



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

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

Permethrin



The SCHEER adopted this document
at its plenary meeting on 25 March 2022

ACKNOWLEDGMENTS

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All Declarations of Working Group members are available at the following webpage:

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SCHEER

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ABSTRACT

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

The SCHEER endorses the **MAC-QS_{fw,eco} = 0.0025 µg L⁻¹** and the **MAC-QS_{sw,eco} = 0.00025 µg L⁻¹** derived with a deterministic procedure.

The SCHEER also endorses the deterministic **AA-QS_{fw,eco} = 0.00027 µg L⁻¹** and the **AA-QS_{sw,eco} = 0.000027 µg L⁻¹**.

For both MAC-QS and AA-QS, the SCHEER agrees with the decision of not performing the probabilistic approach due to the lack of sufficient information. However, it is the opinion of the SCHEER that the amount of reliable data should be carefully checked.

For sediment, the SCHEER endorsed the **QS_{freshwater, sed} = 0.002 mg kg⁻¹** and the **QS_{marinewater, sed} = 0.0002 mg kg⁻¹**.

For secondary poisoning, it is the opinion of the SCHEER that the BAF of 3300 L kg⁻¹ on fish instead of the BCF of 1900 L kg⁻¹ on molluscs should be used. Therefore, the QS_{biota, sec pois, fw} is not endorsed by the SCHEER.

A **QS_{biota, hh, food} = 6.1 mg kg⁻¹_{biota}** is endorsed by the SCHEER.

However, the SCHEER does not endorse the QS_{water, hh food} because the same BCF used for secondary poisoning is used for the calculation. A **QS_{water, hh food} = 0.18 µg L⁻¹** is proposed.

For the exposure *via* drinking water, the SCHEER agrees with the adoption of the general drinking water standard for pesticides (0.1 µg L⁻¹).

Because permethrin is a pyrethroid and therefore sorbs strongly to suspended particles also EQS_{water, total} were determined. The SCHEER endorses the results of the calculation (**total MAC-QS_{fw, eco} = 0.0.0030 µg L⁻¹; total MAC-QS_{sw, eco} = 0.00026 µg L⁻¹; total AA-QS_{fw, eco} = 0.00033 µg L⁻¹; total AA-QS_{sw, eco} = 2.80·10⁻⁰⁵ µg L⁻¹; total QS_{Biota, sec pois, fw} = 0.70 µg 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 has provided a general discussion concerning the procedure and derivation of the EQS values and related topics as well as highlighting unresolved issues and weaknesses which are common to more than one substance and dossier.

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

Section 7 – Effects and Quality Standards

The criteria for the selection of acute and chronic data for the derivation of EQS are described.

It is the opinion of the SCHEER that the criteria are suitable.

However, the SCHEER notes that the selected criteria are not the same in the different dossier. In some cases, the differences are justified by the specific properties of the substance. In other cases, these differences are not justified. It is the opinion of the SCHEER that the selection criteria should be harmonised.

Section 7.1 – Acute Aquatic Ecotoxicity

The SCHEER agrees with the selection of the 96h LC50 on *Hyalella azteca* as the most sensitive acute value. However, the small number of selected toxicity values is surprising. Even looking solely at the US EPA ECOTOX database, available data are numerous. However, also in the ECOTOX database, *H. azteca* is the most sensitive organism.

Therefore, the **MAC-QS_{fw,eco} = 0.0025 µg L⁻¹**, obtained with the deterministic procedure by applying an AF of 10 to the LC50 on *H. azteca*, is endorsed by the SCHEER.

The **MAC-QS_{sw,eco} = 0.00025 µg L⁻¹** is also endorsed by the SCHEER.

For both MAC-QS_{fw,eco} and MAC-QS_{sw,eco} the probabilistic procedure was not applied due to the insufficient number of data. It is the opinion of the SCHEER that the availability of reliable data should be carefully checked.

Section 7.2 – Chronic Aquatic Ecotoxicity

Chronic NOEC values are available for the three trophic levels (algae, *Daphnia* and fish). However, chronic data are not available for the taxonomic group that was detected as the most sensitive in acute data (Amphipods). The acute LC50 on *H. azteca* is about two orders of magnitude lower than those on *Daphnia*.

