Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive"

POLYBROMINATED DIPHENYL ETHERS (PBDEs)

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by written procedure on 24 January 2023

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ABSTRACT

The dossier on Environmental Quality Standards for "PBDEs" is evaluated by the SCHEER according to the general mandate on EQS dossiers.

The current EQS Dossier is a revision of the PBDE dossier published in 2011 (EC, 2011). The revision deals with two sections, viz., the biota and the drinking water sections. Other sections have not been revised. The current Dossier thus proposes new QSs for biota, for secondary poisoning and for human health. Other QSs, which were derived in the 2011 dossier, remain unchanged. In the present Opinion, the SCHEER evaluated the revised sections and QSs (only).

The SCHEER endorses the **$QS_{biota,\ secpois,\ fw}$** of 0.384 µg kg_{ww}^{-1} for fish (rounded to: **0.38 µg kg_{ww}^{-1}**). The SCHEER does not endorse the $QS_{biota,\ secpois,\ sw}$ of 0.0128 because the BMF_2 of 20 is considered to be too low.

The SCHEER endorses the proposed values for **$QS_{water\ biota}$** of 6.11 x 10^{-6} (rounded to **6.1 x 10^{-6}µg L^{-1}**) **for freshwater** but does not endorse the $QS_{water\ biota}$ of 2.03 x 10^{-7} µg L^{-1} for marine waters.

The SCHEER endorses the **$QS_{hh\ dw}$** equal to 1.61 x 10^{-2} (rounded to **1.6 x 10^{-2} ng L^{-1}**).

Although the $QS_{water\ biota}$ could not be endorsed by the SCHEER, it is likely that the AA-QS in both fresh and marine water derived from $QS_{biota\ hh}$, equivalent to **4.5 x 10^{-6} ng L^{-1}**, will be the most critical value.

Taking into account that the application of Concentration Addition is still not possible due to insufficient toxicological information on individual PBDE congeners, the SCHEER considers that the best way forward is to relate the EQS to the sum-concentration of all PBDE congeners detected in an environmental compartment, both expressed on a molar basis.

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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 (EQS) 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 EQS for those substances were established (Directive 2008/105/EC or EQS Directive, EQSD). WFD Article 16 requires the Commission to periodically review the list. The first review led to a Commission proposal in 2011, resulting in the adoption of a revised list in 2013 containing an additional 12 Priority Substances. Technical work to support a second review has been underway for some time, and several substances have been identified as possible candidate Priority Substances. The Commission will be drafting a legislative proposal, with the aim of presenting it to the Council and the Parliament sometime around mid-2022.

The technical work has been supported by the Working Group (WG) Chemicals under the Common Implementation Strategy for the WFD. The WG is chaired by DG Environment and consists of experts from Member States, EFTA countries, candidate countries and several European umbrella organisations representing a wide range of interests (industry, agriculture, water, environment, etc.).

Experts nominated by WG Members (operating as individual substance Expert Groups and through the Sub-Group on Review of Priority Substances, SG-R) have been deriving EQS for the possible candidate substances and have produced draft EQS for most of them. In some cases, a consensus has been reached, but in others there is disagreement about one or another component of the draft dossier. The EQS for a number of existing priority substances are currently also being revised.

The EQS derivation has been carried out in accordance with the Technical Guidance Document on Deriving EQS (TGD-EQS) reviewed by the SCHEER[1].

2. TERMS OF REFERENCE

DG Environment now seeks the opinion of the SCHEER on the draft EQS for the proposed Priority Substances and the revised EQS for a number of existing Priority Substances. The SCHEER is asked to provide an Opinion for each substance. We ask that the SCHEER focus on:
1. whether the EQS have been correctly and appropriately derived, in the light of the available information;
2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.

No other questions or unresolved issues were identified in the appendix-26 to the EQS dossier 'PBDEs'.

For each substance, a comprehensive EQS dossier is or will be available. The dossiers contain much more information than simply the draft EQS; the SCHEER is asked to focus on the latter.

[1] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/ba6810cd-e611-4f72-9902-f0d8867a2a6b/details

In some cases, especially where additional points are raised, additional documents may be provided. Some of the studies referred to in the dossiers are not publicly available. If the SCHEER needs to see these studies, it is invited to please contact DG Environment.

