



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

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

**Acetamiprid**



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

The SCHEER endorses the **MAC-QS<sub>fw,eco</sub> = 0.16 µg L<sup>-1</sup>**, 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<sub>sw,eco</sub> = 0.016 µg L<sup>-1</sup>**.

The SCHEER does not agree with the proposal of the dossier of an additional AF of 5, besides the AF of 10. Therefore, SCHEER is of the opinion that a deterministic **AA-QS<sub>eco,fw</sub> = 0.037 µg L<sup>-1</sup>** should be determined instead of the value of 0.0074 µg L<sup>-1</sup> proposed in the EQS-dossier. The probabilistic procedure is not applied due to the scarcity of data.

For saltwater, the SCHEER proposes the deterministic **AA-QS<sub>sw,eco</sub> = 0.037 µg L<sup>-1</sup>**.

For sediment, the SCHEER endorsed the value of **QS<sub>sedEqPdw</sub> = 0.26 µg kg<sup>-1</sup><sub>dw</sub>** obtained using the Equilibrium Partitioning method.

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

For human health, the SCHEER endorses a **QS<sub>biota,hh</sub> = 3.1 mg kg<sup>-1</sup><sub>ww</sub>** and the adoption of the general drinking water standard for pesticides (0.1 µg L<sup>-1</sup>).

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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<sup>1</sup>.

## 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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<sup>1</sup> <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 document lists several remarks relevant for the selection of the aquatic ecotoxicological tests available to the WG on Chemicals. The SCHEER is of the opinion that the caution in the comment in the last bullet referring to the photodegradation study is not justified based on the information provided in Section 5.2.

#### Section 7.1 – Acute Aquatic Ecotoxicity

##### Derivation of a MAC-QS for the freshwater community (MAC-QS<sub>fw,eco</sub>)

Table 7.1 of the EQS dossier contains 19 ecotoxicity studies selected for the determination of the MAC-EQS, 3 algae species, 1 higher plant, 3 fish, 4 crustaceans, 4 insects, 1 oligochaete worm and 3 marine species, all crustaceans. The SCHEER could endorse this selection. The SCHEER also agrees to merge the freshwater and marine water organisms. The number of marine species is not sufficient for a separate assessment.

##### Deterministic approach

Based on the endpoints in the studies selected and applying an AF of 10 to the lowest EC<sub>50</sub>, 1.6 µg L<sup>-1</sup> for the mayfly *Neocloeon triangulifer* (Raby, *et al.*, 2018a) a **MAC-QS<sub>fw,eco</sub> = 0.16 µg L<sup>-1</sup>** has been derived and is 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<sub>5</sub>. 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<sub>fw,eco</sub> of 0.034 µg L<sup>-1</sup> applying an AF of 10 to the HC<sub>5</sub> value of 0.340 µg L<sup>-1</sup> for aquatic invertebrates, excluding *Daphnia magna*.

##### Conclusion

In conclusion, due to the high degree of uncertainty of the probabilistic approach, preference was given to the value derived using the deterministic approach. Therefore, a final value for the **MAC-QS<sub>fw,eco</sub> = 0.16 µg L<sup>-1</sup>** was proposed. The SCHEER endorses this value.

##### Derivation of a MAC-QS for the saltwater pelagic community (MAC-QS<sub>sw,eco</sub>)

Applying an AF of 100 to the MAC-QS<sub>fw,eco</sub>, to the lowest EC<sub>50</sub>, 1.6 µg L<sup>-1</sup> for the mayfly *N. triangulifer* (Raby, *et al.*, 2018a), a **MAC<sub>sw,eco</sub> = 0.016 µg L<sup>-1</sup>** could be derived. The SCHEER supported this value.



## Section 7.2 – Chronic Aquatic Ecotoxicity

### Derivation of a AA-QS for the freshwater community (AA-QS<sub>fw,eco</sub>)

Table 7.3 of the EQS dossier contains 10 ecotoxicity studies selected for the determination of the AA-EQS, 1 alga species, 1 fish, 3 crustaceans, 4 insects, 1 amphibian. The SCHEER could endorse this selection. No chronic ecotoxicity for marine species were available for assessment.

### Deterministic approach

Based on the endpoints in the studies selected and the application of an AF of 10 to the lowest reliable EC<sub>10</sub> of 0.37 µg L<sup>-1</sup> for the endpoint of emergence measured for the aquatic insect midge *Chironomus dilutus* (Raby, *et al.*, 2018b), an QS<sub>fw,eco</sub> of 0.037 µg L<sup>-1</sup> has been derived. However, it was considered by the WG on Chemicals that this value was considered rather high compared to other neonicotinoids and, therefore, an AF of 50 was considered more appropriate. The SCHEER considered that this reasoning was scientifically weak without further substantiating evidence and, therefore, this value cannot be endorsed by the SCHEER. The SCHEER is of the opinion that a **AA-QS<sub>eco,fw</sub> of 0.037 µg L<sup>-1</sup>** should be determined instead of the value of 0.0074 µg L<sup>-1</sup> proposed in the EQS-dossier.

### Probabilistic approach

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

### Conclusion

In conclusion, the SCHEER deviates from the view presented in the EQS-dossier and proposes a final value for the **AA-QS<sub>fw,eco</sub> = 0.037 µg L<sup>-1</sup>**.

### Derivation of a MAC-QS for the saltwater pelagic community (AA-QS<sub>sw,eco</sub>)

Applying an additional AF of 10 to the MAC-QS<sub>fw,eco</sub>, an **AA<sub>sw,eco</sub> = 0.0037 µg L<sup>-1</sup>** should be derived instead of the value proposed in the EQS-dossier on acetamiprid.

## Section 7.3 – Sediment Ecotoxicity

As no sediment ecotoxicity data were available the WG on Chemicals decided to use the Equilibrium Partitioning method to estimate the QS<sub>sedEqPdw</sub>. The SCHEER endorsed the derived value **QS<sub>sedEqPdw</sub> of 0.256 µg kg<sup>-1</sup><sub>dw</sub>**. Nevertheless, the SCHEER is of the opinion that the number of significant digits is too high and proposes to adjust this value to **QS<sub>sedEqPdw</sub> of 0.26 µg kg<sup>-1</sup><sub>dw</sub>**.

## Section 7.4- Secondary Poisoning

Due to the low affinity of acetamiprid to accumulate in aquatic organisms based on the octanol/water partitioning coefficient (log K<sub>ow</sub> < 3), 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<sub>ow</sub> may be appropriate for acetamiprid.

## Section 7.5 – Human Health

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

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

Considering the acceptable daily intake (ADI) of  $0.025 \text{ mg} \cdot \text{kg}^{-1}_{\text{bw}} \cdot \text{d}^{-1}$  (EFSA, 2016) applying an AF of 100 on the rat developmental neurotoxicity study for which a NOAEL value of  $2.5 \text{ mg} \cdot \text{kg}^{-1}_{\text{bw}} \cdot \text{d}^{-1}$ , a provisional  $QS_{\text{biota hh food}} = 3.07 \text{ mg kg}^{-1}_{\text{ww}}$  was derived, equivalent to **9.59 mg kg<sup>-1</sup><sub>dw</sub>**.

It is opinion of the SCHEER that then procedure is properly applied. However, a rounded value of **3.1 mg kg<sup>-1</sup><sub>ww</sub>** would be more appropriate, in agreement with the suggestion in the introductory preamble of this opinion

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.

#### **4. LIST OF ABBREVIATIONS**

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application 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
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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