



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

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

Heptachlor including heptachlor epoxide



The SCHEER adopted this document
via written procedure on 22 December

ACKNOWLEDGMENTS

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All Declarations of Working Group members are available at the following webpage:
[Register of Commission expert groups and other similar entities \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&code=sdg-11.6.2)

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ABSTRACT

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

In the dossier only the biota sections 7.2 (Secondary poisoning) and 7.3 (Human health) have been updated according to the recent Technical Guidance and to information available after 2011.

For secondary poisoning a $QS_{\text{Biota, sec pois, fw}} = 0.029 \text{ mg kg}^{-1}_{\text{ww}}$ ($29 \text{ } \mu\text{g kg}^{-1}_{\text{ww}}$) is calculated, converted to water concentration as $QS_{\text{water, biota}} = 3.7 \times 10^{-4} \text{ } \mu\text{g L}^{-1}$ (0.37 ng L^{-1}). The QSs are endorsed by the SCHEER.

For the marine environment, to protect top predators, a $QS_{\text{biota, secpois, sw}} = 7.6 \times 10^{-4} \text{ mg kg}^{-1}$ ($0.76 \text{ } \mu\text{g kg}^{-1}$) is calculated, converted to water concentration as $QS_{\text{sw, biota}} = 9.7 \times 10^{-6} \text{ } \mu\text{g L}^{-1}$ ($9.7 \times 10^{-3} \text{ ng L}^{-1}$ or 9.7 pg L^{-1}). The QSs are endorsed by the SCHEER.

For human health via consumption of fishery products, a virtually safe dose (VSD) of $1.1 \times 10^{-7} \text{ mg kg}_{\text{bw}}^{-1} \text{ d}^{-1}$, for carcinogenic effects, is used. A $QS_{\text{biota, hh}} = 1.35 \times 10^{-2} \text{ } \mu\text{g kg}^{-1}_{\text{biota}}$ (to be rounded to $1.4 \times 10^{-2} \text{ } \mu\text{g kg}^{-1}_{\text{biota}}$ or $14 \text{ ng kg}^{-1}_{\text{biota}}$) is derived, converted to water concentration as $QS_{\text{water biota hh}} = 1.7 \times 10^{-7} \text{ } \mu\text{g L}^{-1}$ (0.17 pg L^{-1}). The QSs are endorsed by the SCHEER.

For human health via consumption of drinking water, the general drinking water standard for pesticides ($QS_{\text{dw, hh}} = 0.1 \text{ } \mu\text{g L}^{-1}$) is proposed. The SCHEER agrees.

The most critical EQS is identified as the $QS_{\text{water biota hh}} = 0.17 \text{ pg L}^{-1}$.

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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:

Generic questions to the SCHEER

- Have the EQS been correctly and appropriately derived, in the light of the available information and the TGD-EQS?
- Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

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

3. OPINION

It should be noted that in a separate synthesis Opinion, the SCHEER provides an analysis of weaknesses and unresolved issues common to all dossiers. This includes a discussion of the risk assessment method and of SCHEER's concern regarding the completeness of the data used for the estimation of the different QS values.

In the disclaimer of the revised version of the dossier on Heptachlor (2022), it is explained that the document represents a revision of the previous version (2011), according to the Technical Guidance for EQS derivation updated in 2018 (EC, 2018) and considering additional information available after 2011. In particular, the biota sections 7.2 (Secondary poisoning) and 7.3 (Human health). Moreover, section 2 (Existing evaluations and Regulatory information) has been updated according to the most recent legislation.

It is the opinion of the SCHEER that additional information available after 2011 on aquatic ecotoxicity is relatively scarce and that the procedures used for the derivation of EQS for water and sediment do not differ substantially from those proposed by the 2018 Technical Guidance. Therefore, the SCHEER focuses its assessment on the updated sections.

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

Section 7.2 Secondary poisoning

The characteristics of heptachlor and heptachlor epoxide (log K_{oc} higher than 5, BCF and BMF above the trigger value of 100 and 1 respectively) indicate that the criteria triggering an assessment for secondary poisoning are met.

In mammals and birds, heptachlor is metabolised to the more persistent heptachlor epoxide. Therefore, biomagnification and transfer in the food chain is more relevant for this compound. For marine mammals, very high biomagnification factors have been observed for heptachlor epoxide (e.g., BMF > 20 for beluga whales, *Delphinapterus leucas*).

For the derivation of the QS, the NOAEL of 0.025 mg kg⁻¹_{bw} d⁻¹ for mortality rate in dog pups was used.

The method followed in the dossier, according to the EQS Technical Guidance (EC, 2018), is based on energy-normalised diet concentrations. The DEE (daily energy expenditure) and the energy-normalised diet concentration are calculated with the following equations:

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

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

where the dose is the NOAEL of 0.025 mg kg⁻¹_{bw} d⁻¹ and bw is 10 kg, corresponding to the bodyweight of animals in the experiment. A C_{energy normalised} of 0.053 µg kJ⁻¹ is calculated.

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 (in this case fish), using the following equation:

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

Using the default values proposed by the Technical Guidance (moisture content and energy content of fish 74% and 21 kJ g⁻¹_{dw}, respectively), the result is C_{food item} = 0.29 mg kg⁻¹_{ww} (fish). By applying an AF of 10, the result is **QS_{Biota, sec pois, fw} = 0.029 mg kg⁻¹_{ww} (29 µg kg⁻¹_{ww})** for fish.

It is the opinion of the SCHEER that the calculation is correctly performed and the $QS_{\text{Biota, sec pois, fw}}$ may be endorsed.