3. OPINION

In a separate synthesis Opinion, the SCHEER provided a general discussion concerning the procedure and derivation of the EQS values and related topics and highlighted unresolved issues and weaknesses that are common to more than one substance and dossier.

According to the 'Appendix 26 – PolyBrominated Diphenyl Ethers' received by the SCHEER, two documents were submitted to the SCHEER, viz. the PBDE EQS Dossier (further referred to as the 'Dossier') and the SCHEER mandate addition - PBDE. Specific comments on the relevant sections of the dossier are listed below.

The current EQS Dossier is a revision of the PBDE dossier published in 2011 (EC, 2011) that was prepared by the Sub-Group on Review of the Priority Substances List (under Working Group E of the Common Implementation Strategy for the Water Framework Directive). The revision deals with two sections, viz., the biota and the drinking water sections. Other sections have not been revised. The current Dossier thus proposes new QSs for biota, for secondary poisoning and for human health. Other QSs, which were derived in the 2011 dossier, remain unchanged. In 2011, the SCHER evaluated the 2011 dossier (SCHER, 2011) and commented on a number of issues. In response, some amendments had been made and an explanation added to the dossier. The SCHEER recommends that the full dossier be evaluated for any necessary update.

The current Dossier proposes to derive a single common EQS for all mixtures of all isomers containing between 4 and 9 bromine atoms (tetra-, penta-, hexa-, hepta-, octa-, and nona-BDE congeners). This EQS value, expressed in μg kg^{-1} food and proposed for compliance checks with biota concentrations, are proposed to apply in monitoring terms to the sum of the following six indicator congeners in fish: triBDE 28, tetraBDE 47, pentaBDEs 99 and 100, hexaBDEs 153 and 154.

The current proposed EQSs might, in some cases, be less conservative than an approach where the sum of all BDEs would have been considered. It is noted that this would be the case in sampling sites where the six indicators are not the main contributors to the PBDEs concentration.

The SCHEER will comment on this approach in section 7.2.

Section 7 – Effects and Quality Standards

This EQS dossier on PBDEs has been revised in 2022 only in so far as the biota sections (Section 7.3 and 7.4) and the drinking water section (see Section 7.4) are concerned, due to the new TGD for EQS derivation updated in 2018 (EC, 2018). Section 2 (Existing evaluations and regulatory information) has been updated according to the most recent legislation and an additional section on mixture risk assessment (section 7.2) has been added. It is the opinion of the SCHEER that it would have been worth also revising the other sections of the document, considering that many new aquatic ecotoxicological data have been produced since 2010 (e.g., in the US EPA ECOTOX database).

According to the Dossier, there are "*numerous articles which report endpoints that are not usually accepted as effects assessment endpoints (developmental and behavioural effects, genotoxic effects, dietary exposure instead of direct exposure*)" and accordingly these were

not used in the Dossier. The SCHEER disagrees with this view and considers both developmental effects and dietary exposure relevant.

Most of the tests tabulated in the Tables in section 7.1.1 of the Dossier were conducted with commercial mixtures and it was therefore "*not possible to derive congener-specific QS values based on the commercial product ecotoxicological data because even if the content of the different congeners in each commercial product is well-known, the contribution of these congeners to the overall toxicity is not well-attested. Based on the information available, and considering the relationships between BDE congeners (i.e., possibilities for higher brominated compounds to degrade in lower brominated compounds) it is proposed to use all the data from the cited commercial products and their main components. The dataset contain data for algae, invertebrates and fish for acute and chronic exposures, and QS values will be derived based on the worst-case basis, i.e., derived from the lowest acute and chronic ecotoxicological data.*"

Section 7.1 – Acute and Chronic Aquatic Ecotoxicity

No change to the 2011 Dossier. As indicated above, the SCHEER is aware that additional data are available and recommends an update of the dossier.

