Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Diuron

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ABSTRACT

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

The SCHEER agrees with the final **MAC-$QS_{fw,eco}$ = 0.27 µg L^{-1}** and **MAC-$QS_{sw,eco}$ = 0.054 µg L^{-1}**, derived with a probabilistic procedure, on the basis of the data provided in the dossier. However, it is the opinion of the SCHEER that the availability of reliable data in the literature should be carefully checked.

The SCHEER accepts with reservations the deterministic **AA-$QS_{fw,eco}$ = 0.049 µg L^{-1}** and **AA-$QS_{sw,eco}$ = 0.0049 µg L^{-1}**. The availability of reliable chronic data, including mesocosm studies, should be carefully checked.

For sediment ecotoxicity, the equilibrium partitioning procedure is applied, considering the scarcity of data. The SCHEER agrees with this decision. However, the SCHEER does not agree with the values derived in the dossier (AA-$QS_{sed,EqP,dw}$ = 1 µg kg^{-1}_{dw} for freshwater sediment and 0.1 µg kg^{-1}_{dw} for marine sediment) as in this case the probabilistic results should be preferred, giving the results of **$QS_{sed,fw\ EqP}$ = 2.3 µg kg^{-1}_{dw} and $QS_{sed,sw\ EqPdw}$ = 0.23 µg kg^{-1}_{dw}**. It is the opinion of the SCHEER that the procedure is correctly applied. However, the availability of reliable sediment data should be carefully checked.

It is the opinion of the SCHEER that the procedures on secondary poisoning are properly applied. Therefore, the SCHEER endorses that secondary poisoning is not relevant for diuron.

For human health, the value of **$QS_{biota,hh}$= 860 µg kg^{-1}_{biota}** is calculated, using the ADI of 0.007 mg kg_{bw}^{-1} d^{-1}, proposed by EFSA (2005). The dossier does not calculate the $QS_{water,hh-food}$ as the BCF is 2. The SCHEER endorses this conclusion.

For the exposure *via* drinking water, the SCHEER agrees with the adoption of the general drinking water standard for pesticides (**$QS_{dw,hh}$ = 0.1 µg L^{-1}**).

The most critical EQS (in terms of impact on environment/health) has been identified as the **AA-$QS_{sw,\ eco}$ = 0.0049 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 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

In a separate synthesis Opinion, the SCHEER provided a general discussion concerning the procedure and derivation of the EQS values and related topics and highlighted unresolved issues and weaknesses that are common to more than one substance and dossier.

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

Section 7 – Effects and Quality Standards

The EQSs proposed in the 2005 EQS dossier have been revised, considering more recent literature data in 2020. The data used for the EQS derivation of 2005 were not re-evaluated. New data were assessed using the CRED-criteria. The SCHEER agrees with this approach and also endorses the criteria used to decide whether or not certain data should be taken into account.

Section 7.1 – Acute Aquatic Ecotoxicity

The dataset reports a relatively large amount of data on several taxonomic groups and, as many other compounds, diuron is an intensively studied compound and many more studies than those listed in the dossier are available in the literature. However, in the case of diuron the SCHEER endorses the selection in the dossier having followed a similar procedure adopted by the US EPA.

Deterministic approach

The SCHEER supports the result of the statistical evaluation allowing the fresh water and marine water data of diuron to be pooled. The SCHEER agrees with the selection of the 72h EC50 on *Synechococcus* sp. of 1.4 µg L^{-1} as the most sensitive acute value.

Therefore, the MAC-$QS_{fw,eco}$ = 0.14 µg L^{-1} obtained with the deterministic procedure by applying an AF of 10 to the EC50 on *Synechococcus* sp. is endorsed by the SCHEER. In the determination of the MAC-$QS_{sw,eco}$, the dossier proposes an additional AF of 5, based on the known mode of action of the substances and the availability of ecotoxicological data of the most sensitive groups. The SCHEER supports this AF of 5. This means that the $MAC_{sw,eco}$ = 0.028 µg L^{-1} can also be endorsed by the SCHEER.

