Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Glyphosate

The SCHEER adopted this document
by written procedure on 22 December 2022

ACKNOWLEDGMENTS

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This Opinion has been subject to a commenting period of four weeks after its initial publication (from 30 September to 31 October 2022). Comments received during this period were considered by the SCHEER. For this Opinion, section 7 was amended but the Opinion did not change.

Keywords:
Glyphosate, Water Framework Directive, environmental quality standards

Opinion to be cited as:
SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Final Opinion on Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive - glyphosate, 22 December 2022

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PDF ISSN 2467-4559 ISBN 978-92-68-06270-8 doi:10.2875/330691 EW-CA-23-006-EN-N

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ABSTRACT

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

The SCHEER does, in principle, endorse the employed approaches for the determination of the different QS values, except for the use of an additional AF of 2 for the derivation of the AA-$QS_{fw,eco}$ because no specific reasons are given that would justify a deviation from the standard approach provided by the EQS guidance document (EC 2018). However, the SCHEER cannot, currently, endorse the suggested numerical values for MAC-$QS_{fw,eco}$, $MAC_{sw,eco}$, AA-$QS_{fw,eco}$ and AA-$QS_{sw,eco}$, as all of these QS values are determined using studies that are based on nominal concentrations – despite a specific statement at the beginning of the dossier that only analytically verified concentrations shall be used for the QS determination. The SCHEER recommends reconciling this conflict between the description of the data selection and the actual implementation of the data selection process.

The SCHEER endorses the values of 3.08 mg kg^{-1}_{dw} **(rounded to 3.1 mg kg^{-1}_{dw})** for **$QS_{sediment, fw}$** and 0.308 mg $kg^{-1}_{dw.}$ **(rounded to 0.31 mg kg^{-1}_{dw})** for **$QS_{sediment, sw}$.**

The SCHEER does not endorse the suggested EQS of 0.125 µg L^{-1} but instead supports an EQS of 0.1 µg L^{-1}, based on the $QS_{dw,hh}$ of 0.1 µg L^{-1} for pesticides in drinking water. SCHEER suggests restricting this EQS to surface waters currently used for drinking water abstraction. For surface waters currently not used for producing drinking water, an EQS should be set in accordance with the values for AA-$QS_{fw,eco}$ and AA-$QS_{sw,eco}$. These values should be estimated using the probabilistic approach based on an improved SSD analysis of the available data.

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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 glyphosate. SCHEER is asked to assess:

1. whether the EQS has 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.

In addition, SCHEER is asked the following specific questions:

1. Is the validity of specific ecotoxicity studies included in the draft dossier correct?
2. Is the MAC-$QS_{fw,eco}$ derived correctly using the deterministic approach?
3. Is it correct to include the mesocosm study for the selection of the AF in the probabilistic derivation of the AA-QS?
4. Could be properly justified the additional AF of 2 AF in the probabilistic derivation of the AA-QS?
5. