Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Clothianidin

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

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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 "Clothianin" was reviewed by the SCHEER according to the general mandate on EQS dossiers.

The SCHEER endorses the **MAC-$QS_{fw,eco}$ = 0.34 µg L^{-1}**, derived with a deterministic procedure. The SCHEER agrees with the decision of not considering reliable the probabilistic approach due to the high degree of uncertainty.

For saltwater, the SCHEER endorses the deterministic **MAC-$QS_{sw,eco}$ = 0.034 µg L^{-1}**.

The SCHEER endorses the **AA-$QS_{fw,\ eco}$ = 0.01 µg L^{-1}**, derived with a deterministic procedure. The probabilistic procedure is not applied due to the scarcity of data.

For saltwater, the SCHEER endorses the deterministic **AA-$QS_{sw,eco}$ = 0.001 µg L^{-1}**.

The SCHEER agrees with the decision of not deriving an EQS for secondary poisoning.

For human health, the SCHEER endorses a **$QS_{biota,hh}$ = 12 mg kg^{-1}** and the adoption of the general drinking water standard for pesticides (0.1 µg L^{-1}).

TABLE OF CONTENTS

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.

In the case of acetamiprid the SCHEER did not receive additional points.

3. OPINION

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

Section 7 – Effects and Quality Standards

The SCHEER has no further comments on the introductory paragraph.

Section 7.1 – Acute Aquatic Ecotoxicity

Derivation of a MAC-QS for the freshwater community (MAC-QS$_{fw,eco}$)

Table 7.1 of the EQS dossier contains 17 ecotoxicity studies, of which 6 marine species, were selected for the determination of the MAC-EQS. After excluding unbounded values nine freshwater and 5 marine organisms remained, 2 algae species, 2 crustaceans, 4 insects, 1 oligochaete worm for freshwater and 1 alga and 4 crustaceans for marine water. The SCHEER could agree with this selection. The SCHEER also agrees to merge the freshwater and marine water organisms based on the statistical analysis of the complete dataset.

Deterministic approach

Based on the endpoints in the studies selected and an AF of 10 to the lowest EC_{50} of 0.0034 mg L^{-1} for the endpoint of immobility measured for the insect midge *Chironomus dilutus* (Raby et al., 2018), a **MAC-QS$_{fw,eco}$ = 0.34 µg L^{-1}** has been derived and can be endorsed by the SCHEER.

Probabilistic approach

The SCHEER endorses the development of SSD-curves as sufficient data are available of sufficient different taxonomic groups. SSD curves have been determined for all data selected, for different organisms that showed most sensitivity, and for organisms showing less toxicity. The SCHEER agrees with this process to determine the most relevant HC_5. However, because of the relatively small datasets, a rather high degree of uncertainty was associated with the result achieved. The probabilistic approach revealed a MAC-QS$_{fw,eco}$ of 0.18 µg L^{-1} applying an AF of 10 to the HC_5 value of 1.8 µg L^{-1}.

Conclusion

In conclusion, due to the high degree of uncertainty of the probabilistic approach, based on the small dataset, preference, was given to the value derived using the deterministic approach. Therefore, a final value for the **MAC-QS$_{fw,eco}$ = 0.34 µg L^{-1}** was proposed. The SCHEER endorses this value.

Derivation of a MAC-QS for the saltwater pelagic community (MAC-QS$_{sw,eco}$)

Deterministic approach

Applying an additional AF of 10 to the freshwater MAC-QS derived, the SCHEER endorses the resulting value: **MAC-QS$_{sw,eco}$= 0.034 µg L^{-1}.**

Probabilistic approach

The SCHEER is not able to endorse the MAC-$QS_{sw,eco}$ of 0.018 µg L^{-1} as proposed in the EQS-dossier. In the determination of the MAC-$QS_{fw,eco}$, the reason for not accepting the result was based on the high uncertainty and the SCHEER agreed with that reasoning. It is, however, unclear why the uncertain value is now accepted by the WG on Chemicals without further explanation. Therefore, the SCHEER is of the opinion that the same uncertainty identified is valid in the case of determining the marine water QS.

The SCHEER proposes to apply an additional AF of 10 to the MAC-$QS_{fw,eco}$, resulting in a **$MAC_{sw,eco}$ = 0.034 µg L^{-1}**.

Section 7.2 – Chronic Aquatic Ecotoxicity

Derivation of a AA-QS for the freshwater community (AA-$QS_{fw,eco}$)

Table 7.4 of the EQS dossier contains 12 ecotoxicity studies selected for the determination of the AA-EQS, for freshwater 1 alga species, 1 fish, 3 crustaceans, 4 insects, 1 mollusc; for marine water, 1 copepod and 1 shrimp. The SCHEER endorses this selection.

Deterministic approach

Based on the endpoints in the studies selected and the application of an AF of 10 to the lowest reliable EC_{10} of 0.1 µg L^{-1} for the endpoint of growth measured for the mollusc *Planorbella pilsbryi* (Prosser *et al.*, 2016), an **AA-$QS_{fw,eco}$ = 0.01 µg L^{-1}** has been derived. The SCHEER supports this value.

Probabilistic approach

The SCHEER agreed that, based on the available chronic ecotoxicity data, no probabilistic assessment was possible.

Conclusion

In conclusion, the SCHEER supports the value derived in the EQS-dossier of **AA-$QS_{fw,eco}$ = 0.01 µg L^{-1}**.

Derivation of a MAC-QS for the saltwater pelagic community (AA-$QS_{sw,eco}$)

Applying an additional AF of 10 to the MAC-$QS_{fw,eco}$, an **AA-$QS_{sw,eco}$ = 0.001 µg L^{-1}** could be derived. The SCHEER endorses this value.

Section 7.3 – Secondary Poisoning

Due to the low affinity of clothianidin to accumulate in aquatic organism based on the octanol/water partitioning coefficient (log K_{ow} = 0.7), the assessment of secondary poisoning was not considered necessary.

For neonicotinoids, there is no evidence that bioaccumulation may occur in tissues other than lipids. Therefore, it is the opinion of the SCHEER that deciding on the need for an EQS for secondary poisoning as a function of a trigger based on log K_{ow} may be appropriate for clothianidin.

Section 7.4 – Human Health

For the human health risk *via* consumption of fishery products, according with the EQS Technical Guidance, the following formula was applied:

$$QS_{biota\ hh\ food} = 0.2 * TL_{hh} / 0.001653$$

Considering the acceptable daily intake (ADI) of 0.1 mg kg^{-1}_{bw} d^{-1} (CAR, 2014) applying an AF of 100 on the rat developmental neurotoxicity study for which a NOAEL value of 10 mg kg^{-1}_{bw} d^{-1}, a provisional **$QS_{biota,hh\ food}$ = 12.27 mg kg^{-1}** was derived.

The SCHEER agrees with these conclusions although the precision in the QS-value is not supported. It would be better to determine the **$QS_{biota,hh\ food}$ = 12 mg kg^{-1}**.

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

4. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
CAR	Chemical Assessment Report
EC	Effect Concentration
EQS	Environmental Quality Standards
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
QS	Quality Standard
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.

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