



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

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

Imidacloprid



The SCHEER adopted this document
in the plenary meeting on 7-8 October 2021

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SCHEER

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ABSTRACT

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

The SCHEER endorses the **MAC-QS_{fw,eco} = 0.065 µg L⁻¹**, derived with a deterministic procedure and the **MAC_{fw,eco} = 0.057 µg L⁻¹**, derived with a probabilistic procedure.

For saltwater, the SCHEER endorses the deterministic **MAC-QS_{sw,eco} = 0.0065 µg L⁻¹**.and the probabilistic **MAC_{sw,eco} = 0.0057 µg L⁻¹**.

The SCHEER also endorses the **AA-QS_{fw,eco} = 0.0024 µg L⁻¹**, derived with a deterministic procedure, and the **AA-QS_{fw,eco} = 0.0068 µg L⁻¹**, derived with a probabilistic procedure and, for the marine environment, the deterministic **AA-QS_{sw,eco} = 0.00024 µg L⁻¹**and the probabilistic **AA-QS_{sw,eco} = 0.00068 µg L⁻¹**, may be endorsed.

The SCHEER agrees with the decision of not deriving an EQS for secondary poisoning, as well as for human health risk *via* consumption of fishery products.

For the exposure *via* drinking water, SCHEER agrees with 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.

3. OPINION

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

Section 6. Aquatic environmental concentrations

Section 6.1.1 Freshwater

In a preliminary note, it is explained that the section was written before the derivation of EQSs, using an EQS different from the final one selected. It is the opinion of the SCHEER that the section should be revised using the final EQS. This will change many of the elaborations made in that section.

Section 6.1.2 Coastal/Transitional water

The section is still under development due to the small amount of data available. It is not yet possible to comment on it.

Section 7. Effects and quality standards

Several AA and MAC-EQS, proposed by various organisations (RIVM, UBA, EFSA, etc.) are discussed and the criteria for the selection of toxicity data are listed. It is the opinion of the SCHEER that the criteria are appropriate.

Section 7.1 Acute aquatic ecotoxicity

A large amount of data on aquatic organisms of several taxonomic groups (from bacteria to fish) is listed in table 7.2.

In footnote 13 of the table, a specific question for SCHEER refers to the evaluation of some controversial data on *Ceriodaphnia dubia*. The relative insensitivity of cladocerans to all neonicotinoids is documented in the literature (Morrissey et al., 2015; Rico et al., 2018). Therefore, it is the opinion of the SCHEER that the selected value (48h LC50: 72 mg L⁻¹), comparable to those selected for *Daphnia magna* (48h EC50: 79 mg L⁻¹), is reasonable. A lower value found in the literature (48h LC50: 2.07 µg L⁻¹) should be considered as an outlier.

It is the opinion of the SCHEER that it is appropriate to use the LC50 of 0.65 µg L⁻¹ on the insect *Epeorus longimanus* as the most sensitive value to derive a deterministic MAC-QS with an AF of 10. Therefore, the **MAC_{freshwater, eco} = 0.065 µg 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 the large number (N) of data available: all aquatic organisms (N=37), aquatic invertebrates (N=28), aquatic invertebrates excluding Cladocerans (N=26), aquatic arthropods (N=27), aquatic arthropods excluding Cladocerans (N=25), crustaceans (N=14), aquatic insects (N= 13). For all taxonomic groups, without exclusions, the range of variability of the HC5 is relatively low (from 0.18 to 0.34 µg L⁻¹). Slightly higher values are obtained by excluding Cladocerans (0.56 and 0.61 µg L⁻¹). It is the opinion of the SCHEER that the exclusion of Cladocerans is not justified.

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

- the curve refers to the most sensitive taxonomic group for the insecticide imidacloprid;
- from the statistical point of view, the selected SSD curve corresponds best with the data

It is the opinion of the SCHEER that the reasons for the selection, also considering the small variability among the different HC5, are appropriate.

For the selection of the assessment factor (AF), it is assumed in the dossier that the data-set available, also considering a mesocosm study, may support the reduction of the AF of 10. Therefore, according to Brock et al (2011), an AF of 6 is proposed.

It is appropriate, in the opinion of the SCHEER, to derive a probabilistic MAC-QS using an AF of 6 applied to the SSD curve on aquatic insects, as the most sensitive taxonomic group. Therefore, the **MAC_{fw, eco} = 0.057 µg L⁻¹**, derived with a probabilistic procedure, 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} = 0.0065 µg L⁻¹** and the probabilistic **MAC_{sw, eco} = 0.0057 µg L⁻¹**, may be endorsed.

Section 7.2 Chronic aquatic ecotoxicity

For chronic toxicity as well, a relatively large amount of data (21 freshwater and 1 marine) on eight taxonomic groups was selected, listed in table 7.4.

It is appropriate, in the opinion of the SCHEER, to use the EC10 of 0.024 µg L⁻¹ on the insect *Caenis oraria* as the most sensitive value to derive a deterministic AA-QS with an AF of 10. Therefore, the **AA-QS_{fw, eco} = 0.0024 µg L⁻¹**, derived with a deterministic procedure, is endorsed by the SCHEER.

As for the determination of the probabilistic MAC-QS, several SSD curves were considered: all aquatic organisms (N=22), aquatic invertebrates (N=18), aquatic invertebrates excluding Cladocerans (N=16), aquatic arthropods (N=17), aquatic arthropods excluding Cladocerans (N=15), crustaceans (not enough data for SSD) and aquatic insects (N= 12).

Here too, for the derivation of the probabilistic AA-QS, the SSD curve obtained with aquatic insects was selected. The reasons for this selection are the same as for acute data.

For the selection of the assessment factor (AF), it is assumed in the dossier that the data-set available, also considering a mesocosm study, may support the reduction of the default AF of 5. Therefore, according to Brock et al (2011) an AF of 3 is proposed.

It is appropriate, in the opinion of the SCHEER, to derive a probabilistic AA-QS using an AF of 3 applied to the SSD curve on aquatic insects, as the most sensitive taxonomic group. Therefore, the **AA-QS_{fw,eco} = 0.0068 µg L⁻¹**, derived with a probabilistic procedure, is endorsed by the SCHEER.

For marine water, only one value on marine organisms is 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 **AA-QS_{sw,eco} = 0.00024 µg L⁻¹** and the probabilistic **AA-QS_{sw,eco} = 0.00068 µg L⁻¹**, may be endorsed.

Section 7.3 Secondary poisoning

Considering the physical-chemical properties of the substance and, in particular, the logKow of 0.57, 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, Kow 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 Kow is inappropriate and an experimental BCF must be provided. Therefore, using Kow 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 logKow may be appropriate for imidacloprid.

Section 7.4 Human health

For the human health risk *via* consumption of fishery products, considering the acceptable daily intake (ADI) of 0.06 mg kg⁻¹ body weight (EFSA, 2008; ECHA, 2011), the dossier concludes that there is no need to derive a QS for human exposure *via* fish.

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.

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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