To convert the QS into a water concentration, the BAF on fish of 78,527 is used, resulting in $QS_{\text{water, biota}} = 3.7 \times 10^{-4} \mu\text{g L}^{-1}$ (**0.37 ng L⁻¹**) for fish. The $QS_{\text{water, biota}}$ is endorsed by the SCHEER.

For the marine environment, to protect top predators, a $C_{\text{food item}}$ is recalculated with the above equation using the default values of moisture content and energy content of terrestrial vertebrates (68% and 23 kJ g⁻¹_{dw}, respectively), obtaining a $C_{\text{food item}} = 0.39 \text{ mg kg}^{-1}_{\text{ww}}$. Then, according to the Technical Guidance, a $QS_{\text{biota, sec pois, sw}}$ is calculated with the following equation, using the default lipid fractions for fish of 5% and 10% for birds and mammals:

$$QS_{\text{biota, sec pois, sw}} [\text{mg kg}^{-1}] = (\text{lowest chronic value}/AF * BMF_{\text{b/m}}) * ((\text{lipid}/dw \text{ fraction}_{\text{fish}})/(\text{lipid}/dw \text{ fraction}_{\text{b/m}}))$$

The calculation is performed using the highest BMF available of 25.6 kg_{dw} kg⁻¹_{dw} for beluga whale. The value is very high but the data (Hoekstra et al., 2003) are judged to be reliable. The result is a $QS_{\text{biota, sec pois, sw}} = 7.6 \times 10^{-4} \text{ mg kg}^{-1}$ (**0.76 $\mu\text{g kg}^{-1}$**).

It is the opinion of the SCHEER that the calculation is correctly performed and the $QS_{\text{Biota, sec pois, sw}}$ may be endorsed. However, in the dossier it is indicated as "for fish". It is the opinion of the SCHEER that this is wrong. Indeed, the $QS_{\text{biota, sec pois, sw}}$ is calculated for "top-predators eating fish-eating birds and mammals".

Finally, the back-calculation to water performed with the BAF of 78,527 leads to a $QS_{\text{sw, biota}} = 9.7 \times 10^{-6} \mu\text{g L}^{-1}$ (**9.7 $\times 10^{-3}$ ng L⁻¹ or 9.7 pg L⁻¹**). The $QS_{\text{water, biota}}$ is endorsed by the SCHEER. In this case too, the QS erroneously referred to fish.

The SCHEER is aware that these low QSs may be problematic for analytical detection.

Section 7.3 Human health

Human health via consumption of fishery products

Heptachlor and heptachlor epoxide have a harmonised C&L classification by the EU as suspected carcinogenics (Carc. 2; H351). The value used for the derivation of $QS_{\text{biota hh}}$ is a virtually safe dose (VSD). The VSD or oral-risk-specific dose of $1.1 \times 10^{-7} \text{ mg kg}^{-1}_{\text{bw}} \text{ d}^{-1}$ was estimated from a slope factor of 9.1 per $\text{mg kg}^{-1}_{\text{bw}} \text{ d}^{-1}$ day for heptachlor epoxide (US-EPA, 1993a) by applying the multistage model at a projected incremental cancer risk of 10^{-6} per lifetime.

The $QS_{\text{biota, hh}}$ is calculated with the following equation:

$$QS_{\text{biota, hh}} = (0.2 * TL_{\text{hh}}) / 0.00163$$

Where:

- 0.2 = default fraction of TL_{hh} related to fishery products consumption
- TL_{hh} = threshold limit from mammalian studies (in this case $VSD = 1.1 \times 10^{-7} \text{ mg kg}^{-1}_{\text{bw}} \text{ d}^{-1}$)
- 0.00163 ($\text{kg}_{\text{fish}} \text{ kg}^{-1}_{\text{bw}} \text{ d}^{-1}$) = estimated daily fishery products consumption (default 0.115 kg d^{-1}) per kg body weight (default 70 kg).

The resulting $QS_{\text{biota, hh}} = 1.35 \times 10^{-2} \mu\text{g kg}^{-1}_{\text{biota}}$ (to be rounded to **1.4 $\times 10^{-2} \mu\text{g kg}^{-1}_{\text{biota}}$ or 14 ng kg⁻¹_{biota}**). The calculation is correct. The SCHEER endorses the QS.

The back-calculation to water, performed with the BAF of 78,527, leads to a **QS_{water biota hh} = 1.7x10⁻⁷ µg L⁻¹ (0.17 pg L⁻¹)**. The QS_{water, biota hh} is endorsed by the SCHEER.

The dossier highlights that this concentration might not be able to be measured routinely. The SCHEER agrees.

Human health via consumption of drinking water

The general drinking water standard for pesticides (**QS_{dw, hh} = 0.1 µg L⁻¹**) is proposed. The SCHEER agrees.

4. CRITICAL EQS

In light of the data provided in the dossier, the most critical EQS (in terms of impact on environment/health) is identified as the **QS_{water biota hh} = 0.17 pg L⁻¹**.

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
EQS	Environmental Quality Standard
fw	freshwater
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
QS	Quality Standard
sw	saltwater
TL	Threshold Limit
VSD	Virtually Safe Dose

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.

Hoekstra P.F., O'Hara T.M., Karlsson H., Solomon K.R. and Muir D.C.G. 2003. "Enantiomer specific biomagnification of alpha-hexachlorocyclohexane and selected chiral chlordane-related compounds within arctic marine food web." Environmental Toxicology and Chemistry 22(10): 2482-2491.