



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

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

Deltamethrin



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

ACKNOWLEDGMENTS

Members of the Working Group are acknowledged for their valuable contribution to this opinion. The members of the Working Group are:

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This Opinion has been subject to a commenting period of four weeks after its initial publication (from 7 January 2022 to 7 February 2022). Comments received during this period were considered by the SCHEER. For this Opinion, only some typographical errors in the reported values were corrected in the abstract, in the section 7.3 and in Table 7.4.

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

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ABSTRACT

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

The SCHEER is of the opinion that the substance deltamethrin is a well-studied substance and questions therefore whether or not sufficient data have been taken into account to decide the application of the probabilistic approach using SSD. Therefore, the quality criteria mentioned in this evaluation should be considered preliminary.

The SCHEER endorses the **MAC-QS_{fw,eco} = 0.017 ng L⁻¹** and the **MAC-QS_{sw,eco} = 0.0034 ng L⁻¹** derived with a deterministic procedure.

The SCHEER also endorses the deterministic **AA-QS_{eco,fw} = 0.0017 ng L⁻¹** and the **AA-QS_{sw,eco} = 0.00017 ng 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_{fw,eco} = 0.3 µg kg⁻¹** and the **QS_{sw,eco} = 0.03 µg kg⁻¹**.

For secondary poisoning, it is the opinion of the SCHEER that the BCF of 1800 L kg⁻¹ on fish can be used. The SCHEER endorses the **QS_{biota,sec pois,fw} of 0.17 mg kg_{ww}⁻¹** for fish.

The SCHEER can endorse the **QS_{fw,biota} of 94 ng L⁻¹** and the **QS_{sw,biota} of 47 ng L⁻¹**.

The SCHEER can also endorse the standard for the human health evaluation *via* consumption of fishery products. The endorsed value is **QS_{biota,hh} = 1.2 mg kg⁻¹_{biota}**.

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

Because deltamethrin is a pyrethroid and therefore sorbs strongly to suspended particles also EQS_{water,total} were determined. The SCHEER endorses the established values (**total MAC-QS_{fw,eco} = 280 pg L⁻¹; total MAC-QS_{sw,eco} = 14 pg L⁻¹; total AA-QS_{fw,eco} = 28 pg L⁻¹; total AA-QS_{sw,eco} = 0.69 pg L⁻¹; total QS_{Biota,sec pois,fw} = 2.8 mg L⁻¹**).

SCHEER recommends establishing a groupwise EQS for chemicals with the same mode of action such as the pyrethroids.

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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.

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 is of the opinion that the active substance deltamethrin is an intensively studied compound and that much more acute and chronic ecotoxicity studies are available than the studies mentioned in the dossier that was submitted to the SCHEER for checking the environmental quality standards. The SCHEER is also of the opinion that using more available data from the literature a deterministic and a probabilistic approach would have been possible.

For this Opinion, the SCHEER only used the data presented in the dossier. The evaluation below should, therefore, be considered as preliminary until it is clear whether or not additional data should be taken into account or that, based on a scientific evaluation of more available data, the conclusion that a relevant and sufficiently representative selection has been applied, can be justified.

The SCHEER recognises that in the acute toxicity dataset for deltamethrin, at least one short-term L(E)C₅₀ from each of three trophic levels of the base set (fish, crustaceans, and algae) is reported. The most sensitive species for acute effects is the crustacean *Hyalella azteca* with an 96h-LC₅₀ of 0.17 ng L⁻¹. The dataset is sufficient to apply an assessment factor of 10 to this value. Therefore, the SCHEER endorses with reservation the preliminary deterministic **MAC-QS_{fw,eco} = 0.017 ng L⁻¹**.

For the deterministic MAC-QS_{sw,eco} the SCHEER agrees to combine the freshwater and marine data. The SCHEER also agrees with an additional factor of 5 due to the fact that an additional sensitive species is available in the marine dataset. Therefore, the **MAC-QS_{sw,eco} = 0.0034 ng L⁻¹** is also endorsed by the SCHEER.

For the time being, the SCHEER agrees that the probabilistic procedure was not applied due to the insufficient amount of data in the dossier received. The SCHEER is of the opinion that more data are available in international databases.

Section 7.2 – Chronic Aquatic Ecotoxicity

Sufficient chronic NOEC values would be available for the three trophic levels (algae, *Daphnia* and fish) to apply the standard assessment factor. However, the lowest chronic data for the most sensitive group, *Daphnia magna* 21d-NOEC_{growth} = 0.0041 µg L⁻¹, is higher than the lowest acute value used for establishing the MAC-QS. Therefore, according to the Guidance document (EC, 2018), an assessment factor of 100 is applied to the lowest acute value. The SCHEER agrees with this approach and endorses the value **AA-QS_{fw,eco} = 0.0017 ng L⁻¹**.

Using analogous reasoning, the water quality standard for marine water is determined as **AA-QS_{sw,eco} = 0.00017 ng L⁻¹**. The SCHEER endorses this value.

For the time being, the SCHEER agrees that the probabilistic procedure was not applied due to the insufficient amount of data in the dossier received. The SCHEER is of the opinion that more data are available in international databases.