Probabilistic approach

For the application of the probabilistic approach, data are available for eight taxonomic groups. Although insects were missing in the accepted dataset and considering that other arthropods may be equally sensitive compared to crustaceans it was concluded that all data could be used for the SSD. The SCHEER agrees with this procedure. The results, however, showed an insufficient goodness-of-fit. Therefore, the SSD for all aquatic organisms was rejected. The SCHEER also supports this conclusion. Successively, an SSD was constructed using only the primary producers, in fact the most sensitive group.

Therefore, the MAC-$QS_{fw,eco}$ = 0.268 µg L^{-1} , obtained with the probabilistic procedure using all data on primary consumers and by applying an AF of 10 to the HC5 of 2.68 µg $L^{-1,}$ is endorsed by the SCHEER. The MAC-$QS_{sw,eco}$ = 0.054 µg L^{-1} obtained with the probabilistic procedure by applying an AF of 50 to the HC5 of 2.68 µg L^{-1} is also endorsed by the SCHEER.

Micro-, mesocosm studies and field studies

In the dossier, no reliable microcosm, mesocosm or field studies are reported.

Final MAC-QS

Based on the facts that the SSD was constructed using the most sensitive species and that higher-tier studies (microcosms, mesocosms or field studies) are not available, it was concluded that the SSD-derived MACs should prevail over the deterministic MACs. The SCHEER agrees with this conclusion. Therefore, the values of the **MAC-$QS_{fw,eco}$ = 0.268 (rounded to 0.27) µg L^{-1}** and the **MAC-$QS_{sw,eco}$ = 0.054 µg L^{-1}** are endorsed by the SCHEER.

Section 7.2 – Chronic Aquatic Ecotoxicity

The freshwater dataset in the dossier contains results of eight taxonomic groups, seven chronic values for algae, four for aquatic plants, one insect, one protozoan, three crustacea, two fish, one annelid, and one mollusk. The marine water dataset contains four taxonomic groups, including four algae, one crustacean, one cyanobacterium and two fish. Also, for chronic toxicity, the statistical analysis shows that the freshwater and marine water data may be pooled.

Deterministic approach

For the cyanobacterium *Synechococcus* sp. the lowest no-effect concentration was found in the dataset: 72h-NOEC = 0.21 µg L^{-1} for growth rate. By applying an AF of 10, the AA-$QS_{fw,eco}$ of 0.021 µg L^{-1} is determined. This result is endorsed by the SCHEER. The AA-$QS_{sw,eco}$ is then determined by applying an AF of 10. This gives the value for AA-$QS_{sw,eco}$ of 0.0021 µg L^{-1}. This result is also endorsed by the SCHEER.

Probabilistic approach

The SSD was established in the same way as for the acute data. The SSD for the whole dataset was rejected based on an insufficient goodness-of-fit. Successively, the SSD for the most sensitive taxonomic group, the primary consumers, was calculated, which did show a sufficient goodness-of-fit. The SCHEER endorses this procedure as it is in line with the TGD EQS (2018). Based on the SSD for the sensitive taxa, an HC5 of 0.244 µg L^{-1} was determined. However, the confidence limits for the HC5 (0.089 – 0.47) were considered too high to be reliable. For the AA-QS, an AF of 4 was, therefore, applied to the HC5 with the result AA-$QS_{fw,eco}$ = 0.061 µg L^{-1}. The SCHEER agrees that the confidence limits indicate a less reliable value for the HC5, but does not understand the choice for an AF of 4 in this case. An AF of 5, which is the default value according the TGD EQS (2018), would be more appropriate in the view of the SCHEER. The SCHEER is of the opinion that with the adjusted AF, the results of the SSD should not have been rejected in favour of the deterministic approach. Therefore, the SCHEER considers that the AA-$QS_{fw,eco}$ should be based on the HC5 with an AF of 5. This leads to AA-$QS_{fw,eco}$ = 0.0488 µg L^{-1}. The AA-$QS_{sw,eco}$ can then be determined by applying an additional AF of 10: AA-$QS_{sw,eco}$ = 0.00488 µg L^{-1} (rounded to 0.0049 µg L^{-1}).

Mesocosm and field data

The dossier evaluates two studies under this heading. Both were evaluated as being insufficiently reliable to be considered in the QS derivation. The SCHEER agrees with these conclusions.