Section 7.2 – Preclusion of mixture risk assessment

Evaluations made by the CONTAM Panel of the EFSA (2006, 2011) concluded that due to "*divergent responses*" of different toxicity endpoints and the limited information available, the establishment of common assessment groups of PBDE with the aim of mixture risk assessment (MRA) was precluded. In line with EFSA recommendations, in the 2011 EQS dossier (E.C., 2011) six congeners: triBDE-28, tetraBDE-47, pentaBDE-99 and 100, hexaBDE-153 and 154 were chosen as indicator congeners for BDE compounds in food. The SCHER in their Opinion (SCHER, 2011) considered that if there is no certainty about the similarity of modes of action of PBDE congeners, there is no good scientific basis for using any sum parameter. However, considering the general discussion on the risk assessment for mixtures, SCHER proposed that it should be assumed that all PBDEs exhibit the same mode of action and toxicity. This would support an approach where the total concentration of PBDEs be calculated by summing up individual concentrations (on a molar basis), with the aim of comparing the sum to the EQS (expressed in molar units). SCHER favoured this approach in view of the likely conservative estimation of the combined risks.

The SCHEER is aware that application of Concentration Addition (for example in the form of relative potency factors) is still not possible as the necessary ecotoxicological data to calculate QS values or relative potency factors for each congener are lacking. This is a knowledge gap. While the sum-concentration approach is conservative on the one hand (as not all PBDEs are as potent as BDE-99), it is also under-protective on the other, as no analytical monitoring campaign will be able to include all congeners.

The SCHEER reinforces that the best way forward is to relate the EQS to the sum-concentration of all PBDE congeners detected in an environmental compartment or in biota. For a risk assessment one would then sum up the (molar) concentrations of all the congeners detected in a monitored sample and compare that sum-concentration to the EQS.

It should be noted that many of the toxicological data presented in the literature are based on experimental tests with commercial mixtures of PBDEs rather than with individual PBDE congeners.

Section 7.3 – Secondary Poisoning

For the derivation of the $QS_{biota\ secpois}$, the Draft dossier presents test results for mice, rats and rabbits, including several new data in addition to those already used for the 2011 Dossier (Table 7.2). Reliability scores are not given for these studies. The new data in the Table are for a major part taken from a US-Agency for Toxic Substances and Disease Registry (ATSDR) document (Pohl et al., 2017) in which minimal risk limits on PBDEs were derived.

Due to their high Kow (log Kow=5.8-11), PBDEs are likely to accumulate. The experimental BCFs available vary between 2,100 and 35,000 L kg^{-1} for the tetra- to octaBDE congeners. Since the trigger value of BCF=100 is exceeded, there is a need for the evaluation of secondary poisoning. Reported BAF values of PBDEs are high (from 3.10^3 to 3.10^7) and trophic magnification factors (TMF) and biomagnification factors (BMF) vary between 0.53 to 97 for TMF while for BMF values between 0.4 to 11 (BMF1) and 0.1 to 370 (BMF2) are reported. For the selection of BAF values the Dossier proposes to use geometric means from three more recent studies on BDE-47 and BDE-99: 62,864 and 10,512, respectively. The SCHEER supports this selection. The SCHEER also supports the proposal to use a BMF of 5 (already proposed in the 2011 dossier) as an appropriate value to cover biomagnification from lower trophic levels to fish species (BMF1). While most studies report low values for BMF2, for BDE-47, pentaBDE and BDE-153 some very high values are reported. In the Dossier a value of 20 is proposed for BMF2, based on the observation that, in general, values between 10 and 70 are more frequently encountered. The SCHEER does not support the selection of this BMF2 value of 20. Considering the BMF/TMF values reported in the literature for top predators (birds and mammals), the SCHEER suggests that a higher value is more suitable and recommends that the BMF value be re-evaluated and that it includes some more recent literature reports.

For PBDE, a NOAEL, selected from an ATSDR evaluation of several studies on oral as well as inhalation toxicity of BDEs in mammals (Pohl et al., 2017), was selected as the lowest endpoint with a value of 0.001 mg BDE-47 $kg_{bw}^{-1}d^{-1}$ and used in the calculation of $QS_{biota,\ secpois}$. The SCHEER supports using this value.

The method followed in the dossier, according to the TGD (EC, 2018), is that based on energy normalised diet concentrations, using the following equation together with a bw of 200g for rat:

$$\log DEE\ [kJ/d] = 0.8136 + 0.7149 \cdot \log bw[g]$$

The energy normalised diet concentration for PBDEs can now be calculated with the following equation:

$$C_{energy\ normalised}\ [\mathrm{mg/kJ}] = dose \cdot \frac{bw\ (kg)}{DEE}$$

where the dose is the toxicological endpoint.

