Scientific Committee on Health, Environmental and Emerging Risks SCHEER

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

Bifenthrin

Scientific Committees
on Consumer Safety
on Health, Environmental and Emerging Risks

The SCHEER adopted this document
by written procedure on 6 May 2022

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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, changes were made in the abstract, in section 7.3 sediment ecotoxicity, in the section 7.4. secondary poisoning and a new chapter 4. Critical EQS was drafted.

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ABSTRACT

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

The SCHEER accepts with reservations the **MAC-QS$_{fw,eco}$ = 0.011 μg L^{-1}** and the **MAC-QS$_{sw,eco}$ = 0.0011 μg L^{-1}** derived with a deterministic procedure. It is the opinion of the SCHEER that a more careful collection of data should be performed.

The SCHEER also accepts with reservations the deterministic **AA-QS$_{eco,fw}$ = 0.095 ng L^{-1}** and the **AA-QS$_{sw,eco}$ = 0.0095 ng L^{-1}**.

For both MAC-QS and AA-QS, the SCHEER agrees, provisionally, 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 confirms that the **AA-QS$_{freswater-sed}$ = 0.11 μg kg^{-1}** and the **AA-QS$_{marine water-sed}$ = 0.021 μg kg^{-1}** have been correctly calculated using the database in the dossier but strongly recommends that a more extensive data search should be undertaken to enhance the database.

For secondary poisoning, the **QS$_{biota,secpois,fw}$ of 0.045 mg kg^{-1}** for fish and **0.013 mg kg^{-1}** for bivalves, as well as the **QS$_{fw, biota}$** for fish of **27 ng L^{-1},** and the **QS$_{fw, biota}$** for bivalves of **7.7 ng L^{-1}** are endorsed by the SCHEER.

Due to the lack of an experimental BMF, the SCHEER does not endorse the **QS$_{sw, biota}$**.

For human health, the value of **QS$_{biota, hh}$ = 1.8 mg kg^{-1}$_{biota}$** and the **QS$_{water, hh food}$ = 1.1 μg L^{-1}** are endorsed by the SCHEER.

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 bifenthrin is a highly hydrophobic pyrethroid and therefore sorbs strongly to suspended particles also EQS$_{water,total}$ were determined. The SCHEER endorses the calculated values (**total MAC-QS$_{fw, eco}$ = 0.015 μg L^{-1}; total MAC-QS$_{sw, eco}$ = 0.0024 μg L^{-1}; total AA-QS$_{fw, eco}$ = 13 x 10^{-5} μg L^{-1}; total AA-QS$_{sw, eco}$ = 10 x 10^{-6} μg L^{-1}; total QS$_{Biota, sec pois, fw}$ = 37 ng L^{-1}**).

The most critical EQS (in terms of impact on environment/health) has been identified as the **AA-QS$_{sw, eco}$ = 0.0095 ng L^{-1}.**

The SCHEER supports the view expressed in the dossier of the need for cumulative EQS to be derived for 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 SCHEER[1].

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.

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[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 dossiers. 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.

In particular, for bifenthrin it is not mentioned if tests performed with nominal, non-measured, concentrations were accepted or discarded. For a hydrophobic chemical like bifenthrin, this is a relevant point because, for poorly water-soluble chemicals, it is important to check if actual concentrations, analytically measured, correspond to the nominal ones.

Section 7.1 – Acute Aquatic Ecotoxicity

In the table reporting acute toxicity data, only data on freshwater crustaceans and fish are reported. Data on algae are not available.

The lowest value reported in the acute dataset are the 48 h-EC_{50} for *Daphnia magna* and for *Gammarus pulex*, both of 0.11 µg L^{-1}.

According to the EQS Technical Guidance (2018), the dossier proposes an AF of 10, despite the lack of data on algae, because data for the most sensitive taxonomic group (arthropods) are included in the dataset.

Therefore, a **MAC-QS$_{fw,eco}$=0.011 µg L^{-1}** is proposed.

Nevertheless, the dossier highlights that values for the most sensitive species to pyrethroids, *Hyalella azteca,* are not included. Therefore, without short-term values for *H. azteca*, an AF of 10 can be *bona fide* applied.

