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
at its plenary meeting on 7-8 October 2021

Keywords: pesticides, imidacloprid, Water Framework Directive, environmental quality standards

Opinion to be cited as:

SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Preliminary Opinion on Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive", Imidacloprid, final version of 7-8 October 2021

ACKNOWLEDGMENTS

Members of the Working Group are acknowledged for their valuable contribution to this opinion. The members of the Working Group are:

The SCHEER members:
Marian Scott (Chair), Marco Vighi (Rapporteur), Teresa Borges, Raquel Duarte Davidson, Peter Hoet, Pim de Voogt

All Declarations of Working Group members are available at the following webpage:
Register of Commission expert groups and other similar entities (europa.eu)

About the Scientific Committees (2016-2021)
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.
These committees are the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The Scientific Committees review and evaluate relevant scientific data and assess potential risks. Each Committee has top independent scientists from all over the world who are committed to working in the public interest.
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
This Committee, on request of Commission services, provides Opinions on questions concerning health, environmental and emerging risks. The Committees addresses questions on:
- health and environmental risks related to pollutants in the environmental media and other biological and physical factors in relation to air quality, water, waste and soils.
- complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health, for example antimicrobial resistance, nanotechnologies, medical devices and physical hazards such as noise and electromagnetic fields.

SCHEER members
Roberto Bertollini, Teresa Borges, Wim de Jong, Pim de Voogt, Raquel Duarte-Davidson, Peter Hoet, Rodica Mariana Ion, Renate Kraetke, Demosthenes Panagiotakos, Ana Proykova, Theo Samaras, Marian Scott , Emanuela Testai, Theo Vermeire, Marco Vighi, Sergey Zacharov

Contact
European Commission
DG Health and Food Safety
Directorate C: Public Health
Unit C2: Health information and integration in all policies
Office: HTC 03/073 L-2920 Luxembourg
SANTE-C2-SCHEER@ec.europa.eu

ISSN ISBN
doi: ND

The Opinions of the Scientific Committees present the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The Opinions are published by the European Commission in their original language only.
http://ec.europa.eu/health/scientific_committees/policy/index_en.htm

ABSTRACT

The dossier on Environmental Quality Standards for "Imidacloprid" is revised 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$_{sw, eco}$= 0.0065 µg L^{-1}** and the probabilistic **MAC$_{sw, eco}$ = 0.0057 µg L^{-1}**.

The SCHEER also endorses the **AA-QS$_{fw,eco}$ = 0.0068 µg L^{-1}**, derived with a probabilistic procedure, and the **AA-QS$_{fw,eco}$ = 0.0068 µg L^{-1}**, derived with a probabilistic procedure, as well as, for marine waters, the deterministic **AA-QS$_{sw,eco}$ = 0.00024 µg L^{-1}**and the probabilistic **AA-QS$_{sw,eco}$ = 0.00068 µg L^{-1}**,

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

For human health, the SCHEER agrees with the conclusion that there is no need to derive a QS for human exposure *via* fish and with the adoption of the general drinking water standard for pesticides (0.1 µg L^{-1}).

TABLE OF CONTENTS

ACKNOWLEDGMENTS 2
ABSTRACT 4
1. BACKGROUND 6
2. TERMS OF REFERENCE 6
3. OPINION 7
Section 7.1 Acute aquatic ecotoxicity 7
Section 7.2 Chronic aquatic ecotoxicity 8
Section 7.3 Secondary poisoning 8
Section 7.4 Human health 9
4. LIST OF ABBREVIATIONS 10
5. REFERENCES 11

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.

3. OPINION

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

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), comparable to those selected for Daphnia magna (48h EC50: 79 mg/L), is reasonable. A lower value found in the literature (48h LC50: 2.07 μg/L) 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 on the insect *Epeorus longimanus* as the most sensitive value to derive a deterministic MAC-QS with an AF of 10. Therefore, the **$MAC_{fw,\ eco}$ = 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). Slightly higher values are obtained by excluding Cladocerans (0.56 and 0.61 μg/L). 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 on the insect *Caenis oraria* as the most sensitive value to derive a deterministic AA-QS with an AF of 10. Therefore, the **$AA\text{-}QS_{fw,\ eco}$ = 0.0024 µg L^{-1}**, derived with a deterministic procedure, is endorsed by the SCHEER.

As for the determination of the probabilistic AA-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 **$AA\text{-}QS_{fw,eco}$ = 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 **$AA\text{-}QS_{sw,eco}$ = 0.00024 µg L^{-1}**and the probabilistic **$AA\text{-}QS_{sw,eco}$ = 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 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) 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

5. REFERENCES

Brock TCM, Arts GHP, Ten Hulscher TEM, De Jong FMW, Luttik R., Roex EWM., Smit CE., Van Vliet PJM. (2011). Aquatic effect assessment for plant protection products: Dutch proposal that addresses the requirements of the Plant Protection Product Regulation and Water Framework Directive. Wageningen, The Netherlands. Alterra Wageningen UR (University & Research Centre). Report 2235.

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.

EFSA, 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid. Finalised: 29 May 2008. EFSA Scientific Report (2008) 148, 1-120, Conclusion on the peer review of imidacloprid.

ECHA, 2011. Competent Authority Report of Germany for the evaluation of the biocidal active substance imidacloprid in the frame of the Biocides Directive 98/8/EC to be used in Insecticides, Acaricides and Products to control other Arthropods (Product Type 18).

Morrissey, C. A., Mineau, P., Devries, J. H., Sanchez-Bayo, F., Liess, M., Cavallaro, M. C., & Liber, K. (2015). Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: a review. Environment International, 74, 291-303.

Rico A., Arenas-Sánchez A., Pasqualini J., García-Astillero A., Cherta L., Nozal L., Vighi M. (2018). Effects of imidacloprid and a neonicotinoid mixture on aquatic invertebrate communities under Mediterranean conditions. Aquatic Toxicology, 204, 130-143.