Final AA-QS

In conclusion, the SCHEER does not endorse the AA-QS as determined in the dossier but prefers to determine as AA-QSs the following values based on the probabilistic approach: **AA-$QS_{fw,eco}$ = 0.0488 (rounded to 0.049) µg L^{-1}** and **AA-$QS_{fw,eco}$ = 0.00488 (rounded to 0.0049) µg L^{-1}**.

Section 7.3 – Sediment Ecotoxicity

The SCHEER agrees that a sediment quality standard should be determined. The reference used in the dossier (Tomlin, 1994) cannot be used in the view of the SCHEER because of missing details in the study. The SCHEER also agrees that ecotoxicity data for the sediment compartment are missing and, therefore, equilibrium partitioning should be used. As the SCHEER prefers in this case to use the results of the probabilistic approach, the values of 0.049 and 0.0049 µg L^{-1} should be used for fresh and marine water respectively. Therefore, the SCHEER does not endorse the values of AA-$QS_{sed,EqP,dw}$ = 1 µg kg^{-1}_{dw} for freshwater sediment and 0.1 µg kg^{-1}_{dw} for marine sediment, based on the deterministic AA-$QS_{fw,eco}$ and AA-$QS_{sw,eco}$. Using the probabilistic approach, the following results are calculated: **AA-$QS_{sed,EqP,dw}$ = 2.3 µg kg^{-1}_{dw} for freshwater sediment and for marine sediment 0.23 µg kg^{-1}_{dw}.**

Section 7.5 – Secondary Poisoning

In the dossier, secondary poisoning was not considered because the relevant criteria were not met, based on a log K_{ow} < 3 and a BCF < 100. The SCHEER endorses this decision.

Section 7.6 – Human Health

For the human health risk *via* consumption of fishery products, according to the procedure described in the EQS Technical Guidance (EC, 2018), the following equation is applied:

$$QS_{biota\ hh\ food} = 0.2\ TL_{hh} / 0.00163$$

Where:

- $QS_{biota\ hh,food}$ = Quality standard for human health via consumption of fishery products (mg kg^{-1}_{biota})
- 0.2 = default fraction of TL_{hh} related to fishery products consumption
- TL_{hh} = threshold limit from mammalian studies (ADI or TDI) (mg kg^{-1}_{bw} d^{-1})
- 0.00163 (kg_{fish} $kg_{bw}^{-1} d^{-1}$) = estimated daily fishery products consumption (default 0.115 kg d^{-1}) per kg body weight (default 70 kg).

A $QS_{biota,hh}$ =858.9 µg kg^{-1}_{biota} (to be rounded to **$QS_{biota,hh}$ = 860 µg kg^{-1}_{biota}**) is calculated, using the ADI of 0.007 mg kg_{bw}^{-1} d^{-1}, proposed by EFSA (2005). The SCHEER endorses this value.

The dossier does not calculate the $QS_{water,hh-food}$ The SCHEER is of the opinion that, for diuron, a BAF-value is not required as the BCF is 2. Therefore, an estimation of the $QS_{water,hh-food}$ is not considered necessary.

For the exposure *via* drinking water, the general drinking water standard for pesticides (**$QS_{dw,hh}$ = 0.1 µg L^{-1}**) has been adopted. The SCHEER agrees with this conclusion.

4. CRITICAL EQS

In light of the data provided in the dossier, the most critical EQS (in terms of impact on environment/health) has been identified as the **AA-$QS_{sw,eco}$ = 0.00488 (rounded to 0.0049) µg L^{-1}.**

5. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	body weight
DEE	Daily Energy Expenditure
EC	Effect Concentration
EFSA	European Food Safety Agency
EQS	Environmental Quality Standards
HC	Hazardous Concentration
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
NOEL	No Effect Level
PPP	Plant Protection Products
QS	Quality Standard
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TL	Threshold Level
ww	wet weight

6. REFERENCES

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

EFSA, 2005. Conclusion regarding the peer review of the pesticide risk assessment of the active substance, Diuron. Finalized: 14 January 2005. https://doi.org/10.2903/j.efsa.2005.25r

RIVM (2014). New method for the derivation of risk limits for secondary poisoning. E.M.J. Verbruggen.