Based on the data provided by the dossier, the SCHEER agrees with the procedure adopted and accepts with reservations the MAC-QS$_{fw,eco}$ derived. It is the opinion of the SCHEER that a more careful collection of data should be performed. For example, in the database US EPA ECOTOX, many other acute data are reported, including *H. azteca,* and insects, and the SCHEER advise that these data should be considered in the EQS derivation.

The SCHEER also accept the **MAC-QS$_{sw, eco}$ = 0.0011 µg $L^{-1,}$** with the same reservations and comments as above.

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

Section 7.2 – Chronic Aquatic Ecotoxicity

For the derivation of AA-QS$_{fw,eco}$, only data on invertebrates and fish are available.

The SCHEER agrees with the selection of the 21 day (not 28 as indicated in the text of the dossier) NOEC on *D. magna* reproduction of 0.00095 µg L^{-1} on as the most sensitive acute value.

The same criterion as for the derivation of the MAC-QS$_{fw,eco}$ is applied and a **AA-QS$_{fw,eco}$ = 0.095 ng L^{-1}** obtained with the deterministic procedure by applying an AF of 10 is proposed. In this case, the lack of data on *H. azteca* is not mentioned.

The SCHEER agrees with the procedures, with the same limitations as for the MAC-QS.

The SCHEER also accepts the **AA-QS$_{sw, eco}$ = 0.0095 ng L^{-1}** obtained through the application of an additional AF of 10.

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.

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

Section 7.3 – Sediment Ecotoxicity

For sediment dwelling organisms, a value of NOEC= 0.45 µg kg^{-1} for *H. azteca* has been selected. The test was performed using a sediment with a total organic carbon content of 2.1%.

In accordance with the EQS Technical Guidance (EC, 2018), the NOEC value has been normalised to a standard organic carbon content of 5% using the following equation:

$$\text{TEST RESULT}_{standardised} = \text{TEST RESULT} * F_{oc, standardised} / F_{oc, tested}$$

By applying this formula, the result is:

$$\text{TEST RESULT}_{standardised} = 0.45 * 0.05 / 0.021 = 1.071 \text{ µg kg}^{-1}.$$

The AA-QS$_{freswater-sed}$ is derived by applying an AF of 10 to the normalised NOEC. Therefore, a final **AA-QS$_{freswater-sed}$= 0.1071 µg kg^{-1}**. is obtained (to be rounded to **0.11 µg kg^{-1}**).

For the marine environment, an AF of 50 is applied on the same NOEC, leading to an **AA-QS$_{marine water-sed}$= 0.021 µg kg^{-1}**

The SCHEER confirms that the QS value has been correctly calculated using the database in the dossier but strongly recommends that a more extensive data search should be undertaken. The database should then be enhanced and extended as a result of that more extensive search.

Section 7.4- Secondary Poisoning

Due to the high Kow (log Kow=6.6), bifenthrin is likely to be accumulated. The experimental BCF available (BCF=1703; log BCF=3.213) is lower than expected from Kow. This may indicate some capability for elimination (through metabolism or excretion) as expected for all pyrethroids insecticides (Kaneko, 2010). However, both, Kow and BCF, support the need for the evaluation of secondary poisoning.

The method followed in the dossier, according to the EQS Technical Guidance (EC, 2018), is 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:

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

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

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

where the dose is the toxicological endpoint.

For bifenthrin, the 29-day NOAEL on rat (1 mg $kg_{bw}^{-1}d^{-1}$) is selected. Using a value of 358 g, corresponding to the bodyweight (bw) of female rats in the experiment, a DEE of 435.88 kJ d^{-1} and a $C_{energy\ normalised}$ of 0.82 µg kJ^{-1}.

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:

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

or:

$$C_{food\ item}\ [mg/kg_{ww}] = C_{energy\ normalised}\ [mg/kJ] * energy\ content_{food\ item,\ fw}$$

using an energy content of 5523 kJ g_{fw}^{-1} for fish and of 1602 kJ g_{fw}^{-1} for bivalves (Verbruggen, 2014), the results are:

- For fish: $C_{food\ item}\ [\text{mg kg}_{ww}^{-1}] = 4.53$
- For bivalves: $C_{food\ item}\ [\text{mg kg}_{ww}^{-1}] = 1.32$

The SCHEER agrees with these values.

