



**Scientific Committee on Health, Environmental and Emerging Risks
SCHEER**

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

HBCDD



The SCHEER adopted this document
By written procedure on 16 January 2023

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ABSTRACT

The dossier on Environmental Quality Standards for "HBCDD" is evaluated by the SCHEER according to the general mandate on EQS dossiers. However, in the case of HBCDD, the SCHEER was asked specifically to evaluate only the revision of the QSs that relate to secondary poisoning of top predators ($QS_{\text{secpois, biota}}$) and to human health due to food uptake ($QS_{\text{biota, hh}}$). The SCHEER therefore did not evaluate other QSs in the Dossier. Those other QSs were evaluated in 2011. The SCHEER recommends to update the other QSs because many new data on the aquatic toxicity of HBCDD have become available in the period 2011-2022.

The SCHEER endorses the $QS_{\text{biota, secpois, fw}}$ of $89.68 \mu\text{g kg}_{\text{ww}}^{-1}$ (rounded to **$90 \mu\text{g kg}_{\text{ww}}^{-1}$**) and the $QS_{\text{biota, secpois, sw}}$ of **$3.5 \mu\text{g kg}_{\text{ww}}^{-1}$** , both for **fish**.

The SCHEER also endorses the corresponding $QS_{\text{fw, biota}}$ equal to **$4.6 \times 10^{-4} \mu\text{g L}^{-1}$** , and the $QS_{\text{sw, biota}}$ of **$2 \times 10^{-5} \mu\text{g L}^{-1}$** .

The SCHEER endorses the $QS_{\text{water, biota hh}}$ of **$0.064 \mu\text{g L}^{-1}$** .

The SCHEER observes that the most critical EQS (in terms of impact on environment/health) has been correctly identified, being the $QS_{\text{sw, eco}}$ of **$2 \times 10^{-5} \mu\text{g L}^{-1}$** .

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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 other 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 on Deriving EQS (TG-EQS) reviewed by the SCHEER¹.

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 and to focus on:

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

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.

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.

In the case of the HBCDD dossier, this is an updated version of the Dossier published in 2011. The new version has been updated for the biota section due to the new Technical

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

Guidance for EQS derivation updated in 2018 (EC, 2018). Therefore, only the QS_{sec. pois.} and QS for human health have been updated.

We would like to draw the attention of the SCHEER to the fact that the provisional QS_{sec. pois.} is quite low compared to the previous one from 2011. In 2011, no distinction was made between a QS for freshwater and salt water, which is no longer the case. The provisional QS_{sec. pois.} for freshwater is 89.68 kg⁻¹_{biota ww} (the current one is 167 µg.kg⁻¹_{biota ww}) while for salt water is 3.5 kg⁻¹_{biota ww}.

We recommend the one for salt waters which has been refined thanks to the available biomagnification factors. Consequently, the SCHEER is asked to focus on the following (generic) questions in the request, reproduced below, and on the additional points identified in this cover note.

Generic questions to the SCHEER

- Have the EQS for secondary poisoning of top predators (QS_{secpois, biota}) and for human health due to food uptake (QS_{biota, hh}) been correctly and appropriately derived, in the light of the available information?
- Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

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 several other substances and dossiers.

The SCHEER received two documents, including the Hexabromocyclododecane EQS dossier-revision 2022 (further referred to as the 'Dossier') and the mandate addition entitled Appendix 33 – Hexabromocyclododecane.

Because the SCHEER was asked specifically to evaluate the revision of the QSs that relate to EQS for secondary poisoning of top predators (QS_{secpois, biota}) and for human health due to food uptake (QS_{biota, hh}), the SCHEER did not evaluate other QSs in the Dossier. Those other QSs were evaluated in 2011. The SCHEER notes, however, that since 2010 more than 700 aquatic records from 22 studies have been added to the US-EPA ECOTOX database. The SCHEER therefore recommends revising also other QSs for HBCDD.

Hexabromocyclododecane (HBCDD) is a widely used flame retardant in polymer and textile industry, and the sources of human exposure include production, industrial use, use of consumer products and indirect environmental exposure. HBCDD used in applications is a mixture of three diastereomers. The compounds are not readily biodegradable and may accumulate in biota (SCHER, 2008). According to the Dossier, the technical HBCDD products consist primarily of the γ-stereoisomer and with some α- and β-HBCDD. The stereoisomers have different chemical and physical properties. However, in most toxicity studies, commercial products containing all stereoisomers have been used. It is thus not possible to derive QSs for the stereoisomers separately. Furthermore, there is evidence for both abiotic and biotic isomerisation between diastereoisomers. The composition in environmental compartments therefore differs from the technical products and it can also shift within food webs. The QSs and EQS are derived for the sum of stereoisomers.

