



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

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

Esfenvalerate



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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ABSTRACT

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

Without access to the primary reference used for some QSs the SCHEER is unable to evaluate the reliability of the data, and so cannot endorse the proposed numerical values.

The SCHEER cannot endorse the MAC-QS_{fw,eco}, the MAC-QS_{sw,eco}, the AA-QS_{eco,fw} and the AA-QS_{sw,eco}, all derived with a deterministic procedure.

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 endorses the **QS_{freshwater, sed} = 0.4 µg kg⁻¹** and the **QS_{marinewater, sed} = 0.04 µg kg⁻¹**.

For secondary poisoning, it is the opinion of the SCHEER that several mistakes and inconsistencies are present in the calculation, based on energy normalised diet concentrations. Therefore, the SCHEER suggests to fully reconsider this section.

For human health, the value of **QS_{biota, hh} = 2.1 mg kg⁻¹_{biota}** is endorsed by the SCHEER. However, the SCHEER does not endorse the QS_{water, hh food}, because the BAF value used should be better supported.

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 esfenvalerate is a pyrethroid and therefore sorbs strongly to suspended particles also EQS_{water, total} were determined. The SCHEER agrees with the procedure but cannot endorse the calculated values, given the reasons mentioned above.

TABLE OF CONTENTS

ACKNOWLEDGMENTS.....	2
ABSTRACT	4
1. BACKGROUND	6
2. TERMS OF REFERENCE.....	6
3. OPINION	7
Section 7 – Effects and Quality Standards	7
Section 7.1 – Acute Aquatic Ecotoxicity	7
Section 7.2 – Chronic Aquatic Ecotoxicity	8
Section 7.3 – Sediment Ecotoxicity	8
Section 7.4- Secondary Poisoning.....	8
Section 7.5 – Human Health	9
Section 7.6- Estimation of EQS _{water total}	10
4. LIST OF ABBREVIATIONS	11
5. REFERENCES	12

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.

Without access to the primary reference used (Bradley et al, 2013), the SCHEER is unable to evaluate the reliability of the data, and so cannot endorse the proposed numerical EQS values, although the SCHEER is still able to comment on the procedures followed.

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

In the table reporting acute toxicity data, two values of EC50 on freshwater algae are reported (10 and 10.75 $\mu\text{g L}^{-1}$) that are much higher than the water solubility of the substance (1 to 2 $\mu\text{g L}^{-1}$). Methodological procedures to support these concentrations (e.g. use of solvents) are not mentioned and the reliability of the data is not reported. It is the opinion of the SCHEER that these values should be considered as unreliable.

The dossier proposes the selection of the 96h LC50 of 0.00085 $\mu\text{g L}^{-1}$ on *Hyalella azteca* as the most sensitive acute value. The SCHEER is unable to endorse this value since the SCHEER was not able to evaluate the primary data source on which the calculations are based. It was also noted that this LC50 was more than one order of magnitude lower than the rest of the ecotoxicity data provided.

If the data on algae are considered unreliable, only data on invertebrates and fish are available. However, considering that data on the most sensitive taxonomic group are available (arthropods, including crustaceans and insects), it is the opinion of the SCHEER that the application of an AF of 10 is suitable. However, the $\text{MAC-QS}_{\text{fw,eco}} = 0.085 \text{ ng L}^{-1}$, obtained with the deterministic procedure by applying an AF of 10 to the LC50 on *H. azteca*, cannot be endorsed by the SCHEER due to the issue raised above.

The $\text{MAC-QS}_{\text{sw,eco}} = 0.0085 \text{ ng L}^{-1}$ cannot be endorsed by the SCHEER.

For both $\text{MAC-QS}_{\text{fw,eco}}$ and $\text{MAC-QS}_{\text{sw,eco}}$, the probabilistic procedure was not applied due to the insufficient number of data. The SCHEER agrees with this decision.

Section 7.2 – Chronic Aquatic Ecotoxicity

Chronic NOEC values are available for the three trophic levels (algae, crustaceans, and fish).

The SCHEER cannot agree with the selection of the 28 day NOEC on *Americamysis bahia* reproduction of 0.00017 µg L⁻¹ on as the most sensitive acute value because the key reference value could not be evaluated.

Therefore, the AA-QS_{fw,eco} = 0.017 ng L⁻¹, obtained with the deterministic procedure by applying an AF of 10 to the 28 days NOEC on *A. bahia*, is not endorsed by the SCHEER.

The AA-QS_{sw,eco} = 0.0017 ng L⁻¹ is not 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 selection of reliable data should be carefully checked.

Section 7.3 – Sediment Ecotoxicity

For sediment-dwelling organisms, a reliable value of NOEC=5.2 µg kg⁻¹ is available on *Chironomus dilutus*. The test was performed using a sediment with a total organic carbon content of 1.3%.

According with 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 20 µg kg⁻¹.

