



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

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

**Thiacloprid**



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 "Thiacloprid" was reviewed by the SCHEER according to the general mandate on EQS dossiers, dossier also including two specific questions for thiacloprid.

The SCHEER endorses the **MAC-QS<sub>fw,eco</sub>=0.08 µg L<sup>-1</sup>**, derived with a deterministic procedure.

The SCHEER does not agree with the proposal of the dossier of an additional AF of 5, besides the AF of 10 for the probabilistic procedure. Therefore, SCHEER is of the opinion that a deterministic **MAC-QS<sub>eco,fw</sub>=0.05 µg L<sup>-1</sup>** should be determined instead of the lower value proposed in the EQS-dossier.

For saltwater, the SCHEER endorses the deterministic **MAC<sub>sw,eco</sub>=0.008 µg L<sup>-1</sup>** and the probabilistic **MAC<sub>sw,eco</sub>=0.005 µg L<sup>-1</sup>**.

For the derivation of the AA-QS, the SCHEER does not agree with the proposal of the dossier of an additional AF of 5, besides the AF of 10 for the deterministic procedure. Therefore, SCHEER is of the opinion that a deterministic **AA-QS<sub>fw,eco</sub>=0.01 µg L<sup>-1</sup>** should be determined instead of the value of 0.002 proposed in the EQS-dossier.

The probabilistic procedure is not applied due to the scarcity of data.

Therefore, for saltwater, the SCHEER proposes the deterministic **AA-QS<sub>sw,eco</sub>=0.001 µg L<sup>-1</sup>** instead of the value of 0.0002 proposed in the EQS-dossier.

The SCHEER agrees with the decision of not deriving an EQS for sediment, but the reasons should be mentioned in the text of the dossier.

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> = 1.2 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.

## **Additional questions for thiacloprid**

### **Background**

Following the consultation of the WG chemicals group, the JRC received further comments on the ecotoxicity data selection and the AF choice.

Briefly, the experts recommended to review the MAC-QS<sub>fw</sub> and AA-QS<sub>fw</sub> suggesting to include the mesocosm studies Englert et al. (2012) and Beketov et al. (2008) for the MAC-QS derivation and the studies performed by Heimbach (1997, cited in EFSA, 2019) and Liess and Beketov (2011) for the AA-QS derivation. Oekotoxzentrum report (2016) considered studies with formulations of thiacloprid as supporting information, arguing that the additives could influence the toxicity. Those studies were not used directly for the EQS derivation. However, members of the WG Chemicals and experts of the sub-group on neonicotinoids disagreed on leaving mesocosms studies with formulated products out of consideration beforehand. Therefore, some members of the WG Chemicals and experts subgroup on neonicotinoids recommended to include the mesocosms studies for derivation of the EQS.

Furthermore, it was suggested to compare the toxicity effects of thiacloprid with imidacloprid. The study performed by Van den Brink et al. (2016) stated that thiacloprid is about two-fold more toxic than imidacloprid (acute and chronically). This issue of comparison of substances having a similar mode of action was also taken into account into the draft dossier of other neonicotinoids. Therefore, it was concluded to increase the AF of 5 either for MAC-EQS or for AA-QS, total 50 and 500 for fresh and marine water respectively.

- **Question 2.2.a:**  
Is it correct to include the mesocosm studies for deriving the EQS and determining the AF choice, even if Oekotoxzentrum report (2016) considered studies with formulations of thiacloprid as supporting information?
- **Question 2.2.b:**  
Could be properly justified the additional AF of 5, by comparing the toxicity effects of substances having a similar mode of action, to be more in line with the provisional QS value derived for the other neonicotinoids?

### 3. OPINION

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

#### Section 3.1 Environmental Quality Standards (EQS)

In the synoptic table of EQSs, the human health QS via consumption of drinking water is reported as  $0.01 \mu\text{g L}^{-1}$  while in the main text of section 7.4 the existing drinking water standard of  $0.1 \mu\text{g L}^{-1}$  is reported.

#### Section 7. Effects and quality standards

The criteria for the selection of acute and chronic data for the derivation of EQS are described.

In general, it is the opinion of the SCHEER that the adopted criteria are acceptable. Some comments may be made. In particular:

- “Unbounded values (in ">" and "<"), even if they are valid, were not used directly for EQS derivation, neither for deterministic nor probabilistic approach, but were considered as supporting information. ”

The SCHEER notes that this criterion is different from those used for thiamethoxam, where unbounded values were used for the derivation of the SSD curve (probabilistic approach). It is the opinion of the SCHEER that it is preferable not to use unbounded values for the SSD curve. Therefore, the SCHEER agrees with the criterion adopted for thiacloprid.

- “If chronic exposure was less than, or equal to, 10 days, especially for invertebrate species, it was agreed among the expert subgroup on neonicotinoids to consider these data as supporting information.”

The chronic exposure time should refer to the lifespan of the organisms considered. For example, for algae, a 72h exposure, covering several generations, is considered as chronic. The SCHEER agrees that, in general, this is not the case for animal species (vertebrates and invertebrates). Therefore, the SCHEER suggest substituting the words “especially for invertebrate species” with the words “for animal species” and agrees to consider these data as supporting.

#### Section 7.1 Acute aquatic ecotoxicity

The selected acute toxicity data on aquatic organisms of several taxonomic groups (from algae to fish) is listed in table 7.1.

