states in chapter 6.1 that "*...for the risk characterisation, values [from model calculations] for  $PEC_{(regional\ freshwater)}$  and  $PEC_{(regional\ marine\ water)}$  were modified so that the resulting regional parts of the biota PECs became equal to median measured values selected to represent regional concentrations in ...fish ... and marine mammals...*". SCHER agrees in principle with such modifications, but it is not clear from the document which median values were used and, hence, it is not possible for SCHER to judge if proper modifications were indeed made. Moreover, SCHER is of the opinion that the reasons why the EUSES model provides overestimations for concentrations in regional waters should be clarified.

The AA-QS<sub>freshwater, eco</sub> is derived using the standard approach, i.e. an AF of 10 is applied to the most sensitive laboratory NOEC, as the three taxonomic groups are included in the dataset. SCHER considers the value of 0.0031 mg/L, chosen as the most sensitive chronic NOEC, to be reasonably close to the other NOEC value reported as >0.0025, and agrees with the arguments provided to reject the studies from Zhang et al. (2008) and Lower and Moore (2007). The AF of 100 applied to the lowest EC50 value for deriving the MAC-QS is acceptable.

The dossier does not make any comment on the possible differences between effects on freshwater and marine species. The data presented do not indicate that a clear difference would exist. Yet, an additional factor of 10 is applied in the derivation of the MAC- and AA-QS<sub>saltwater, eco</sub> for pelagic marine organisms. As indicated before

(SCHER, 2010) the SCHER does not support this approach and considers that potential differences between freshwater and marine ecosystems should be assessed case-by-case based on the available information and not by a generic addition of an additional factor of 10. Similarly for marine benthic organisms an additional factor of 5 is used, which SCHER does not support.

SCHER considers the choice of the critical NOEC study for secondary poisoning, being the quail study, as appropriate, also given the data presented in a recent review published by Arnot et al (2011), and appreciates the additional work done to find further evidence that confirms the mammalian toxicity data in the RAR. The dossier properly justifies the selection of the BMF values.

The strong bioaccumulation potential of HBCDD is clearly indicated by its bioconcentration factor in fish. The dossier properly justifies the selection of the BCF value and the ecologically relevant mammalian NOEC used in the assessment. The SCHER agrees with the proposed  $QS_{\text{biota}}$  value.

SCHER considers the NOAEL level selected ( $10 \text{ mg.kg}^{-1}.\text{d}^{-1}$ ) for evaluation of human health as inappropriate, since some lower values have been reported. The dossier does not provide a justification why these lower values were disregarded. The AF applied does however provide sufficient protection and the resulting  $QS_{\text{biota,hh}}$  is still more than 10x the  $QS_{\text{biota}}$ .

## **2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

The SCHER, therefore, considers that the most critical EQS in terms of impact on environment/health has been correctly identified.

## **4. LIST OF ABBREVIATIONS**

AA-QS	annual average quality standard
DAR	draft assessment report
DT50	half life for degradation or dissipation
EQS	environmental quality standard
FOCUS	FORum for the Coordination of pesticide fate models and their USE
HC5	hazardous concentration for 5% of the species
MAC-QS	maximum allowable concentration quality standard
PEC	Predicted Environmental Concentration
PBT	Persistent, Bioaccumulative and Toxic
SSD	species sensitivity distribution
TGD-EQS	Technical Guidance Document - Environmental Quality Standards
twa-MEC	time-weighted averaged Measured Environmental Concentration
WFD	Water Framework Directive

## **5. REFERENCES**

SCHER (Scientific Committee on Health and Environmental Risks) (2010), Opinion on Chemicals and the Water Framework Directive: Technical Guidance for Deriving Environmental Quality Standards, 16 September 2010

Tema Nord. (2008) Hexabromocyclododecane as a possible global POP. Nordic Council of Ministers, Copenhagen, DK.

European Commission RAR (2008) Risk assessment hexabromocyclododecane, CAS-no.: 25637-99-4, einecs-no.: 247-148-4, final draft may 2008; Swedish Chemicals Agency: Sundbyberg, Sweden, 2008; p 492.

Arnot JA, Armitage JM, McCarthy LS, Wania F, Cousins IT, Toose-Reid L (2011) Toward a consistent evaluative framework for POP risk characterization. Environ. Sci. Technol. 45, 97-103 and Supporting information.