



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

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

Hexachlorobenzene



The SCHEER adopted this document
during the plenary meeting on 13 October 2022
CORRIGENDUM adopted on 5 December 2022

ACKNOWLEDGMENTS

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[Register of Commission expert groups and other similar entities \(europa.eu\)](https://europe.ec.europa.eu/en/commission-ec-main-portal/press-and-news/press-releases/2022/10/13-ec-releases-2022-10-13)

This Opinion has been subject to a commenting period of four weeks after its initial publication (from 6 September to 4 October 2022). Comments received during this period were considered by the SCHEER. For this Opinion, main changes were made in sections 8.1, 8.3. and in the abstract.

The Commission provided corrections on the QS_{biota, secpois, fw} and the critical EQS after publication of the text. This **CORRIGENDUM** was adopted by the SCHEER on 5 December 2022.

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ABSTRACT

The dossier on Environmental Quality Standards for "Hexachlorobenzene" 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 opinion of the SCHEER that all the procedures must be updated, in accord 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.

An **AA-QS_{fw, eco} = 0.013 µg L⁻¹**, derived with the deterministic procedure is endorsed by the SCHEER.

The same value is proposed as AA-QS_{sw,eco}. The SCHEER does not agree with the proposal

The QS_{SPM.freshwater} and QS_{SPM.saltwater} are calculated using a formula taken from an old (2004) EQS Manual. The SCHEER suggests revising using the more recent guidance.

A MAC-QS_{fw, eco} = 0.05 µg L⁻¹, derived with the deterministic procedure by applying an AF of 100 is not endorsed by the SCHEER. It is the opinion of the SCHEER that an AF of 10 is more appropriate, leading to a **MAC-QS_{fw, eco} = 0.5 µg L⁻¹**.

The QS_{sediment} 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.

The SCHEER endorses the **QS_{biota, secpois, fw} of 8.2 µg kg⁻¹_{ww}**, the **QS_{biota, secpois, sw} of 1.0 µg kg⁻¹_{ww}**, and, for the back calculation, the **QS_{fresh water, biota} of 22 pg L⁻¹** and the **QS_{saltwater, biota} of 2.8 pg L⁻¹**.

The **QS_{biota, hh food} = 19.63 µg kg⁻¹_{biota}** (rounded to **QS_{biota, hh food} = 20 µg.kg⁻¹_{biota}**) and the **QS_{water, hh food} = 0.0525 ng L⁻¹** (rounded to **QS_{water, hh food} = 0.053 ng L⁻¹**) are endorsed by the SCHEER.

For the exposure *via* drinking water, the SCHEER agrees with using the general drinking water standard for pesticides (**QS_{dw, hh} = 0.1 µg L⁻¹**) since HCB is a fungicide, although no longer in commercial use.

The most critical EQS is the **QS_{saltwater, biota} of 2.8 pg 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 Document on Deriving EQS (TGD-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. We ask that the SCHEER focus on:

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

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.

For hexachlorobenzene, 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 (sections 8.3 to 8.6) 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 (2003, 2004). It is the opinion of the SHEER that all the procedures must be updated, according with the 2018 TGD.

Specific comments on the different sections of the dossier are listed below.

Section 6 – Effect data (aquatic environment)

It is surprising to see that in tables 6.1 and 6.2 (toxicity data on water and sediment dwelling organisms respectively), all data refers to studies done prior to 2000. This seems in contradiction with the statements of the disclaimer.

None of the references quoted in tables 6.1, 6.2 and 6.3 appears in the reference list (section 9). Therefore, it is unclear if the original papers have been evaluated or if the values and the reliability scores are directly taken from the master references without additional evaluation.

Tables 6.3 and 6.4 should appear under section 7 (human health). In the caption of table 6.3 birds are mentioned but they do not appear in the table.

Section 7 – Effect data (human health)

The origin of the reported NO(A)ELs for non-neoplastic effects ($0.05 \text{ mg kg}_{\text{bw}}^{-1}\text{day}^{-1}$ (WHO, 1997) and $0.08 \text{ mg kg}_{\text{bw}}^{-1}\text{day}^{-1}$ (US EPA, 1991) is not mentioned in in any table in the dossier. In addition, for the lowest NOEL value ($0.05 \text{ mg kg}_{\text{bw}}^{-1}\text{day}^{-1}$) used for the TDI derivation, there is no clear mention of the study reference however, it may be reported in the WHO Environmental Health Criteria Report (WHO, 1997) quoted for the derivation of the TDI of $0.17 \text{ } \mu\text{g kg}_{\text{bw}}^{-1}\text{day}^{-1}$.

