



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

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

Thiamethoxam



The SCHEER adopted this document
at its plenary meeting on 25 March 2022

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Two independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

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In addition, the Commission relies upon the work of other Union bodies, such as the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHEER

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ABSTRACT

The dossier on Environmental Quality Standards for "Thiamethoxam" was reviewed by the SCHEER according to the general mandate on EQS dossiers. The dossier also included two specific questions for thiamethoxam.

The SCHEER endorses the **MAC-QS_{fw,eco} = 0.55 µg L⁻¹**, derived with a deterministic procedure and the **MAC-QS_{fw,eco} = 0.77 µg L⁻¹**, derived with a probabilistic procedure.

For saltwater, the SCHEER endorses the deterministic **MAC_{sw,eco} = 0.0055 µg L⁻¹** and the probabilistic **MAC_{sw,eco} = 0.0077 µg L⁻¹**.

The SCHEER endorses the **AA-QS_{fw,eco} = 0.043 µg L⁻¹**, derived with a deterministic procedure. The probabilistic procedure is not applied due to the scarcity of data.

In a mesocosm study, a NOEC of 0.3 µg L⁻¹ was observed. The dossier proposes an AF of 3 to be applied to the mesocosm NOEC. It is the opinion of the SCHEER that there are not sufficient reasons to support this reduction of the AF. Therefore, the default AF of 5 should be applied. The SCHEER proposes a mesocosm-based **AA-QS_{fw,eco} = 0.06 µg L⁻¹**, instead of 0.1, proposed in the dossier.

For saltwater, the SCHEER endorses the deterministic **AA-QS_{sw,eco} = 0.0043 µg L⁻¹**.

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

For human health, the SCHEER endorses a **QS_{biota,hh} = 0.74 mg kg⁻¹** and the adoption of the general drinking water standard for pesticides (0.1 µg L⁻¹).

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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 SCHEER¹.

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.

Additional questions for thiamethoxam

The SCHEER is asked to consider **the two generic questions in the request**, as well as the following **additional points** on which the Sub-Group on Review of Priority Substances (SG-R) has put a specific question.

The SCHEER's Opinion is requested on whether the MAC-QS_{fw,eco} is derived correctly using the probabilistic approach.

In the derivation of the MAC-QS_{fw,eco} using the probabilistic approach, there are acute toxicity data for *Chaoborus crystallinus/Chaoborus sp.*, and *Cloeon dipterum/Cloeon sp.*, in both cases with very similar endpoints (Table 7.1.). The species sensitivity distribution (SSD) assessment for the insects' dataset with ten datapoints was rejected due to the fit, and in consequence, the aquatic invertebrates' dataset was used to derive the MAC-QS_{fw,eco}.

However, stakeholder suggest not to consider *Chaoborus crystallinus/Chaoborus sp.* and *Cloeon dipterum/Cloeon sp.* separately. Therefore, the insects' dataset would be rejected for the probabilistic approach due to insufficient number of data (in this case only eight data points, below the recommended minimum number of ten). Nevertheless, it was considered that for the aquatic invertebrates dataset, this reduction of data points would not make a difference between 22 or 24 species and it would not affect the MAC-QS_{fw,eco} result significantly.

The SCHEER's Opinion is requested on whether the Assessment Factor (AF) is applied correctly to the SSD to derive the MAC-QS.

The experts suggested an AF freshwater of 10 with an additional AF of 2 for the marine environment according to the guidelines. The MAC-QS value is 0.77 µg/L and 0.077 µg/L for fresh and marine water respectively.

However, stakeholders suggest to reduce the AF to 6 for determining the MAC-QS_{fw,eco}, in the probabilistic approach, instead of 10, resulting in a value of 1.3 µg/L. The reasons for the reduced AF are: (a) whether compare thiamethoxam with other neonicotinoids, e.g. for imidacloprid, with 26 acute data, there has been selected an AF of 6, and in the contrary, for clothianidin with 10 values an AF of 10 has been chosen; (b) with 24 values in the dataset, it should be expected that the value would be below the HC₅ value; (c) the goodness of fit tests are all acceptable – the histogram visual test combines the data into large categories and so is not very informative, looking at the visual fit of the SSD curves it looks fine; (d) there are mesocosm studies (in appendix Table 9.1.3) with a single or multiple applications i.e. where concentrations were not maintained, which typically would be considered relevant to MAC-QS (but not AA-QS).