In 2008, the SCHER was asked to evaluate the health part of the Risk Assessment Report (RAR) on HBCDD (SCHER, 2008). The SCHER concluded that the health part of the RAR was

of good quality, comprehensive, and that the exposure and effects assessment followed the then prevailing Technical Guidance Document. The RAR was said to cover all available studies relevant for exposure and hazard assessment of HBCDD. In addition, as acknowledged in the RAR, further relevant information on health effects of HBCDD would be published in the near future.

In 2011, the SCHER was asked to evaluate the updated dossier on the QSs and EQS proposed for HBCDD (SCHER, 2011). The SCHER then concluded that the most critical EQS, being the $QS_{\text{biota, sec pois}}$, corresponding to an AA- QS_{sw} of $0.00080 \mu\text{g}\cdot\text{L}^{-1}$, had been correctly identified.

The SCHEER notes that in the current mandate given to the SCHEER (see section 2. above), the provisional QS values are given in incomplete units.

Section 7 – Effects and Quality Standards

Section 7.2 - Secondary Poisoning

Secondary Poisoning of top predators

The SCHEER agrees with the view that because HBCDD is classified as both POP and PBT substance with a high K_{ow} ($\log K_{ow} \sim 5.5$), and also suspected to be toxic to reproduction (ECHA), HBCDD fits the criteria to perform a $QS_{\text{biota, sec pois}}$ assessment. Furthermore, HBCDD is also listed as a substance of very high concern (SVHC).

The revised Dossier used as a starting point a NOAEL of $0.7 \text{ mg kg}^{-1}_{\text{bw}} \text{ d}^{-1}$ taken from a Japanese quail study (MOEJ, 2009), while disqualifying a mice study that found increased body and liver weight at $1.75 \mu\text{g kg}^{-1}_{\text{bw}} \text{ d}^{-1}$ as non-relevant at a population level. The SCHEER endorses the selection of the quail study.

The method followed in the dossier, according with the EQS Technical Guidance (EC, 2018), is that based on energy normalised diet concentrations. The calculation is based on the following procedure: The DEE (daily energy expenditure) is calculated with the following equation that represents the regression (experimentally determined) between DEE and body weight in non-passerine birds:

$$\log \text{DEE [kJ/d]} = 0.8387 + 0.6694 \cdot \log \text{bw[g]} \quad \text{Eq.1}$$

The body weight (bw) of 115 g from control animals (MOEJ, 2009) was used in Equation 1 to calculate a DEE of 162.25 kJ d^{-1} . According to the SCHEER the latter value should read 165.25 kJ d^{-1} (which is the value used in further derivations).

The SCHEER notes that equation 1 used in the Dossier is taken from a document from 2007 (DEFRA, 2007) instead of using the equation (for passerine birds) given in the TGD (EC, 2018). The JRC informed the SCHEER that equation 1 particularly refers to Galliformes (to which quail belong) and therefore the SCHEER endorses the value of the DEE presented in the Dossier. The SCHEER recommends adding this explanation in the amended Dossier.

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

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

where the dose is the toxicological endpoint. The obtained $C_{\text{energy normalised}}$ was equivalent to $0.487 \mu\text{g kJ}^{-1}$, which is calculated correctly and therefore endorsed by the SCHEER.

To derive thresholds for secondary poisoning, the energy-normalised endpoints should be 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:

$$C_{\text{food item}} [\text{mg/kg}_{\text{ww}}] = C_{\text{energy normalised}} [\text{mg/kJ}] \cdot \text{Energycontent}_{\text{fooditem,dw}} \cdot (1 - \text{moisturefraction}_{\text{fooditem}})$$

or:

$$C_{\text{food item}} [\text{mg/kg}_{\text{ww}}] = C_{\text{energy normalised}} [\text{mg/kJ}] * \text{energy content}_{\text{food item, fw}}$$

using an energy content of 21 kJ g⁻¹_{dw} and a moisture fraction of 73.7% for fish, (Verbruggen, 2014), the resulting $C_{\text{food item}} [\text{mg kg}^{-1}_{\text{ww}}] = 2.69 \text{ mg kg}^{-1}_{\text{ww}}$, which is calculated correctly. According to the Dossier the critical food item is fish, for which a motivation is given as follows "If the TMF(lipid)>0.8 or TMF(dry weight)>1.0 the critical food item is fish. The highest TMF for HBCDDs is 6.3, therefore the critical food item is fish". The SCHEER endorses the value.

