



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

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

**Hexachlorobutadiene**



The SCHEER adopted this document  
via written procedure on 15 December 2022

## **ACKNOWLEDGMENTS**

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### **Keywords**

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## ABSTRACT

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

The proposed dossier is a revision of a previous EQS dossier (2015) based on recent data and the procedure proposed in the new EQS Technical Guidance (2018). However, several sections of the dossier refer to old technical documents (2003, 2004). It is the recommendation of the SCHEER that other sections also be updated, in line with the 2018 EQS Technical Guidance.

Moreover, all effect data used are older than 2005. This seems in contradiction with the statements of the dossier.

The **AA-QS<sub>fw, eco</sub> = 0.44 µg HCBD L<sup>-1</sup>** is calculated with the deterministic procedure. The SCHEER endorses the value.

The QS<sub>SPM.fw</sub> and QS<sub>SPM.sw</sub> are calculated using a formula taken from an old (2004) EQS Manual that allows calculation of a QS as concentration in the SPM (QS<sub>SPM</sub>), while the 2018 Guidance allows calculation of a QS as total concentration (dissolved + bound to SPM). The SCHEER suggests revising using the more recent guidance.

A **MAC-QS<sub>fw, eco</sub> = 0.59 µg L<sup>-1</sup>**, derived with the deterministic procedure is endorsed by the SCHEER.

The QS<sub>sediment</sub> is calculated using the equilibrium partitioning method with procedures taken from an old (2004) EQS Manual. The SCHEER suggests revising using the more recent guidance.

It is the opinion of the SCHEER that the procedure used for the calculation of secondary poisoning is based on an inappropriate NOAEL therefore, the SCHEER suggests revising the whole calculation with an adequate NOAEL.

The **QS<sub>biota, hh food</sub> = 24.53 µg.kg<sup>-1</sup>biota** (rounded to **QS<sub>biota, hh food</sub> = 25 µg.kg<sup>-1</sup>biota**) and the **QS<sub>water, biota hh</sub> = 1.1 ng L<sup>-1</sup>** are endorsed by the SCHEER.

It is likely that the most critical EQS is the **QS<sub>water, hh water</sub> = 1.1 ng L<sup>-1</sup>**, unless a lower QS will result from the revision of the QS for secondary poisoning.

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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 Document on Deriving EQS (TGD-EQS) reviewed by the SCHEER<sup>1</sup>.

## 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.

Generic questions to the SCHEER:

- Have the EQS for secondary poisoning of top predators ( $QS_{\text{secpois, biota}}$ ) and for human health due to food uptake ( $QS_{\text{biota, hh}}$ ) been correctly and appropriately derived, in the light of the available information?

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

- Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

Where there is disagreement between experts of WG Chemicals or there are other unresolved issues, we ask that the SCHEER consider additional points, identified in the cover note(s).

For each substance, a comprehensive EQS dossier is or will be available. DG Environment is providing three EQS dossiers ahead of the 3-4 March SCHEER Plenary and expects to provide most of the remaining dossiers over the next three months. 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.

### **3. OPINION**

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.

For hexachlorobutadiene, the EQSs proposed in the 2005 EQS dossier have been revised considering recent literature data. In particular, in the disclaimer of the dossier, it is said that the biota section and the drinking water section (section 8.1 to 8.3) have been revised due to new data available after 2005 and to the new Technical Guidance for EQS derivation updated in 2018 (EC, 2018). However, several sections of the dossier refer to old technical documents (EC, 2003; Lepper, 2004). It is the recommendation of the SCHEER that all the sections should be updated, in line with the 2018 TGD. Specific comments on the different sections of the dossier are listed below.

#### **Section 6 – Effect data (aquatic environment)**

In tables 6.1 (toxicity data on fresh and saltwater organisms) and 6.2 (toxicity data mammals and birds), all data refers to studies done prior to 2000. This is in contradiction with the statements of the disclaimer.

#### **Section 7 – Effect data (human health)**

In the dossier it is mentioned that “No experimental data with relevance to human health have been provided”; however it seems not to be case, as in table 6.2, toxicity data on mammals are reported.

The WHO drinking water limit for HCBd of 0.6 µg L<sup>-1</sup> is mentioned.

## Section 8 – Calculation of quality standards

### Section 8.1 – Quality standards for water

To avoid confusion, the SCHEER suggests that the same terminology used in the Technical Guidance for Deriving Environmental Quality Standards (EC, 2018) be used in the dossier: AA-QS<sub>fw, eco</sub>, AA-QS<sub>sw, eco</sub>, MAC-QS<sub>fw, eco</sub>, MAC-QS<sub>sw, eco</sub>,

#### **Freshwater**

Long-term toxicity data are available for fish, daphnia and algae: short-term acute data for fish, crustaceans and one mollusc species (see table 6.1 of this data sheet).

Based on the available information, the crustacean species *Daphnia magna* appears to be the most sensitive species in long-term tests (NOEC for *D. magna* of 4.4 µg L<sup>-1</sup>), leading to an **AA-QS<sub>fw, eco</sub> = 0.44 µg L<sup>-1</sup>**. The appropriate assessment factor according to the TGD is 10 as long-term toxicity data across the 3 trophic levels algae, daphnia and fish are available. It is the opinion of the SCHEER that the procedure is properly applied. The SCHEER endorses the value.

