Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Nicosulfuron

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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

External experts :
Thomas Backhaus, Andrew Johnson, Jan Linders

All Declarations of Working Group members are available at the following webpage:
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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-SCHEER@ec.europa.eu

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ABSTRACT

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

The SCHEER endorses the **MAC-QS$_{fw,eco}$ =0.23 µg L^{-1}**, and the **AA-QS$_{eco,fw}$ =8.7 10^{-3} µg L^{-1}** derived with a deterministic procedure. The SCHEER agrees with the decision of not performing the probabilistic approach due to the scarcity of data.

For saltwater, the SCHEER endorses the deterministic **MAC$_{sw, eco}$ of 0.023 µg L^{-1}**, and the **AA-QS$_{sw, eco}$ of 8.7 10^{-4} µg L^{-1}**.

The SCHEER agrees that an EQS for sediments, as well as for secondary poisoning, is not necessary.

For human health, the SCHEER endorses a **QS$_{biota,hh\ food}$ = 120 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 around the middle of 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 some others, there is disagreement about one or other component of the draft dossier. 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) has 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, 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 and Chronic Aquatic Ecotoxicity

It is unclear which data were considered valid and which were validated by the authors of the factsheet. The procedure followed for the validation of the data is not mentioned.

For the derivation of a $MAC_{fw, eco}$, reliable acute data are available on algae (green and blue-green), macrophytes (*Lemna*) and fish. Some data on invertebrates (*Daphnia* and *Chironomus*) are defined as Not assignable.

However, considering that nicosulfuron is an herbicide with specific mode of action on plants, it is opinion of the SCHEER that the use of *Lemna* EC50 growth rate as the most sensitive value to derive MAC-QS with an AF of 10 is appropriate.

Therefore, the tentative **$MAC_{fw, eco}$ of 0.23 µg L^{-1}**, derived with a deterministic procedure, is endorsed by the SCHEER.

For the derivation of the $AA\text{-}QS_{fw, eco,}$ reliable chronic data are available on algae (green and blue-green), macrophytes (*Lemna*), invertebrates and fish. As for acute data, the most sensitive organism is *Lemna*.

It is opinion of the SCHEER that the use of *Lemna* 7d NOEC growth rate as the most sensitive value to derive AA-QS with an AF of 10 is appropriate.

Therefore, the tentative **$AA\text{-}QS_{fw, eco,}$ of 8.7 10^{-3} µg L^{-1}** , derived with a deterministic procedure, is endorsed by the SCHEER.

In total, reliable chronic data on 8 species (two blue-green algae, two green algae, two macrophytes, one invertebrate and one fish) are available. However, the probabilistic approach for the derivation of the $AA\text{-}QS_{fw, eco,}$ is not used. The SCHEER agrees because it is in line with the technical guidance, which requires a minimum of 10 species to be used.

Two different studies on freshwater mesocosms are available but they are classified as "not reliable".

No data are available in marine organisms. Therefore, the $MAC_{sw, eco}$ and the $AA\text{-}QS_{sw, eco}$ are derived using freshwater data with an AF of 100. It is opinion of the SCHEER that the procedure is appropriate.

Therefore, the tentative **$MAC_{sw, eco}$ of 0.023 µg L^{-1}**, and the **$AA\text{-}QS_{sw, eco}$ of 8.7 10^{-4} µg L^{-1}**, derived with a deterministic procedure, are endorsed by the SCHEER.

No data are available on sediment-dwelling organisms. However, considering the physical-chemical properties of the substance and, in particular, the low potential of adsorption onto sediment, no sediment effect assessment was undertaken. The SCHEER agrees that an EQS for sediments is not necessary.

Section 7.2. Secondary Poisoning

Considering the physical-chemical properties of the substance and, in particular, the logKow of 0.61, 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.

As there is no evidence that sulfonylurea chemicals bioaccumulate in tissue other than lipids, it is the opinion of the SCHEER that an EQS for secondary poisoning based on logKow is appropriate for nicosulfuron.

Section 7.3. 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 SCHEER agrees with the assessment performed, namely, the use of the two-year rat carcinogenicity study with a NOAEL of 199 mg kg^{-1}_{bw} d^{-1} which was also used by EFSA (2007) to derive the ADI, in order to calculate the TL_{hh} of 2 mg kg^{-1}_{bw} d^{-1} and derive the tentative **$QS_{biota,\ hh\ food}$ of 120 mg kg^{-1}**.

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 this conclusion.

4. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
AF	Application Factor
AMR	Anti-Microbial Resistance
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
EQS	Environmental Quality Standards
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Observed Adverse Effect Level
PNEC	Predicted No Effect Concentration
TL	Threshold Limit

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.

EFSA, 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance nicosulfuron. EFSA Scientific Report 120, 1-91.