It is the opinion of the SCHEER that it is appropriate to use the LC50 of  $0.0008 \text{ mg L}^{-1}$  on the dipteran insect *Chironomus dilutus* as the most sensitive value to derive a deterministic MAC-QS with an AF of 10. Therefore, the **MAC-QS<sub>fw,eco</sub> =  $0.08 \mu\text{g L}^{-1}$** , derived with a deterministic procedure, is endorsed by the SCHEER.

For the determination of the probabilistic MAC-QS, SSD curves were considered using all aquatic organisms (N=17), and aquatic invertebrates (N=14).

For the derivation of the probabilistic MAC-QS, the SSD curve obtained with aquatic invertebrates was selected because the curve includes the most sensitive taxonomic group for the insecticide imidacloprid (11 arthropods with 4 insect species) and is accepted at all P levels in all goodness-of-fit tests for normality. The HC<sub>5</sub> of the SSD curve is  $0.5 \mu\text{g L}^{-1}$  and the application of an AF of 10 gave an SSD-based **MAC-QS<sub>fw,eco</sub> =  $0.05 \mu\text{g L}^{-1}$**  which the SCHEER endorses.

Although it is the opinion of the SCHEER that studies performed using formulations may be used for deriving EQS (to answer to question 2.2a), it is the opinion of the SCHEER that the application of an additional factor of 5 (leading to a total AF of 50) on the basis of mesocosm studies is not sufficiently justified and therefore the additional question 2.2.b is



answered negatively. The information provided by mesocosm studies should reduce, not increase, the AF.

For marine water, a few data on marine organisms are available. Therefore, freshwater and marine data were combined and, according to the Technical Guidance for Deriving Environmental Quality Standards (EC, 2018), an additional AF of 10 is applied.

It is the opinion of the SCHEER that the deterministic  $\text{MAC}_{\text{sw,eco}} = 0.008 \mu\text{g L}^{-1}$  and the probabilistic  $\text{MAC}_{\text{sw,eco}} = 0.005 \mu\text{g L}^{-1}$  are adequate.

## Section 7.2 Chronic aquatic ecotoxicity

The selected chronic toxicity data are listed in table 7.2.

An AF of 10 is applied to the NOEC of  $0.0001 \text{ mg L}^{-1}$  on the insect *Chironomus riparius* as the most sensitive value, resulting in a deterministic  $\text{AA-QS}_{\text{fw,eco}} = 0.01 \mu\text{g L}^{-1}$ .

As for the MAC-QS, it is the opinion of the SCHEER that the application of an additional factor of 5 (leading to a total AF of 50) on the basis of mesocosm studies is not sufficiently justified.

For the determination of the probabilistic AA-QS, no sufficiently reliable data are available. Therefore, the probabilistic  $\text{AA-QS}_{\text{fw,eco}}$ , is not derived.

In the table at page 31 (no number of table and no caption are reported), it is indicated that the AA-QS for sediment is not required, without any mention in the text. Considering the physical-chemical properties of the compound, the SCHEER agrees with this decision, however, it should be mentioned in the text of the dossier.

## Section 7.3 Secondary poisoning

Considering the physical-chemical properties of the substance and, in particular, the  $\log K_{\text{ow}}$  which is below the trigger value of 3, no secondary poisoning assessment was undertaken in the dossier.

In the Technical Guidance for Deriving Environmental Quality Standards, it is suggested to use experimental values of bioconcentration or bioaccumulation factors (BCF or BAF  $\geq 100$ ) or of biomagnification factor (BMF  $\geq 1$ ) as triggers for secondary poisoning. If no data are available,  $K_{\text{ow}}$  may be used as a surrogate. It is the opinion of the SCHEER that the procedure must be considered with care. Indeed, for some types of contaminants, the sink for bioaccumulation is other than lipids (for example proteins, as for perfluorinated compounds). In these cases, a trigger based on  $K_{\text{ow}}$  is inappropriate and an experimental BCF must be provided. Therefore, using  $K_{\text{ow}}$  as a surrogate may be appropriate where there is evidence that the chemical can bioaccumulate in lipids.

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  $\log K_{\text{ow}}$  may be appropriate for thiamethoxam.

## Section 7.4 Human health

For the human health risk *via* consumption of fishery products, a QS was calculated considering the acceptable daily intake (ADI) of  $0.01 \text{ mg kg}^{-1}_{\text{bw}}$  (EFSA, 2019), and a daily consumption of  $1.6 \text{ g kg}^{-1}_{\text{bw}}$  and a default allocation factor of 0.2.

The  $\text{QS}_{\text{biota,hh,food}}$  is calculated using the following equation (EC, 2018),

$$\text{QS}_{\text{biota,hh food}} [\text{mg kg}_{\text{biota}}^{-1}] = (0.2 * 0.01) / 0.0016$$

From these data a **QS<sub>biota,hh food</sub> = 1.23 mg kg<sup>-1</sup><sub>ww</sub>** is calculated.

In the dossier the value is reported as **QS<sub>biota,hh food</sub> = 1.23 µg kg<sup>-1</sup><sub>ww</sub>**

It is opinion of the SCHEER that this is a mistake.

Moreover, it is opinion of the SCHEER that a rounded value of **1.2 µg 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 µg L<sup>-1</sup>) has been adopted.

The SCHEER agrees with these conclusions.

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

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
AMR	Anti-Microbial Resistance
BAF	Bioaccumulation Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
EQS	Environmental Quality Standards
MAC-QS	Maximum Acceptable Concentration Quality Standard
SSD	Species Sensitivity Distribution

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