For neoplastic effects, an intake value of $0.16 \text{ } \mu\text{g kg}_{\text{bw}}^{-1}\text{day}^{-1}$ (WHO, 1997) was considered.

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) is used in the dossier: AA-QS_{fw, eco}, AA-QS_{sw, eco}, MAC-QS_{fw, eco}, MAC-QS_{sw, eco},

An AA-QS_{fw,eco} is derived with the deterministic procedure by applying an AF of 10 to the lowest selected chronic value (21 d NOEC for *Daphnia magna* of 0.13 µg L⁻¹), leading to an **AA-QS_{fw,eco} = 0.013 µg L⁻¹**. It is the opinion of the SCHEER that the procedure is properly applied. The SCHEER endorses the value.

In the dossier it is said that "The detection limit of HCB in water may be higher than the calculated water quality standard". It is the opinion of the SCHEER that the limit of detection of modern analytical methods, in the order of pg L⁻¹ (Necibi and Mzoughi, 2020), is lower than the established QS.

QS_{SPM.freshwater} is calculated using a formula taken from an old (2004) EQS Manual. The formula is quite different from those proposed in the EQS Technical Guidance (2018) to calculate the EQS_{SPM} and uses a different default C_{SPM} value. The SCHEER suggests using the more recent guidance. The same suggestion applies to the derivation of the QS_{SPM.saltwater}.

For the AA-QS_{sw,eco}, the same value is proposed as for freshwater, considering that data on five marine taxonomic groups (annelids and molluscs besides algae crustaceans and fish) are available. However, the SCHEER notes that all data available on marine taxa are acute. No chronic data are available on marine species. Therefore, it is the opinion of the SCHEER that the AA-QS_{sw,eco} cannot be endorsed and an additional AF of 10 should be applied to the AA-QS_{fw,eco}.

A MAC-QS_{fw,eco} is derived with the deterministic procedure by applying an AF of 100 to the lowest selected acute value (acute LC50 for *Daphnia magna* of 4.73 µg L⁻¹), leading to a MAC-QS_{fw,eco} = 0.05 µg L⁻¹. It is the opinion of the SCHEER that, excluding unbounded values and data not considered reliable (i.e., much higher than water solubility) from table 6.1, the remaining acute data on algae, crustacean and fish are very similar (range 4.73 to 13 µg L⁻¹), with very low standard deviation of the log transformed data (SD=0.17). Therefore, according to the EQS Technical Guidance (2018), a AF of 10 should be applied leading to a **MAC-QS_{fw,eco} = 0.5 µg L⁻¹**.

Estimation of EQS_{water total}

For highly hydrophobic compounds (log Kow>6), such as pyrethroids, the EQS Technical Guidance proposes to convert the water column standard as derived for the dissolved concentration (the final EQS value) into an equivalent total concentration in water (EQS_{water,total}) that corresponds to the quantity of the substance that is in true solution plus any of the substance sorbed to SPM. It is the opinion of the SCHEER that the EQS_{water,total} should be calculated for HCB.

Section 8.2 –Quality standards for sediment

All available data on sediment dwelling organisms are unbounded values. This does not allow direct derivation of a QS_{sediment}. Therefore, the QS_{sediment} is calculated using the equilibrium partitioning method. However, the whole section refers to old Technical Documents (2004).

The equation used and, in particular, the default assumptions, are different from those proposed by the recent 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

Considering the characteristics of hexachlorobenzene, the evaluation of secondary poisoning is considered necessary. The SCHEER agrees with this decision.

The SCHEER agrees with the selection of the most sensitive mammalian toxicity study available (1 generation reproduction of mink, *Mustela vison* and *Mustela putorius furo*) with an EC10 of 0.1 mg kg_{diet}⁻¹ (although not specified, it may be assumed that it refers to fresh weight of diet).

The method followed in the dossier, according to the EQS Technical Guidance (EC, 2018) in the case of toxicological endpoint expressed as diet concentration, is based on energy normalised diet concentrations.