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

Section 7.3 – Sediment Ecotoxicity

According to the dossier, reliable chronic sediment toxicity studies are available, three long-term tests with species representing different living and feeding conditions are present in the chronic sediment dataset (*H. azteca*, *Chironomus dilutus*, *Chironomus riparius* and *Lumbriculus variegatus*). However, for acute and chronic aquatic studies, all studies with some characteristics are summarised in the dossier, but for the sediment toxicity studies only the most sensitive organism has been mentioned: the NOEC for *C. dilutus* of 1.5 µg kg_{dw}⁻¹. Although this value can be accepted, the SCHEER is of the opinion that all relevant data should be presented in the dossier in order to make a justified choice.

This NOEC value has been normalised to a standard organic carbon content of 5% as described in the EQS Technical Guidance (EC, 2018). The normalised NOEC value is, therefore, 3.0 µg kg_{dw}⁻¹.

Applying an assessment factor of 10, the **QS_{fw,eco} = 0.3 µg kg_{dw}⁻¹**, obtained with the deterministic procedure. This value is endorsed by the SCHEER.

Applying an additional assessment factor of 10 leads to the **QS_{sw,eco} = 0.03 µg kg_{dw}⁻¹**. This value is also endorsed by the SCHEER.

Section 7.4 – Estimation of EQS_{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_{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:

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

where:

- EQS_{water, total} = quality standard for the total concentration in water;
- EQS_{water, dissolved} = quality standard expressed as dissolved concentration;
- K_{p, susp} = partition coefficient to suspended matter (L·kg⁻¹);
- C_{SPM} = concentration of suspended matter (mg·L⁻¹);

- 10^{-6} = 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 $EQS_{water,total}$ reported in Table 7.4 (rounded to two significant figures) of the dossier are correct.

However, it is the opinion of the SCHEER that, in section 7.4 of the dossier, some more details explaining the calculations performed would have been useful.

In addition, the SCHEER recognises that in table 7.4, the unit of $AA-QS_{sw,eco}$ is erroneously indicated as $ng L^{-1}$; it should, however, be $pg L^{-1}$.

Table 7.4. Quality standard values derived according to the EC (2018a) for QS_{water} compared to the $EQS_{water,total}$.

	$EQS_{water,dissolved}$	$EQS_{water,total}$
MAC-$QS_{fw,eco}$	17 $pg L^{-1}$	280 $pg L^{-1}$
MAC-$QS_{sw,eco}$	3.4 $pg L^{-1}$	14 $pg L^{-1}$
AA-$QS_{fw,eco}$	1.7 $pg L^{-1}$	28 $pg L^{-1}$
AA-$QS_{sw,eco}$	0.17 $pg L^{-1}$	0.69 $pg L^{-1}$
$QS_{Biota,sec\ pois, fw}$	170 $\mu g L^{-1}$ (fish)	2.8 $mg L^{-1}$

Section 7.5- Tentative QS

This section is just a table reporting the QSs already discussed above. The SCHEER has no additional comments on them.

Section 7.6- Secondary Poisoning

The SCHEER agrees with the selection of the most sensitive mammalian toxicity study available with a NOAEL of $1 mg kg_{bw}^{-1}d^{-1}$ based on neurological effects in a sub-chronic 90d-rat study. This study is used for the derivation of the biota standards according to EC (2018).

Based on the log K_{ow} (range 4.6 – 6.4) and the 28d-BCF (*Lepomis macrochirus*, measured $BCF = 1800 L kg^{-1}$), the evaluation of secondary poisoning is considered necessary. The SCHEER agrees with this conclusion.

According to the standard calculation in EC (2018) and applying an assessment factor of 30, the final **$QS_{biota,sec\ pois, fw}$ of $0.05 mg kg_{ww}^{-1}$** for bivalves and **$0.17 mg kg_{ww}^{-1}$** for fish was achieved. The SCHEER can agree with these results.

The SCHEER recognised that no information on the BAF is available in the dossier, as no data have been reported. The SCHEER also agrees with the reasoning given in the dossier for estimating BAF at a value of 1800.

The resulting value for the **$QS_{fw,biota} = 0.094 \mu g L^{-1}$** is endorsed by the SCHEER.

For the marine environment, a separate calculation is applied based on the assumption that top predators also have to be taken into account. According to the standard procedures in EC (2018), the following value has been calculated: **$QS_{sw,biota} = 0.047 \mu g L^{-1}$** for fish. The SCHEER also endorses this value.

Section 7.7 – 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:

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

Where:

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

Based on this equation, a value of **$QS_{\text{biota, hh}} = 1.2 \text{ mg kg}^{-1}_{\text{biota}}$** is calculated, according to the procedure described in the EQS Technical Guidance (EC, 2018), using the lowest value of avian and mammalian NOEL of $1.0 \text{ mg kg}^{-1}_{\text{bw}} \text{d}^{-1}$ and applying an assessment factor of 100. The SCHEER can endorse this value.

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

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
NOEC	No Effect Concentration
QS	Quality Standard
SPM	Suspended Particulate Matter
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
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.