Koc values between approximately 10,000 and 1,260,000 dm<sup>3</sup> kg<sup>-1</sup> have been estimated for hexachlorobutadiene (HCBd). Hence, the log K<sub>pSUSP</sub> ranges between 3 and 5.1 and the trigger criterion to calculate the corresponding concentration to the QS<sub>fw</sub> in SPM is met.

However, the calculation in the dossier does not follow the procedure described in the EQS Technical Guidance (2018). Indeed, the formula used derives from a previous EQS manual (Lepper, 2004) and allows the calculation of a QS as concentration in the SPM (QS<sub>SPM</sub>). On the contrary, the procedure described in the EQS TGD calculates the QS as total concentration (dissolved + bound to SPM) in water (EQS<sub>water total</sub>).

The SCHEER suggests using the procedure described in the EQS Technical Guidance (2018). The same suggestion applies to the derivation of the QS<sub>SPM.sw</sub>.

#### **Transitional, coastal and territorial waters**

There are short-term toxicity tests with saltwater species representing 4 different taxonomic groups available (fish, crustacea, mollusca, echinodermata). It is not possible to judge on the basis of the available data whether saltwater and freshwater species of the same taxonomic groups are equally sensitive to HCBd. However, in the EURO CHLOR risk assessment for HCBd, it is stated that "*from an evaluation of the available toxicity data for other chlorinated aliphatic compounds (e.g. Calow, 1998f), it is reasonable to conclude that the sensitivity of marine and freshwater organisms is quite similar*". It is therefore suggested to calculate the QS<sub>sw</sub> from the same data set as used for the derivation of the QS<sub>fw</sub>. To this end, the TGD assessment factor method as proposed for the marine effect's assessment is used.

Additional data on 2 marine taxa beside fish, crustaceans and algae are available (molluscs, echinodermata) and these additional taxa do not appear to represent the most sensitive species. Therefore, the appropriate additional assessment factor for the derivation of the QS<sub>sw</sub> is 10. The lowest NOEC is 4.4 µg L<sup>-1</sup> for the crustacean species *D. magna*. Therefore,



the **AA-QS<sub>sw,eco</sub> = 0.044 µg L<sup>-1</sup>**. It is the opinion of the SCHEER that the procedure is properly applied. The QS is endorsed by the SCHEER.

For the calculation of the EQS<sub>saltwater total</sub>, see comments in the section above.

### **Quality standard accounting for transient concentration peaks (MAC-QS)**

It is suggested to derive the MAC-QS on the basis of the lowest acute toxicity test available in the combined freshwater and saltwater database. This is the LC50 of 59 µg L<sup>-1</sup> obtained for the saltwater crustacean species *Mysidopsis bahia*.

Based on the guidance given in the TGD (EC, 2003) on the effect's assessment for intermittent releases, it is suggested to apply an assessment factor of 100 in order to derive the **MAC-QS<sub>fw,eco</sub> = 0.59 µg HCBd L<sup>-1</sup>**. Although the quoted procedure refers to an old TGD, it corresponds to those described in the EQS Technical Guidance (2018). Therefore, the SCHEER endorses the MAC-QS.

For the determination of the MAC-QS<sub>sw,eco</sub>, an additional AF of 10 is applied. Therefore, the **MAC-QS<sub>sw,eco</sub> = 0.059 µg L<sup>-1</sup>**. The SCHEER endorses the MAC-QS.

## **Section 8.2 –Quality standards for sediment**

The log K<sub>p,susp</sub> of HCBd is estimated to be 3 – 5.1. It is therefore required to derive a QS<sub>sediment</sub>.

No toxicity data for sediment dwelling organisms are available. According to the TGD, the PNEC<sub>sediment</sub> (≈ QS<sub>sediment</sub>) may be calculated by the equilibrium partitioning method in the absence of ecotoxicological data of sediment-dwelling organisms. However, the whole section refers to an old Technical Document (Lepper, 2004).

The equation used and the default assumptions are different from those proposed by the recent EQS TGD (EC, 2018). Therefore, it is the opinion of the SCHEER that the whole section should be revised according to the new EQS TGD.

## **Section 8.3 –Secondary poisoning**

Hexachlorobutadiene has a BCF > 100. Thus, the trigger criterion to derive a quality standard referring to the protection of top predators from secondary poisoning is met.

The lowest NOAEL<sub>oral</sub> is 0.2 mg kg<sup>-1</sup><sub>bw</sub> d<sup>-1</sup> for chronic effects investigated in rats and mice studies, based on renal toxicity (hyperplasia, functional and histopathological changes). Instead, the NOAEL for mice of 2.0 mg kg<sup>-1</sup><sub>bw</sub> d<sup>-1</sup> based on body weight gain was selected and used for the calculation of the QS<sub>biota, secpois</sub>. The SCHEER considered that the chronic effects observed in rats and mice could be relevant at population level. Therefore, the SCHEER does not support this approach and considers that the lower NOAEL of 0.2 mg kg<sup>-1</sup><sub>bw</sub> d<sup>-1</sup> should be kept for the QS<sub>biota, secpois</sub>.