The QS_{sediment, fw} = 0.4 µg kg⁻¹, obtained with the deterministic procedure by applying an AF of 50 to the normalised NOEC on *C. dilutus*, is endorsed by the SCHEER.

The QS_{sediment, sw} = 0.04 µg kg⁻¹ is also endorsed by the SCHEER.

Section 7.4- Secondary Poisoning

For esfenvalerate, there is experimental evidence of bioconcentration (BCF > 3000 L kg⁻¹ on three fish tests)

The method followed in the dossier, according with the EQS Technical Guidance (EC, 2018), is that based on energy-normalised diet concentrations. The calculation is based on the following procedure. The DEE (daily energy expenditure) is calculated with the following equation that represents the regression (experimentally determined) between DEE and body weight in mammals; a default bw of 250 g is assumed for rat:

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

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

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

where the dose is the toxicological endpoint. For esfenvalerate the 90-day neurotoxicity NOAEL on rat (2.5 mg kg_{bw}⁻¹d⁻¹) is selected. This value, reported in table 11.4 of the appendix, is different from the value (1.75 mg kg_{bw}⁻¹d⁻¹) used for human health assessment (see Section 7.5). The reasons for this choice are not supported.

The procedure is correct but, in the dossier, there are several mistakes:

- in the text the dose is indicated as 5 mg kg_{bw}⁻¹d⁻¹ (instead of 2.5 mg kg_{bw}⁻¹d⁻¹);
- by using the dose of 2.5 mg kg_{bw}⁻¹d⁻¹, the result is **C_{energy normalised} = 0.00018 mg kJ⁻¹** (instead of 0.0018 mg kJ⁻¹ as indicated in the dossier).

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, using the following equation:

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

In the dossier it is stated:

“ as it was pointed out by experts of the subgroup on pyrethroids during the revision of the dossier on esfenvalerate in 2021, that it seems more appropriate to derive the $QS_{\text{sec pois}}$ for both the QS_{biota} for fish and bivalves. ”

The reasons for this decision are not supported in the dossier. Anyway, using a moisture content of 92% and an energy content of 19 kJ $\text{g}_{\text{dw}}^{-1}$ for bivalves and a moisture content of 72% and an energy content of 21 kJ/ g_{dw} for fish, as proposed in the Technical Guidance, the results are:

- For bivalves: **$C_{\text{food item}} [\text{mg kg}_{\text{ww}}^{-1}] = 0.27$**
- For fish: **$C_{\text{food item}} [\text{mg kg}_{\text{ww}}^{-1}] = 0.98$**

However, also using the wrong value of $C_{\text{energy normalised}} = 0.0018 \text{ mg kg}^{-1}$, it is unclear how the values reported in the dossier (2.28 $\text{mg kg}_{\text{ww}}^{-1}$ for bivalves and 10.12 $\text{mg kg}_{\text{ww}}^{-1}$ for fish) have been obtained.

Moreover, the last three lines on page 26 of the text of the dossier are incomprehensible.

The calculation in the dossier continues. However, it is the opinion of the SCHEER that, considering the mistakes and inconsistencies, this section must be fully reconsidered, and the calculations repeated correctly.

Section 7.5 – 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:

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

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).

The value for TL_{hh} is the ADI = $0.0175 \text{ mg}/\text{kg}_{\text{bw}}^{-1} \cdot \text{d}^{-1}$ obtained by applying an AF of 100 to the neurotoxicity in rats NOAEL of $1.75 \text{ mg}/\text{kg}_{\text{bw}}^{-1} \cdot \text{d}^{-1}$. The SCHEER agrees with this choice. However, as mentioned above, it is unclear why this value is different from those selected for secondary poisoning.

The value **$QS_{\text{biota, hh}} = 2147.24 \mu\text{g kg}^{-1}_{\text{biota}}$** (to be rounded to **$2.1 \text{ mg kg}^{-1}_{\text{biota}}$**) is endorsed by the SCHEER.

The **$QS_{\text{water, hh food}}$** is based on a BAF value for invertebrates of $5.68 \text{ L kg}^{-1}_{\text{ww}}$. No comments on the reliability of this value and information on the availability on other (BCF, BAF, BMF) data are provided in the dossier. The value seems quite low considering the hydrophobicity ($\log K_{\text{ow}} > 6$) of the substance.

The procedure for the calculation of the $QS_{\text{water, hh food}} = 37.8 \mu\text{g L}^{-1}$ (to be rounded to $38 \mu\text{g L}^{-1}$) is correct. However, for the reasons explained above, the SCHEER does not endorse this value.

For the exposure *via* drinking water, the general drinking water standard for pesticides ($0.1 \mu\text{g L}^{-1}$) 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 are correct. However, given the reasons mentioned above, the SCHEER cannot endorse the presented values.

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

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
DEE	Daily Energy Expenditure
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
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.

Bradley MJ (2013). Esfenvalerate - Acute Toxicity to Freshwater Amphipods (*Hyalella azteca*) Under Flow-Through Conditions. Smithers Viscient Study No. 13656.6169.