The SCHEER's Opinion is requested on whether the AF is applied correctly to the AA-QS_{freshwater}.

The suggested AF AA-QS_{freshwater} is 10 according to the EQS Technical Guidance (EC, 2018). The AA-QS value for freshwater is 0.043 µg/L.

However, stakeholders suggest using an AF of 5 for the AA-QS_{freshwater}, deterministic approach, instead of 10. The motivation for the reduction was that *Cloeon sp.* has the most sensitive chronic endpoint of the lab species tested and is used to derive the deterministic AA-QS. Based on this suggestion the proposed AA-QS_{fw} would be 0.086 µg/L. It was also pointed out that this is still below the mesocosm derived AA-QS (page 37) of 0.1 µg/L.

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, an AA-EQS for freshwater of $0.04 \mu\text{g L}^{-1}$ (and $0.004 \mu\text{g L}^{-1}$ for marine waters) is reported while in the main text, the AA-EQS is $0.043 \mu\text{g L}^{-1}$ (and $0.0043 \mu\text{g L}^{-1}$ for marine waters).

While rounding of values is a widely accepted approach, for the sake of uniformity, a general rule on the number of digits to be used for EQS should be established. At the very least, the same rule should be used in a single document.

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 some of these criteria are unacceptable, although their relevance in the derivation of the EQS for thiamethoxam is negligible. In particular:

“Unbounded values were not used for EQS derivation but were considered when selecting the assessment factor and for constructing the Species Sensitivity Distribution (SSD) based on acute toxicity data for all aquatic organisms (for comparison purposes).”

The use of unbounded values in SSD implies that lower EC50 values than the real ones are introduced in the SSD, and this may alter the slope of the curve. In the case of thiamethoxam, unbounded values refer to relatively resistant organisms that are not used in the SSD curve used for the derivation of EQS.

“If chronic exposure was less than, or equal to, 10 days, it was agreed among the expert’s subgroup to consider these data as supporting information, unless the test species represented a sensitive life stage, e.g., larvae.”

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. In the case of thiamethoxam, the exclusion of data on algae (that are relatively resistant organisms) does not affect substantially the derivation of EQS.

Section 7.1 Acute aquatic ecotoxicity

A relatively large amount of 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 0.0055 mg L^{-1} on the ephemeropteran insect *Neocloeon triangulifer* as the most sensitive value to derive a deterministic MAC-QS with an AF of 10. Therefore, the **MAC-QS_{fw,eco} = $0.55 \mu\text{g L}^{-1}$** , derived with a deterministic procedure, is endorsed by the SCHEER.

For the determination of the probabilistic MAC-QS, several SSD curves were considered using a relatively large number (N) of data available: all aquatic organisms (N=35, also including unbounded values), aquatic invertebrates (N=24), aquatic invertebrates excluding *Daphnia magna* and *Erpobdellidae* (N=22), aquatic arthropods (N=21), aquatic arthropods excluding *Daphnia magna* (N=20), aquatic insects (N= 10).

The exclusion of *D. magna* and *Erpobdellidae* produced very minor changes in the calculation of HC5. However, it is the opinion of the SCHEER that the exclusion of *D. magna* and *Erpobdellidae* is not justified.

For the derivation of the probabilistic MAC-QS, the SSD curve obtained with aquatic invertebrates was selected. The reasons for supporting the selection are:

- the curve includes the most sensitive taxonomic group for the insecticide imidacloprid (10 insect species);
- from the statistical point of view, the selected SSD is accepted at all P levels in all goodness-of-fit tests for normality.

It is the opinion of the SCHEER that the reasons for the selection are appropriate, also considering the small variability among the different, statistically acceptable, HC₅ (from 0.006 to 0.008 mg L⁻¹).

About the specific question in the Appendix 6 of the Mandate, it is the opinion of the SCHEER that not considering *Chaoborus crystallinus/Chaoborus sp.* and *Cloeon dipterum/Cloeon sp.* separately does not change the probabilistic derivation of the MAC-QS. Indeed, considering the data together would support the exclusion of the insect SSD curve and would not affect substantially the invertebrate SSD curve.