However, the procedure is not clearly reported. Equation 1 of the dossier is:

$$C_{\text{energy normalised}} [\text{mg/kJ}] = C_{\text{energy normalised}} [\text{mg/kg}_{\text{dw}}] / (\text{energy content}_{\text{diet, fw}} * 1 - \text{moisture fraction})$$

The correct equation from the TGD is:

$$C_{\text{energy normalised}} [\text{mg/kJ}] = C_{\text{diet}} [\text{mg/kg}_{\text{fw}}] / (\text{energy content}_{\text{diet, dw}} * (1 - \text{moisture fraction}))$$

or

$$C_{\text{energy normalised}} [\text{mg/kJ}] = C_{\text{diet}} [\text{mg/kg}_{\text{dw}}] / \text{energy content}_{\text{diet, dw}}$$

Moreover, some default values for energy content (6656 KJ kg⁻¹_{fw}) and moisture fraction (68.4%, resulting in a dry weight fraction of 1 - 0.684 = 0.316) are taken from a 2004 RIVM report instead of the TGD. Using the correct equation and the proposed values for the energy content and moisture fraction the calculation has been performed correctly.

Then, the following equation is applied:

$$C_{\text{food item}} [\text{mg/kg}_{\text{ww}}] = C_{\text{energy normalised}} [\text{mg/kJ}] \cdot \text{Energy content}_{\text{food item, dw}} \cdot (1 - \text{moisture fraction}_{\text{food item}})$$

The SCHEER can endorse the calculated value of C_{food item} = 0.245 mg kg⁻¹_{ww} and subsequently also the final **QS_{biota, secpois, fw} of 8.18 µg kg⁻¹_{ww}** for fish (to be rounded to **8.2 µg kg⁻¹_{ww}**), the **QS_{biota, secpois, sw} of 1.027 µg kg⁻¹_{ww}** for fish (to be rounded to **1.0 µg kg⁻¹_{ww}**), and, for the back calculation, the **QS_{fresh water, biota} of 21.9 pg L⁻¹** (to be rounded to **22 pg L⁻¹**) and the **QS_{saltwater, biota} 2.76 pg L⁻¹** (to be rounded to **2.8 pg L⁻¹**).

However, the SCHEER notes that, although the calculation is correct, in the text of the dossier there are several mistakes:

- a *C_{energy normalised}* of 4.4 x 10⁻¹⁰ mg kJ⁻¹ is reported, instead of 4.4 x 10⁻⁵ mg kJ⁻¹; the energy content on a dry weight basis for fish is indicated as 21 kJ kg⁻¹_{fw}, instead of 21 kJ g⁻¹_{dw} (EC, 2018);
- a moisture fraction of 26.3% is indicated while the moisture fraction is 73.7% (EC, 2018), 0.263 is the result of (1-0.737) and is the dry fraction;
- the dry fraction in food is defined as "lipid fraction".

All these mistakes make the dossier very confusing.

The SCHEER recommends to revise and amend the Dossier.

Section 8.4 –Quality standards referring to food uptake by humans

The QS_{biota, hh, food} (expressed as µg kg⁻¹ biota) is calculated, according with the TGD, using the following equation:

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

Using a TDI= $0.16 \mu\text{g kg}_{\text{bw}}^{-1}\text{day}^{-1}$ (WHO, 1997), a $\text{QS}_{\text{biota, hh food}} = 19.63 \mu\text{g kg}^{-1}\text{biota}$ (to be rounded to $\text{QS}_{\text{biota, hh food}} = 20 \mu\text{g kg}^{-1}\text{biota}$). is obtained.

The back-calculation to water is based on a BAF value of $372,000 \text{ L kg}^{-1}$ (Verbruggen et al., 2014). giving a $\text{QS}_{\text{water, hh food}} = 0.0525 \text{ ng L}^{-1}$ (to be rounded to $\text{QS}_{\text{water, hh food}} = 0.053 \text{ ng L}^{-1}$).

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

For the exposure *via* drinking water, the general drinking water standard for pesticides ($\text{QS}_{\text{dw, hh}} = 0.1 \mu\text{g L}^{-1}$) is proposed, since HCB is a fungicide although no longer in commercial use . The SCHEER agrees with this conclusion.

4. CRITICAL EQS

The most critical EQS is the $\text{QS}_{\text{saltwater, biota}}$ of 2.8 pg L^{-1} .

5. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
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
HC	Hazardous Concentration
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
NOEL	No Effect Level
PPP	Plant Protection Products
QS	Quality Standard
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TL	Threshold Level
ww	wet weight

6. REFERENCES

EC (European Commission), 2018. Technical Guidance for Deriving Environmental Quality Standards (TGD-EQS). Common Implementation Strategy for the Water Framework Directive. Guidance Document No. 27 Updated version 2018.

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