Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

PBDE

SCHER adopted this opinion via written procedure on 15 July 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 (EMEA), 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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ISSN 1831-4775 ISBN 978-92-79-30708-9
doi:10.2772/95861 ND-AR-11-009-EN-N

ACKNOWLEDGMENTS

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Keywords: SCHER, scientific opinion,

Opinion to be cited as:

SCHER (Scientific Committee on Health and Environmental Risks), Opinion on draft environmental quality standards under the Water Framework Directive – PBDE, 15 July 2011

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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 Document on EQS (TGD-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. The SCHER should focus on:

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

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

[1] 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, the SCHER should consider **additional points**.

2.2 Specific requests on polybrominated diphenyl ethers (PBDE)

In addition, in the context of the first generic question, the SCHER is asked to consider whether the overall approach to deriving the EQS for the PBDEs is appropriate, given that the EQS is based on toxicological data for BDE 99 but intended to cover other PBDEs. BDE 99 is the most potent of the four congeners for which adequate toxicological studies appear to exist. (see also point (iii) below.)
In the context of the second generic question, the SCHER is asked to consider:

i. whether the recommendation in Sections 7.2 and 7.3 to monitor in fish and ideally in carnivorous fish is appropriate;

ii. whether appropriate BCF and BMF values have been used to calculate the corresponding values in water (to the biota standards) - see sections 7.2 and 7.3;

iii. whether, in view of the approach used to derive the EQS, based on toxicological data for BDE 99, it is appropriate to apply it to the sum of the monitored concentrations of the following six indicator congeners: triBDE 28, tetraBDE 47, pentaBDE 99 and 100, hexaBDE 153 and 154., or whether only BDE99 should be monitored, or (third alternative) whether the EQS should apply to the sum of the three congeners for which good toxicological data are available, i.e. BDEs 47, 99 and 153[2].

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;

General
The group of PBDEs constitutes a complex mixture with 206 individual substances[3]. The dossier proposes to derive a single EQS for the pentaBDE and octaBDE, including data on their main components which are tetra-, penta-, hexa- and hepta-BDE where appropriate. This EQS value, expressed in µg/kg food and proposed for compliance check with biota concentrations, will apply in monitoring terms to the sum of the following six indicator congeners in fish: triBDE 28, tetraBDE 47, pentaBDE 99 and 100, hexaBDE 153 and 154.
The dossier argues that: "There are not enough reliable congener-specific ecotoxicological data available to allow the derivation of congener-specific QS values or identify the most toxic congener.", and "As for direct toxicity), the interpretation of the toxicity data for BDE compounds is not straightforward as data are not available for all congeners separately and as the relative toxicity of these congeners is not elucidated."

[2] These three congeners are expected to be identified in a forthcoming EFSA opinion on the polyBDEs, along with another congener (BDE 209) less relevant to the aquatic environment.

[3] The three mono brominated congeners are excluded from the definition of polybrominated diphenylethers (PBDE)

The major criticism to the approach followed in the EQS derivation is that the toxicological studies selected in the dossier in some instances refer to the testing of commercial PBDE mixtures, whereas in others single-compound studies are used for the evaluation. In so far as can be judged by SCHER no corrections were applied to normalize to a single congener (e.g. PBDE 99) or, vice versa, from a single congener to a mixture, so as to make all studies more comparable. Although SCHER acknowledges the variability and uncertainties in congener composition of commercial mixtures, this normalization approach may be more optimal than the one actually used and should perhaps be considered.

Specific Quality Standards (QS)

For the derivation of $QS_{water,eco}$ and QS_{sed}, different compounds are identified as the most toxic ones, i.e. the EQS are based on the NOECs for the tetra- and hexaBDE, respectively. Comparison of the EQS with monitored concentrations of different compounds assumes that the same mode of action and toxicity apply, which may not be so, although it is a practical approach in the absence of more data on the individual substances (see answer to specific question (iii) below).

On the $QS_{biota,human\ health}$, the dossier provided to SCHER states:' As regards their toxicity potential, BDE compounds have shown various responses, such as Ah-receptor-dependent responses, e.g. thyroid hormone perturbation (Hallgren and Darnerud, 2002; Zhou *et al.*, 2002; Stoker *et al.*, 2004), hepatic CYP 1A1 enzyme induction (Peters *et al.*, 2004), impaired spermatogenesis (Kuriyama *et al., 2005*), neurodevelopmental toxicity (Eriksson *et al.*, 2001b; Eriksson *et al.*, 2002; Viberg *et al.*, 2003b; Viberg *et al.*, 2003c; Viberg *et al.*, 2004; Viberg *et al.*, 2006; Sand *et al.*, 2004), or neurobehavioural toxicity (Branchi *et al.*, 2002). Yet, the study of Kuriyama may not be relevant until the ambiguity about the Ah-receptor dependent endpoints has been solved.' And: 'Given the above considerations on the weakness of the argumentation in favour of taking account of Ah-receptor-dependent endpoints, the former threshold level (based on LOAEL from Branchi's studies) should be used for the derivation of the $QS_{biota,\ hh}$.'