Therefore, the SCHEER agrees with the use of an AF of 50 instead of 10, applied to the 21 d NOEC on *Daphnia* and the **AA-QS_{fw,eco} = 0.00027 µg L⁻¹** is endorsed by the SCHEER.

The **AA-QS_{sw,eco} = 0.000027 µg L⁻¹** is also endorsed by the SCHEER.

For both AA-QS_{fw,eco} and AA-QS_{sw,eco} the probabilistic procedure was not applied due to the insufficient number of data. In this case too, it is the opinion of the SCHEER that the availability of reliable data should be carefully checked.

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

Section 7.3 – Sediment Ecotoxicity

For sediment dwelling organisms, a reliable value of NOEC=0.1 mg kg⁻¹ is available on *Chironomus riparius*.

According to the EQS Technical Guidance (EC, 2018), the NOEC value has been normalised to a standard organic carbon content of 5%. The normalised NOEC value is 0.2 mg kg⁻¹.

The **QS_{freshwater, sed} = 0.002 mg kg⁻¹**, obtained with the deterministic procedure by applying an AF of 100 to the normalised NOEC on *C. riparius* is endorsed by the SCHEER.

The **QS_{marinewater, sed} = 0.0002 mg kg⁻¹** is also endorsed by the SCHEER.

Section 7.4- Secondary Poisoning

For permethrin, there is experimental evidence of bioconcentration (BCF=1900 L kg⁻¹ on the mollusk *Crassostrea virginica*) and of bioaccumulation (BAF= 3300 L kg⁻¹ on the fish *Pimephales promelas*). On the contrary, there is no experimental evidence of biomagnification. This may be explained by the rapid depuration rate and metabolism of permethrin in vertebrates, as expected for all pyrethroids insecticides (Kaneko, 2010).

According to the procedure described in the EQS Technical Guidance (EC, 2018), a **QS_{biota, sec pois, fw} = 1.094 mg kg⁻¹_{ww}** (rounded to **QS_{biota, sec pois, fw} = 1.1 mg kg⁻¹_{ww}**) is calculated using the lowest value of avian and mammalian NOEL (5 mg kg⁻¹_{bw} d⁻¹) and the BCF on molluscs (1900 L kg⁻¹). This value led to a **QS_{water, biota} = 5.76 µg L⁻¹** (rounded to **QS_{water, biota} = 5.8 µg L⁻¹**).

The choice of the BCF on molluscs is justified in the dossier by the absence of biomagnification. However, from the data available, the bioaccumulation (or bioconcentration) potential is higher in fish than in molluscs. Therefore, it is the opinion of the SCHEER that the BAF on fish (3300 L kg⁻¹), instead of the BCF on molluscs, should be used. Therefore, the **QS_{water, biota}** is not endorsed by the SCHEER.

For the marine environment, it is proposed that a separate QS is not necessary as permethrin does likely not biomagnify in small birds or mammals. The SCHEER agrees with the proposal to use, for the marine environment, the same **QS_{biota, sec pois fw}**.

Section 7.5 – Human Health

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

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

Where:

- **QS_{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_{bw}⁻¹d⁻¹) = estimated daily fishery products consumption (default 0.115 kg d⁻¹) per kg body weight (default 70 kg).

A **QS_{biota, hh food} = 6.13 mg kg⁻¹_{biota}** (rounded to **QS_{biota, hh, food} = 6.1 mg kg⁻¹_{biota}**) is calculated, using the lowest value of avian and mammalian NOEL (5 mg kg⁻¹_{bw} d⁻¹), and is endorsed by the SCHEER.

For the calculation of the $QS_{\text{water, hh food}} = 0.32 \mu\text{g L}^{-1}$ the BCF on molluscs (1900 L kg^{-1}) is used. The calculation procedure is applied correctly. However, it is the opinion of the SCHEER that the BAF on fish (3300 L kg^{-1}), instead of the BCF on molluscs should be used. Therefore, the $QS_{\text{water, hh food}}$ is not endorsed by the SCHEER and should be substituted by the following: **$QS_{\text{water, hh food}} = 0.18 \mu\text{g L}^{-1}$** .