Therefore, it is the opinion of the SCHEER that the selection of an HC₅ of 0.0077 mg L⁻¹, obtained without unbounded values, is appropriate.

For the selection of the assessment factor (AF), it is assumed in the dossier that the data-set available, considering some minor uncertainties and the absence of a mesocosm study, cannot support the reduction of the AF of 10. Therefore, the default AF of 10 is proposed and is endorsed by the SCHEER, also considering the specific question in the Appendix 6 of the Mandate.

Therefore, the **MAC_{fw,eco} = 0.77 µg L⁻¹**, derived with a probabilistic procedure and in reasonable agreement with the deterministic value, is endorsed by the SCHEER.

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 **MAC_{sw,eco} = 0.0055 µg L⁻¹** and the probabilistic **MAC_{sw,eco} = 0.0077 µg L⁻¹**, may be endorsed.

Section 7.2 Chronic aquatic ecotoxicity

The selected chronic toxicity data are listed in table 7.4. The SCHEER agrees with the selection, although the inclusion of 96h NOECs on algae are in contradiction with the selection criteria mentioned above.

An AF of 10 is applied to the EC10 of 0.00043 mg L⁻¹ on the ephemeropteran insect *Cloeon dipterum* as the most sensitive value to derive a deterministic AA-QS. About the specific question in the Appendix 6 of the Mandate, it is the opinion of the SCHEER that a lower AF is not justified. Therefore, the **AA-QS_{fw,eco} = 0.043 µg L⁻¹**, derived with a deterministic procedure, is endorsed by the SCHEER.

As for the determination of the probabilistic AA-QS, no sufficiently reliable data are available. Therefore, the probabilistic AA-QS_{fw,eco} is not derived.

In a mesocosm study, a NOEC of 0.3 µg L⁻¹ was observed on *C. dipterum* (Pickford et al., 2018). The EQS Technical Guidance proposes a default AF of 5 unless specific conditions allow to lower this AF. The dossier proposes an AF of 3 to be applied to the mesocosm NOEC.

It is the opinion of the SCHEER that there are not sufficient reasons to support this reduction of the AF. Therefore, an AF of 5 should be applied.

As a consequence, the SCHEER does not agree with the mesocosm-based **AA-QS_{fw,eco} = 0.1 µg L⁻¹**. It is the opinion of the SCHEER that a mesocosm-based **AA-QS_{fw,eco} = 0.06 µg L⁻¹**, obtained by applying the default AF of 5 to the NOEC of 0.3 µg L⁻¹, is more suitable.

For marine water, 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 **AA-QS_{sw,eco} = 0.0043 µg L⁻¹**, may be endorsed.

The probabilistic AA-QS_{sw,eco}, is not derived due to the lack of sufficient data.

In the table at page 34 (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, the reasoning 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_{ow} of -0.13, 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 ≥100) or of biomagnification factor (BMF ≥1) as triggers for secondary poisoning. If no data are available, K_{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_{ow} is inappropriate and an experimental BCF must be provided. Therefore, using K_{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_{ow} may be appropriate for thiamethoxam.

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:

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

The QS was calculated considering the acceptable daily intake (ADI) of 0.006 mg kg⁻¹ body weight (RAC, 2019), and a daily consumption of 1.6 g kg⁻¹_{bw}.

From these data a **QS_{biota, hh food} = 0.736 mg kg⁻¹** is calculated.

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 these conclusions. However, it is opinion of the SCHEER that a rounded value of **0.74 mg kg⁻¹** would be more appropriate, in agreement with the suggestion in the introductory preamble of this opinion.

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
TL	Threshold Level
SSD	Species Sensitivity Distribution

5. REFERENCES

EC (European Commission), 2018. Technical Guidance for Deriving Environmental Quality Standards. Common Implementation Strategy for the Water Framework Directive. Guidance Document No. 27 Updated version 2018.

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RAC (Committee for Risk Assessment). 2019b. Annex 1. Background document to the Opinion proposing harmonised classification and labelling at EU level of thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-N-nitroamine. EC Number: 428-650-4. CAS Number: 153719-23-4. CLH-O-000006724-70-01/F. Adopted 5 December 2019.