An AF of 30 was then applied to derive the **QS_{biota, secpois, fw}** of 89.68 µg kg⁻¹_{ww} for fish (rounded value **90 µg kg⁻¹_{ww}**). The SCHEER endorses this value.

Since there is ample evidence for bioaccumulation and biomagnification in the marine food web and in top predators, an additional step was included. Using an adjusted $C_{\text{food.item}}$ for birds and mammals of 3.5714 and a BMF of 17 and applying again an AF of 30, the resulting $\text{QS}_{\text{biota, secpois,sw}}$ of 3.50 µg kg_{ww}⁻¹ for fish was obtained. The SCHEER can accept the values chosen for BMF and AF and endorses the resulting **QS_{biota secpois sw}** of **3.5 µg kg⁻¹_{ww}** for **fish**.

For the back-calculation of the $\text{QS}_{\text{fw, biota}}$, the dossier proposes to divide the $\text{QS}_{\text{biota, secpois, fw}}$ by a BAF. A BAF of 195,000 L kg⁻¹_{ww} (Harrad et al., 2009, 2010) was used in the equation:

$$\text{QS}_{\text{water, biota}} = \text{QS}_{\text{biota, secpois}} / \text{BAF}$$

thus obtaining a value for fish of **QS_{fw, biota}** equal to **4.6 x 10⁻⁴ µg L⁻¹**, and equal to **QS_{sw, biota}** of **2 x 10⁻⁵ µg L⁻¹**.

The SCHEER endorses the BAF selected and the corresponding QS_{biota} values.

Section 7.6 – Human Health

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

$$\text{QS}_{\text{biota hh food}} = 0.2 \text{ TL}_{\text{hh}} / 0.00163$$

where:

- $\text{QS}_{\text{biota hh, food}}$ = Quality standard for human health via consumption of fishery products (mg kg⁻¹_{biota})
- 0.2 = default fraction of TL_{hh} related to fishery products consumption
- TL_{hh} = threshold limit from mammalian studies (ADI or TDI) (mg kg⁻¹_{bw} d⁻¹)
- 0.00163 (kg_{fish}kg⁻¹_{bw} d⁻¹) = estimated daily fishery products consumption (default 0.115 kg d⁻¹) per kg body weight (default bw=70 kg).

A Derived No Effect Level of 0.102 mg kg⁻¹_{bw} d⁻¹ was selected from the ECHA dossier (ECHA, 2012) as threshold level for human health (TL_{hh}). Therefore, the resulting $\text{QS}_{\text{biota, hh}}$ is equal to 12.5 mg kg⁻¹_{biota ww}. Using a BAF of 195,000 L kg⁻¹_{ww} the resulting **QS_{water, biota hh}** is equal to **0.064 µg L⁻¹**. The SCHEER endorses this value.

For the exposure *via* drinking water, the same DNEL was selected as TL_{hh} and the formula

$$\text{QS}_{\text{dw, hh}} = (0.2 * \text{TL}_{\text{hh}} * \text{bw}) / \text{uptake}_{\text{dw}}$$

was used to calculate a provisional drinking water QS. Using the default values for bw and intake resulted in a provisional value of $QS_{dw, hh}$ equal to $710 \mu\text{g L}^{-1}$. This value is above the aqueous solubility of HBCDD. Furthermore, the $QS_{dw, hh}$ is higher than the other QS_{water} proposed. Therefore, according to the EQS Technical Guidance (EC, 2018), no AA- $QS_{dw, hh}$ needs to be derived and no further work is required. The SCHEER agrees with this conclusion.

4. CRITICAL EQS

On the basis of the data provided in the dossier, the SCHEER observes that the most critical EQS (in terms of impact on environment/health) is the **$QS_{sw, eco}$ of $2 \times 10^{-5} \mu\text{g L}^{-1}$** .

5. LIST OF ABBREVIATIONS

AA	Annual Average
AF	Assessment Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	body weight
DEE	Daily Energy Expenditure
dw	dry weight
EFSA	European Food Safety Agency
fw	fresh water of fresh weight
EQS	Environmental Quality Standards
NOAEL	No Adverse Effect Level
NOEC	No Effect Concentration
QS	Quality Standard
TGD	Technical Guidance (Document) (EC, 2018)
TL	Threshold Level
TMF	Trophic Magnification Factor
ww	wet weight

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