Therefore, the values of **$QS_{biota,secpois,fw}$ of 0.045 mg kg^{-1}** for fish and **0.013 mg kg^{-1}** for bivalves, obtained by applying an AF of 100 to the $C_{food\ item}$, are endorsed by the SCHEER.

For the calculation of the $QS_{fw,\ biota}$, the dossier proposes to divide the $QS_{biota,secpois,fw}$ by a BAF. If not available, the BAF may be estimated as:

BAF=BCF*BMF

In absence of a BMF, the default value proposed by the Technical Guidance (BMF=1 if BCF<2000) may be used.

With respect to the specific characteristics of the pyrethroids and bifenthrin in particular, the SCHEER considers the application of a BMF of 1 inappropriate, although this approach is recommended by the TGD of EQS (EC, 2018).

Nevertheless, the SCHEER considers acceptable the derivation of the $QS_{fw,\ biota}$ dividing the $QS_{biota,secpois,fw}$ by the BCF.

Therefore, the **$QS_{fw,\ biota}$ for fish** of **27 ng L^{-1},** and the **$QS_{fw,\ biota}$ for bivalves of 7.7 ng L^{-1}** are endorsed by the SCHEER.

For the marine environment, the SCHEER is of the opinion that biomagnification in top predators is unlikely to occur for pyrethroids. Therefore, a $QS_{sw,\ biota}$ should be derived for fish and other aquatic organisms on the basis of the BCF, as for freshwater while not considering biomagnification on top predators, like fish-eating birds and mammals.

The SCHEER proposes to adopt as $QS_{sw,\ biota}$ the same values derived for fish and bivalves in freshwater.

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:

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

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$_{bw}^{-1}$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= 0.015 mg/kg $_{bw}$ $^{-1}$ d^{-1} obtained by applying an AF of 100 to a 1-year NOAEL of 1.5 mg/kg $_{bw}$ $^{-1}$ d^{-1}. The SCHEER agrees with this choice.

The **QS$_{biota,\ hh}$= 1.84 mg kg$^{-1}_{biota}$** (to be rounded to **1.8 mg kg$^{-1}_{biota}$**) and the **QS$_{water,\ hh\ food}$ = 1.08 µg L^{-1}** (to be rounded to **1.1 µg L^{-1}**) are endorsed by the SCHEER.

For the exposure *via* drinking water, the general drinking water standard for pesticides (0.1 µg L^{-1}) has been adopted. The SCHEER agrees with this conclusion.

Section 7.6- 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.

The calculation is based on the following equation:

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

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} 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$_{water,total}$ reported in Table 7.4 of the dossier (rounded to two significant figures) are correct, except for the QS$_{biota,secpois,fw}$, for which the concentration in fish (0.045 mg kg^{-1}) is used instead of the derived concentration in water (27 ng L^{-1}). In the table below the corrected value is reported.

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

	$EQS_{water,dissolved}$	$EQS_{water,total}$
MAC-QS$_{fw, eco}$	0.011 µg L^{-1}	0.015 µg L^{-1}
MAC-QS$_{sw, eco}$	0.0011 µg L^{-1}	0.0024 µg L^{-1}
AA-QS$_{fw, eco}$	9.5 x 10^{-5} µg L^{-1}	13 x 10^{-5} µg L^{-1}
AA-QS$_{sw, eco}$	9.5 x 10^{-6} µg L^{-1}	10 x 10^{-6} µg L^{-1}
QS$_{Biota, sec pois, fw}$	27 ng/L	37 ng L^{-1}

4. CRITICAL EQS

In the light of the data provided in the dossier, the most critical EQS (in terms of impact on environment/health) has been identified as the **AA-QS$_{sw, eco}$ = 0.0095 ng L^{-1}.**

However, it is the opinion of the SCHEER that there exists other relevant and reliable data which should be further checked and assessed for the refinement of the QSs presented in the dossier. This could result in change of the most critical EQS.

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
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
OC	Organic Carbon
QS	Quality Standard
SPM	Suspended Particulate Matter
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TL	Threshold Level
WG	Working Group (on Chemicals)

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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