To derive thresholds for secondary poisoning, the energy-normalised endpoints were converted into threshold concentrations in the prey that is considered as the critical food item in the food chain (here fish and bivalves), using the following equation:

$$C_{food\ item}\ [\mathrm{mg/kg_{ww}}] = C_{energy\ normalised}\ [\mathrm{mg/kJ}] \cdot \mathrm{E}nergycontent_{fooditem,dw} \cdot \left(1 - moisturefraction_{fooditem}\right)$$

or:

$$C_{food\ item}\ [mg/kg_{ww}] = C_{energy\ normalised}\ [mg/kJ] * energy\ content_{food\ item,\ fw}$$

The energy contents used (RIVM, 2014) on a dry weight basis were 21 kJ g^{-1}_{dw} with a moisture fraction of 73.70% for fish and 19.3 kJ g^{-1}_{dw} for bivalves with a moisture fraction of 91.70%, respectively. The obtained $C_{food\ item}$ were:

- For fish: $C_{food\ item}$ [mg kg_{ww}^{-1}] = 0.00384.
- For bivalves: $C_{food\ item}$ [mg kg_{ww}^{-1}] = 0.001.

According to the SCHEER these values are correctly calculated.

The Dossier considers that "*Given that . . . bioaccumulation and biomagnification . . . depend on the congener considered, and given that biota repartition depends largely on geographical parameters, the recommendation of a given biota to monitor is more particularly tricky. However, it is well acknowledged that most BDEs covered in the present factsheet do bioconcentrate (e.g. tetraBDE, pentaBDE and hexaBDEs) and that some BDEs do biomagnify along the trophic food chain. Therefore, fish should be recommended as the trophic level to monitor when considering BDE congeners . . . . Therefore, an AF of 10 (AF 1 from Table 9, and AF 10 from Table 10 of the TGD (EC, 2018)) was applied to the $C_{food\ item}$ for fish, obtaining a final* ***$QS_{biota,\ secpois,\ fw}$*** *of 0.384 µg* kg_{ww}^{-1} ***for fish****).*" (rounded to **0.38 µg kg_{ww}^{-1}**).

The SCHEER agrees with applying these AFs and endorses the $QS_{biota,\ secpois,\ fw}$.

For the marine environment, the SCHEER agrees with the Draft dossier that biomagnification in top predators can occur for PBDEs. According to the TGD (EC, 2018), the $C_{food\ item}$ was obtained multiplying the $C_{energy\ normalized}$ by the energy content for birds and mammals of 23.2 kJ g^{-1}_{dw} and a moisture fraction of 68.4%. Afterwards, the value obtained is divided by the BMF from fish (BMF_1) to birds or mammals (BMF_2) (Equation 4). Afterwards, a proper lipid fraction normalisation between birds/mammals (10%) and fish (5%) was performed (Equation 4). The SCHEER, therefore, deleted this dry weight correction from equation 4.

$$QS_{biota,\ secpois,\ sw}\ [mg/kg] = (C_{food\ item,\ b/m}/(AF*BMF_{b/m}))*(lipid\ fraction_{fish}/lipid\ fraction_{b/m})$$

Equation 4

For the derivation of the $QS_{biota\ secpois,sw}$ the following bioconcentration, bioaccumulation and biomagnification values are used: BCF=35100, BAF= 62864, BMF_1 = 5 and BMF_2 = 20. The SCHEER does not agree with the BMF_2 value selected (see above).

The $QS_{biota,\ secpois,\ sw}$ obtained was 0.0128 µg kg_{ww}^{-1} for fish. The SCHEER does not endorse this value.

The associated **$QS_{water\ biota}$** was obtained by applying a BAF for fish of 62,864 L $kg^{-1}_{BDE\text{-}47ww}$ resulting in values of 6.11 x 10^{-6} (rounded to **6.1 x 10^{-6} µg L^{-1}**) **for freshwater.** The SCHEER endorses this value but **does not endorse** the value of 2.03 x 10^{-7} µg L^{-1} for marine waters.

