Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Cypermethrin

The SCHEER adopted this document
by written procedure on 9 August 2022

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

The SCHEER members:
Marian Scott (Chair), Marco Vighi (Rapporteur), Thomas Backhaus, Teresa Borges, Peter Hoet, Rodica Mariana Ion, Pim de Voogt

The external Experts:
Andrew Johnson, Jan Linders

All Declarations of Working Group members are available at the following webpage:
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SCHEER members
Thomas Backhaus, Roberto Bertollini, Teresa Borges, Wim de Jong, Pim de Voogt, Raquel Duarte-Davidson, Peter Hoet, Rodica Mariana Ion, Renate Kraetke, Demosthenes Panagiotakos, Ana Proykova, Theo Samaras, Marian Scott, Emanuela Testai, Theo Vermeire, Marco Vighi, Sergey Zacharov

Contact
European Commission
DG Health and Food Safety
Directorate C: Public Health
Unit C2: Health information and integration in all policies
L-2920 Luxembourg
SANTE-C2-SCHEER@ec.europa.eu

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ABSTRACT

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

The SCHEER accepts with reservations the **MAC-$QS_{fw,eco}$ = 0.6 ng L^{-1}** and the **MAC-$QS_{sw,eco}$ = 0.06 ng L^{-1}** derived with a probabilistic procedure. It is the opinion of the SCHEER that a more careful collection of data should be performed.

For the same reason, the SCHEER does not endorse the AA-$QS_{fw, eco}$ and the AA-$QS_{sw, eco}$. In particular, the SCHEER cannot accept, without sufficient transparent support, that the probabilistic approach SSD cannot be applied due to the lack of data.

The SCHEER cannot endorse the proposed $QS_{sediment}$ because data, reported in the 2011 dossier and relevant for deriving the QS, are not reported in the present dossier.

The SCHEER endorses the **$QS_{biota,secpois,fw}$ = 1.0 mg kg^{-1}** for fish and **0.30 mg kg^{-1}** for bivalves, as well as the back-calculated **$QS_{fw, biota}$ = 0.87 µg L^{-1}** for fish and **$QS_{fw, biota}$ = 0.25 µg L^{-1}** for bivalves.

For human health, different QS are derived for cypermethrin, alpha-cypermethrin and zeta-cypermethrin, due to different ADI values. However, in the EU evaluation of cypermethrin under PPP and Biocides Directives, only the ADI for cypermethrin was used.

Therefore, for the sake of "one substance, one assessment" harmonisation, it is the opinion of the SCHEER that the same approach should be used. Using themostrecent ADI proposed by EFSA, the SCHEER proposes the **$QS_{biota,hh}$ =0.61 mg $kg^{-1}{}_{biota}$** , for cypermethrin, as well as the back-calculated **$QS_{water, hh\ food}$ = 0.51 µg L^{-1}**.

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}**).

The most critical EQS cannot be indicated by the SCHEER because some relevant QS have not been endorsed.

To harmonise the dossier with the other pyrethroid dossiers, the SCHEER suggests including a section for the estimation of $EQS_{water,total}$.

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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.

[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.

For cypermethrin, the EQSs proposed in the 2011 EQS dossier have been revised considering recent literature data. In particular, the MAC and AA-QSs for fresh and marine waters and the $QS_{sec\ biota}$ have been revised. In the preliminary section of the dossier, it is said that no changes are proposed for $QS_{sediment}$, and $QS_{sec\ hh}$.

The SCHEER noted that a reference to the 2011 SCHER Opinion is missing. The responses of the WG on Chemicals to the comments of the SCHER are also missing, although in the beginning of the dossier document it is stated that these would be provided at the end of the document.

The SCHEER notes that, due to the hydrophobicity of the compounds, a section was included for the estimation of $EQS_{water,total}$ in the dossiers on all other pyrethroids (bifenthrin, deltamethrin, esfenvalerate, permethrin). The SCHEER suggests including this section to harmonise the dossiers of substances of the same chemical class.

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

Section 7 – Effects and Quality Standards

The ecotoxicity data presented in the 2011 EQS dossier have been retained without re-assessment of reliability.

Some criteria for the new data selection are briefly described. It is the opinion of the SCHEER that the description of criteria for data selection should be harmonised throughout the different dossiers.

The assessment was performed on the combination of ecotoxicity values for cypermethrin, alpha-cypermethrin and zeta-cypermethrin. No QSs were set for theta-cypermethrin and beta-cypermethrin, since no commercial uses for them are known in Europe at this time. The SCHEER endorses this procedure.

Section 7.1 – Field experiment

Several mesocosm studies are available for cypermethrin. However, the results are solely used as indicative because of the fast degradation of cypermethrin in water (the SCHEER would consider this to be "dissipation" instead of "degradation") and because the acute peak exposure in the mesocosm studies are not suitable for assessing chronic effects. It is the opinion of the SCHEER that the same type of exposure is likely to occur in natural systems (except perhaps in cases of repeated and continuous emissions). Therefore, the relevance of mesocosm studies should be better considered.