The method followed in the dossier, in accordance with the EQS Technical Guidance (EC, 2018), is that based on energy-normalised diet concentrations. The DEE (daily energy expenditure) is calculated with the following equation:

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

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

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

where the dose is the toxicological endpoint.

A body weight (bw) value of 26.5 g was selected and the obtained  $C_{energy\ normalised}$  was equivalent to  $7.82 \times 10^{-4} \text{ mg kJ}^{-1}$ .

The concentration in the critical food item is calculated using the following equation:

$$C_{food\ item} [mg/kg_{ww}] = C_{energy\ normalised} [mg/k] \cdot Energycontent_{fooditem,dw} \cdot (1 - moisturefraction_{fooditem})$$

The standard moisture content and energy content of bivalves are 92% and  $19 \text{ kJ g}^{-1}_{dw}$ , 74% and  $21 \text{ kJ g}^{-1}_{dw}$  for fish, and 68% and  $23 \text{ kJ g}^{-1}_{dw}$  for other vertebrates.

The concentration in the critical food item is determined to be  $1.25 \text{ mg kg}^{-1}_{ww}$  for bivalves,  $4.32 \text{ mg kg}^{-1}_{ww}$  for fish, and  $5.73 \text{ mg kg}^{-1}_{ww}$  for mammals and birds.

The calculation is correct; however, it is based on the NOAEL of  $2.0 \text{ mg kg}^{-1}_{bw} \text{ d}^{-1}$ .

Therefore, the SCHEER cannot endorse the derivation of the  $QS_{biota, secpois}$ , or of the  $QS_{water, biota}$ . It is the opinion of the SCHEER that, unless the reasons for not considering the lower NOAEL are adequately justified and supported, the whole procedure should be recalculated.

### Section 8.4 –Quality standards referring to food uptake by humans

The WHO has established a drinking water standard that is based on a tolerable daily intake (TDI) of  $0.2 \mu\text{g kg}^{-1}_{bw}$  by applying an AF of 1000 to a chronic toxicity study not involving possible carcinogenic effects (WHO, 2004). This TDI is used for the calculation.

The  $QS_{biota, hh\ food}$  is intended to protect humans against adverse health effects from consuming contaminated fishery products. According to the EQS Technical Guidance, the  $QS_{biota, hh, food}$  should be derived from the equation:

$$QS_{biota, hh\ food} = 0.2 * TDI / 0.00163$$

where:

- 0.2 = default fraction of TDI allocated to fishery products consumption
- 0.00163 ( $\text{kg}_{fish} \text{ kg}^{-1}_{bw} \text{ d}^{-1}$ ) = estimated daily fishery products consumption (default  $0.115 \text{ kg d}^{-1}$ ) per kg body weight (default 70 kg).

For the purpose of the QS derivation, the TDI of  $0.2 \mu\text{g kg}^{-1}_{bw}$  was used. Therefore, the resulting  $QS_{biota, hh}$  is  **$24.53 \mu\text{g kg}^{-1}_{biota}^{-1}$**  (to be rounded to  **$25 \mu\text{g kg}^{-1}_{biota}^{-1}$** ).

According to the EQS Technical Guidance, the back calculation to water is performed. Using the BAF of  $22,240 \text{ L kg}^{-1}$ , the resulting  $QS_{water, biota\ hh}$  is equal to  **$0.0011 \mu\text{g L}^{-1}$  or  $1.1 \text{ ng L}^{-1}$** . It is the opinion of the SCHEER that the procedure is correctly applied. The SCHEER endorses these values.

### Section 8.5 Quality standard for drinking water abstraction

No "A1-value" has been set for drinking water abstraction in Council Directive 75/440/EEC and also no limit value for HCBD in drinking water applies according to Council Directive

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98/83/EC. The revised Drinking Water Directive (Directive (EU) 2020/2184) did not include HCBd.

The dossier proposes to adopt the World Health Organisation (WHO) guidance value of 0.6  $\mu\text{g L}^{-1}$  for drinking water.

However, HCBd has been also used as a pesticide for some agricultural applications. Therefore, it is the opinion of the SCHEER that the pesticide standard of **0.1  $\mu\text{g L}^{-1}$**  for drinking water is more adequate.

#### 4. CRITICAL EQS

In light of the data provided in the dossier, the most critical EQS (in terms of impact on environment/health) has been identified as the  **$\text{QS}_{\text{water,biota hh}} = 1.1 \text{ ng L}^{-1}$** , unless a lower QS will result from the revision of the QS for secondary poisoning.

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## 5. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
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
EQS	Environmental Quality Standards
fw	freshwater
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
NOEC	No Effect Concentration
NOEL	No Effect Level
PPP	Plant Protection Products
QS	Quality Standard
SPM	Suspended Particulate Matter
sw	saltwater
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TL	Threshold Level
WHO	World Health Organisation
ww	wet weight

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## 6. REFERENCES

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