Section 7.4- Human Health

For the human health risk *via* the consumption of fishery products, according to the procedure described in the TGD (EC, 2018), the following equation is applied:

$$QS_{biota\ hh\ food} = 0.2\ TL_{hh} / 0.00163$$

The chosen value for TL_{hh} was a NAEL for reproductive toxicity from a study with BDE99 (Bakker et al, 2008) of 0.23 ng kg_{bw}^{-1} d^{-1}. The SCHEER endorses the selection of this value especially because BDE99 appeared to be the most toxic congener from three BDEs evaluated by EFSA (2011). Applying the equation above and an AF of 100 because of using a NAEL, a **$QS_{biota,\ hh}$** was calculated equal to 2.82 x 10^{-4}**,** rounded to **2.8 x 10^{-4} µg $kg^{-1}_{biota\ ww}$.** Applying next the aforementioned BAF of 62,864, the resulting **$QS_{biota\ hh}$** corresponds to a level of 4.48 x 10^{-9} rounded to **4.5 x 10^{-9} µg L^{-1}** in water. These values are correctly calculated according to the SCHEER.

For the exposure *via* drinking water, the are no standard guideline values available according to the Dossier. A calculated value of 0.00161 µg L^{-1} or 1.61 * 10^{-2} ng L^{-1} is therefore proposed using the TGD equation $QS_{dw, hh}$ = (0.2*TL_{hh}*bw)/$uptake_{dw}$, with a bw of 70 kg and an uptake of 2 L d^{-1} and the above mentioned TLhh of 0.23 ng kg_{bw}^{-1} d^{-1} with an AF of 100 because a NAEL was used for the TL. The SCHEER notes that the value in the Dossier text expressed in µg L^{-1} (0.00161) is not equivalent to the value expressed in ng L^{-1}(1.61 x 10^{-2}). The SCHEER, however, accepts the value tabulated in section 3, expressed in ng L^{-1}: the **$QS_{dw,hh}$** equal to 1.61 x 10^{-2} ng L^{-1} (rounded to **1.6 x 10^{-2} ng L^{-1}**).

4. ENDOCRINE DISRUPTION

In the past decades increasing evidence has become available that some brominated flame retardants may have endocrine-disrupting potencies (Hamers et al, 2006) both in humans and wildlife. PBDEs have been implicated in the disruption of estrogenic activity and signalling, and estrogen levels regulate thyroid hormones (Allen et al., 2016, Thornton et al., 2016). PBDE disruptions to thyroid signalling in fish appear to proceed through multiple pathways. PBDE exposures have also been linked to impacts on reproductive health with reductions in fecundity, spawning, hatching success, and offspring survival observed in some species, as well as impaired fertility (Noyes and Stapleton, 2014).

The SCHEER recommends further investigation of the effects of PBDEs on reproduction and on endocrine sensitive endpoints so that these effects can be included in the assessment of the ecotoxicity and human toxicity of PBDEs in the near future.

5. OPINION CRITICAL EQS

Although the $QS_{water\ biota}$ could not be endorsed by the SCHEER, it is likely that the AA-QS in both freshwater and marine water derived from $QS_{biota\ hh}$, equivalent to 4.5 x 10^{-6} ng L^{-1}, will be the most critical value. This value is also much lower than any of the MAC/AA-QSs that were derived in 2011 from acute and chronic ecotoxicity test data, respectively.

The SCHEER is aware of the very low value of the critical EQS, which will pose analytical problems when implemented.

6. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
AF	Application Factor
ATSDR	US-Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BDE	Brominated diphenyl ether
BMF	Biomagnification Factor
bw	body weight
DEE	Daily Energy Expenditure
dw	dry weight
EC	Effect Concentration
EFSA	European Food Safety Agency
EQS	Environmental Quality Standards
fw	freshwater, or fresh weight
hh	human health
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
NOEC	No Effect Concentration
QS	Quality Standard
PBDE	Polybrominated diphenyl ether
SCCS	Scientific Committee on Consumer Safety
SPM	Suspended Particulate Matter
SSD	Species Sensitivity Distribution
sw	saltwater, marine water
TGD	Technical Guidance Document for Deriving EQS (EC, 2018)
TL	Threshold Level
WG	Working Group (on Chemicals)
ww	wet weight

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