Section 7.2 – Acute Aquatic Ecotoxicity

A MAC-$QS_{fw,eco}$ is derived with the deterministic procedure by applying an AF of 10 to the lowest selected acute toxicity value (LC50 for *Hyalella azteca* of 7 ng L^{-1}), leading to a

MAC-$QS_{fw, eco}$ =0.7 ng L^{-1}. For marine waters, an additional AF of 10 is applied, leading to a MAC-$QS_{sw, eco}$ =0.07 ng L^{-1}.

The selected LC50 value is the geometric mean of several values reported in two different studies (Clark et al. 2015; Weston and Jackson 2009). The results of the Clark et al. article are nominal and not measured, as requested by one of the selection criteria mentioned in the dossier. Therefore, the SCHEER is not able to endorse this deterministic MAC QS value.

The probabilistic approach is based on an SSD developed with 16 acute toxicity values on arthropods that represent the more sensitive taxonomic group. An HC5=6 ng L^{-1} is obtained and a MAC-$QS_{fw, eco}$ =0.6 ng L^{-1} is derived. For marine waters, an additional AF of 10 is applied, leading to a MAC-$QS_{sw, eco}$ =0.06 ng L^{-1}.

As the probabilistic MAC-QS was obtained with a suitable number of data on the most sensitive taxonomic group and was slightly lower (not higher as erroneously mentioned in the dossier) than the deterministic one, the **MAC-$QS_{fw, eco}$ = 0.6 ng L^{-1}** and the **MAC-$QS_{sw, eco}$ = 0.06 ng L^{-1}** based on the probabilistic approach were therefore chosen as final standards.

On the basis of the data provided in the dossier, the procedure was properly applied. However, the SCHEER notes that only three new values (more recent than 2011) were added in the database. This is surprising for an extensively studied compound like cypermethrin. Therefore, the SCHEER endorses these values only with substantial reservations. It is the opinion of the SCHEER that more data are available in international databases and that the availability of reliable data should be carefully checked. The reasons for their rejection must be transparently reported and supported by scientific criteria.

The SCHEER is aware that these low QSs may be problematic being lower than the present technically achievable LOD.

Section 7.3 – Chronic Aquatic Ecotoxicity

The dataset reports only seven chronic values, only two of them are more recent than the 2011 dossier.

The lowest chronic value is the 28-day NOEC of 1.5 ng L^{-1} for the reproduction of the marine crustacean *Americamysis bahía*. An AF of 50 can is applied to the lowest chronic value because the dossier states that no chronic data are available for amphipods (such as *Hyalella* and *Gammarus*) that, from the acute data set, seems to be the most sensitive group among arthropods. Therefore, an AA-$QS_{fw, eco}$ = 0.03 ng L^{-1} is proposed. For marine waters, an additional AF of 10 is applied leading to an AA-$QS_{sw, eco}$ = 0.003 ng L^{-1}.

The probabilistic approach was not applied due to the lack of sufficient data.

The SCHEER notes that cypermethrin is one of the most extensively studied among plant protection products. In the US EPA ECOTOX database, chronic toxicity data are reported for about 100 different aquatic species, many of them arthropods, including data on amphipods. In the dossier, no justifications are provided for rejecting such an extensive amount of data. Therefore, the SCHEER cannot endorse the proposed AA-QSs, without a more extensive assessment of the literature.

Section 7.4 – Sediment toxicity

An AA-$QS_{sediment}$ is proposed, despite in the introduction of the dossier it was reported that no changes are proposed for $QS_{sediment}$ in comparison to the 2011 EQS dossier.

In the dataset, only one chronic-sediment toxicity value is reported on *Chironomus dilutus*. Therefore, according to the EQS Technical Guidance an AF of 100 and an AF of 1000 are

applied to derive the $QS_{sediment, fw}$ and $QS_{sediment, sw}$, respectively, leading to a $QS_{sediment, fw}$ = 89.5 ng kg^{-1} and a $QS_{sediment, sw}$ = 8.95 ng kg^{-1}.

In the 2011 EQS dossier, sediment data on *H. azteca* and *Chironomus tentans* were reported. The rejection of these data is not justified in the new dossier. Therefore, the SCHEER cannot endorse the proposed $QS_{sediment}$.

Section 7.6 – Secondary Poisoning

Based on the log K_{ow} (range 5.3 – 5.6), the evaluation of secondary poisoning is considered necessary. The SCHEER agrees with this decision.

The SCHEER agrees with the selection of the most sensitive mammalian toxicity study available with a NOAEL of 2.5 mg $kg_{bw}^{-1}d^{-1}$ from a 3 generational study on rats.

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) is calculated with the following equation that represents the regression (experimentally determined) between DEE and bodyweight in mammals:

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

The energy-normalised diet concentration for cypermethrin can then be calculated with the following equation:

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

where the dose is the 'reference' value for a toxicological endpoint (such as the NOAEL, LOAEL, LD50 or similar, expressed as daily dose in mg/kgbw/d).