Hence, although there are more references demonstrating Ah-receptor mediated responses due to PBDEs, the study of Kuriyama is disqualified because the possible (but not proven?) presence of 2,3,7,8-tetrachlorodibenzodioxin in the PBDE mixture used for testing. Whether or not the other toxicity studies presented in the document have been judged using the same criticism is not clarified by the dossier, and hence the criticism of the Kuriyama study seems rather arbitrary for the time being.

The dossier correctly concludes that "Conversion from EQS in biota to an equivalent concentration into water should be considered with caution, since the BCF and BMF chosen for the conversion have been derived from data on individual compounds."

The dossier notes that for PBDEs, there are few marine toxicity data but that no further indications exist of a difference in sensitivity between freshwater vs. saltwater organisms. The single marine algal species tested does not show a higher sensitivity than its freshwater counterparts, and the marine fish data may show a slightly more sensitive species but the data cannot be compared properly as different endpoints have been used. Yet, an additional factor of 10 is applied in the derivation of the MAC- and AA-$QS_{saltwater,\ eco}$ for pelagic marine organisms. Similarly a factor of 5 is used for marine sediment/dwelling 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 application of an additional factor of 10 or 5.

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

The $QS_{biota\ human\ health}$ is properly identified as the most critical EQS of the ones derived in the dossier. However, due to the considerations given above, SCHER concludes that deriving a QS from the dataset presented is subject to large uncertainties.

3.2 Responses to specific requests on PBDEs

(i) whether the recommendation in Sections 7.2 and 7.3 to monitor in fish and ideally in carnivorous fish is appropriate;

Determination of concentrations of PBDEs in fish would be appropriate for monitoring compliance with the proposed annual average quality standard (AA-EQS) and human health exposure.

(ii) whether appropriate BCF and BMF values have been used to calculate the corresponding values in water (to the biota standards) - see sections 7.2 and 7.3;

A. BMF

It is not clear to SCHER how the selection of BMF1 and BMF2 values (5 and 20 respectively) has been made. According to Table 5.3 mean single BMF1 values range from 0.4 to 11, and BMF2 from 0.1 to 700. As for BMF 1, the dossier argues that "it covers almost all trophic chains among the ones reported in TMF studies, except the ones including top predators, e.g. seabirds." It is not clear to SCHER why seabirds should be exempted from the selection of BMF1. The dossier also states that the more frequently "encountered values for BMF 2 are between 10 and 70 and that a high(er) degree of biomagnification for seabirds has been shown", but gives no clear arguments why a value of 20 has been chosen.

B. BCF:

The dossier states that BCF potential of tetra, penta and hexa congeners is much higher than hepta and octa congeners. However, data shown in Table 5.3 show : tetra : 19000-46000 ; penta 1400-46000; hexa 2500-46000, hepta 2100 (only one value tabulated) ; octa 175-40000. Most of these data are BCF values estimated from log Kow and do not clearly confirm the conclusion of the higher bioconcentration potential. This conclusion cannot be based on the measured data presented, as measured data are only tabulated for tetra, penta and hexa, whereas for hepta and nona no measured data appear available. For octaBDE Table 5.3 states 'experimental results indicate that octaBDE does not bioconcentrate' which SCHER considers insufficient (i.e. non quantitative) evidence. SCHER does, however, accept the viewpoint that the tetra and penta congeners have BCFs at the high end of the range of BCFs available for PBDEs, as well as the selection of the measured BCF value of 35100 of tetraBDE as the basis for the $QS_{biota\ secpois}$.

(iii) whether, in view of the approach used to derive the EQS, based on toxicological data for BDE 99, it is appropriate to apply it to the sum of the monitored concentrations of the following six indicator congeners: triBDE 28, tetraBDE 47, pentaBDE 99 and 100, hexaBDE 153 and 154., or whether only BDE99 should be monitored, or (third alternative) whether the EQS should apply to the sum of the three congeners for which good toxicological data are available, i.e. BDEs 47, 99 and 153.

SCHER considers none of the proposed approaches ideal, as indicated in the response to question 1. As long as there is no certainty about the similarity of modes

of action of all the congeners mentioned here there seems no firm scientific basis to use any of the three alternatives.

However, following the general discussion on the risk assessment for mixtures (SCHER 2011), SCHER proposes that it be assumed as a practical approach for the time being that all substances have the same mode of action and toxicity. This practical approach would mean that the total concentration of PBDEs (i.e. the sum of all individual PBDEs quantified in a sample) should be calculated and compared to the EQS. The assumption of a similar mode of action provides a likely conservative estimation of the risk (SCHER 2011); and the assumption of similar toxicity is supported in part by the toxicokinetic information which suggests the possibility for significant debromination in fish (Roberts et al. 2011). SCHER emphasises that these assumptions should be revised as soon as sufficient information on the mode of action and toxicity for each congener could become available.

4. LIST OF ABBREVIATIONS

AA-QS	annual average quality standard
EQS	environmental quality standard
MAC-QS	maximum acceptable quality standard
PBDE	polybrominated diphenylether
c-PBDE	commercial PBDE mixture
TGD-EQS	technical guidance document- environmental quality standard

5. REFERENCES

Roberts SC, Noyes PD, Gallagher EP, Stapleton HM. 2011. Species-specific differences and structure-activity relationships in the debromination of PBDE congeners in three fish species. Environ Sci Technol. 2011 Mar 1;45(5):1999-2005.

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