For the exposure *via* drinking water, the general drinking water standard for pesticides (**$QS_{\text{dw, hh}} = 0.1 \mu\text{g L}^{-1}$**) has been adopted. The SCHEER agrees with this conclusion.

Section 7.6 – Estimation of $EQS_{\text{water, total}}$

For highly hydrophobic compounds ($\log K_{ow} > 6$), 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 ($EQS_{\text{water, total}}$) that corresponds to the quantity of the substance that is in true solution plus any of the substance sorbed to SPM.

The calculation is based on the following equation:

$$EQS_{\text{water, total}} = EQS_{\text{water, dissolved}} \cdot (1 + K_{p, \text{susp}} \cdot C_{\text{SPM}} \cdot 10^{-6})$$

where:

- $EQS_{\text{water, total}}$ = quality standard for the total concentration in water;
- $EQS_{\text{water, dissolved}}$ = quality standard expressed as dissolved concentration;
- $K_{p, \text{susp}}$ = partition coefficient to suspended matter ($\text{L} \cdot \text{kg}^{-1}$);
- C_{SPM} = concentration of suspended matter ($\text{mg} \cdot \text{L}^{-1}$);
- 10^{-6} is = the conversion factor from mg into kg.

Default values are proposed in the Technical Guidance for the fraction of organic carbon in SPM and for C_{SPM} in fresh and marine water.

It is the opinion of the SCHEER that the calculations have been performed properly and the values of $EQS_{\text{water, total}}$ reported in Table 7.3 of the dossier (rounded to two significant figures) are correct.

However, it is the opinion of the SCHEER that, in section 7.6 of the dossier, it would have been useful to have more details explaining the calculations performed.

Moreover, the SCHEER notes some inconsistencies in the data reported in table 7.3 (for example $0.0025 \mu\text{g L}^{-1}$ does not correspond to 2.82 ng L^{-1}).

Table 7.3. Quality standard values derived according to the EC (2018) for QS_{water} compared to the $EQS_{\text{water, total}}$.

| | $EQS_{\text{water, dissolved}}$ | $EQS_{\text{water, total}}$ |
|-----------------------------------------------------|---------------------------------------------------|-----------------------------------------------|
| MAC-$QS_{\text{fw, eco}}$ | $0.0025 \mu\text{g L}^{-1}$ | $0.0030 \mu\text{g L}^{-1}$ |
| MAC-$QS_{\text{sw, eco}}$ | $0.00025 \mu\text{g L}^{-1}$ | $0.00026 \mu\text{g L}^{-1}$ |
| AA-$QS_{\text{fw, eco}}$ | $0.00027 \mu\text{g L}^{-1}$ | $0.00033 \mu\text{g L}^{-1}$ |
| AA-$QS_{\text{sw, eco}}$ | $0.000027 \mu\text{g L}^{-1}$ | $2.80 \cdot 10^{-5} \mu\text{g L}^{-1}$ |
| $QS_{\text{Biota, sec pois, fw}}$ | $0.58 \mu\text{g L}^{-1}$ | $0.70 \mu\text{g L}^{-1}$ |

4. 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 |
| EC | Effect Concentration |
| EFSA | European Food Safety Agency |
| EQS | Environmental Quality Standards |
| MAC-QS | Maximum Acceptable Concentration Quality Standard |
| NOAEL | No Adverse Effect Level |
| NOEL | No Effect Level |
| QS | Quality Standard |
| SSD | Species Sensitivity Distribution |
| SPM | Suspended Particulate Matter |
| TL | Threshold Level |
| WG | Working Group (on Chemicals) |

5. 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.

Kaneko H (2010). Pyrethroid Chemistry and Metabolism. In: Krieger r (Ed.), Hayes' Handbook of Pesticide Toxicology (Third Edition), Academic Press. <https://doi.org/10.1016/B978-0-12-374367-1.00076-8>.