Using a value of 275 g, corresponding to the average bodyweight (bw) of female and male rats in the experiment, a DEE of 360.97 kJ d^{-1} and a $C_{energy\ normalised}$ of 1.9 µg kJ^{-1} are 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, using the following equation:

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

using an energy and moisture content of 21 kJ g_{dw}^{-1} and 74% respectively for fish and of 19 kJ g_{dw}^{-1} and 92% for bivalves (EC, 2018), the results are:

- For fish: $C_{food\ item}$ [mg kg_{ww}^{-1}] = 10.51
- For bivalves: $C_{food\ item}$ [mg kg_{ww}^{-1}] = 3.05

Apart from minor differences in calculation, the SCHEER agrees with these values.

Therefore, the values of **$QS_{biota,secpois,fw}$ of 1.05 mg kg^{-1}** (rounded to **1.0 mg kg^{-1}**) for fish and **0.305 mg kg^{-1}** (rounded to **0.30 mg kg^{-1}**) for bivalves, obtained by applying an AF of 10 to the $C_{food\ item}$, are endorsed by the SCHEER.

For the back-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, for which biomagnification is unlikely, the SCHEER considers the application of a BMF of 1 conceptually 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. A BCF = 1204 for fish is used for both fish and bivalves.

The SCHEER agrees with the procedure. Therefore, the **$QS_{fw,\ biota}$ = 0.87 µg L^{-1}** for fish and the **$QS_{fw,\ biota}$ = 0.25 µg L^{-1}** for bivalves 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 7.7 – 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} allocated 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).

Different ADI values are proposed for the different isomers: 0.05, 0.015 and 0.03 mg kg^{-1}_{bw} d^{-1} for cypermethrin, alpha-cypermethrin and zeta-cypermethrin, respectively.

Using these ADI as TL_{hh}, the $QS_{biota,hh}$ =6.13 mg kg^{-1}_{biota} (to be rounded to $QS_{biota,hh}$ = 6.1 mg kg^{-1}_{biota}), $QS_{biota,hh}$ = 1.84 mg kg^{-1}_{biota} (to be rounded to $QS_{biota,hh}$ = 1.8 mg kg^{-1}_{biota}) and $QS_{biota,hh}$ = 3.06 mg kg^{-1}_{biota} (to be rounded to $QS_{biota,hh}$ = 3.1 mg kg^{-1}_{biota}) are calculated for cypermethrin, alpha-cypermethrin and zeta-cypermethrin respectively.For the back calculation of the $QS_{water,\ hh\ food}$ the BCF on fish is used, leading to a $QS_{water,\ hh\ food}$ =5.09 µg L^{-1} (to be rounded to $QS_{water,\ hh\ food}$ = 5.1 µg L^{-1}), $QS_{water,\ hh\ food}$ = 1.52 µg L^{-1} (to be rounded to $QS_{water,\ hh\ food}$ = 1.5 µg L^{-1}), $QS_{water,\ hh\ food}$ = 3.06 µg L^{-1} (to be rounded to $QS_{water,\ hh\ food}$ = 3.1 µg L^{-1}), are calculated for cypermethrin, alpha-cypermethrin and zeta-cypermethrin respectively.

It is the opinion of the SCHEER that the procedures are properly applied. However, in the EU evaluation of cypermethrin under PPP and Biocides Directives as well as JECFA, only a single ADI for cypermethrin is used. The value has been derived, considering that commercial cypermethrin is a mixture of isomers of which 20-40% alpha-cypermethrin, the most toxicologically active isomer. Moreover, in a more recent EFSA Opinion (EFSA, 2018), a group ADI for cypermethrin (including the alpha and zeta isomers) of 0.005 mg kg^{-1}_{bw} d^{-1} is used. It is the opinion of the SCHEER that the same approach should be applied here. Therefore, the SCHEER proposes using the **$QS_{biota,hh}$ =0.61 mg kg^{-1}_{biota}** and the **$QS_{water,\ hh\ food}$ = 0.51 µg L^{-1}** , derived for cypermethrin.

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

4. Critical EQS

Some EQSs have not been endorsed by the SCHEER. Therefore, the most critical EQS cannot be indicated by the SCHEER.

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
bw	body weight
DEE	Daily Energy Expenditure
dw	dry weight
EC	Effect Concentration
EFSA	European Food Safety Agency
EQS	Environmental Quality Standards
HC	Hazardous Concentration
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
NOEL	No Effect Level
PPP	Plant Protection Products
QS	Quality Standard
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TL	Threshold Level
ww	wet weight

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.

EFSA (European Food Safety Authority), 2018. Peer review of the pesticide risk assessment of the active substance cypermethrin. EFSA Journal, 16(8), 5402, doi:10.2903/j.efsa.2018.5402.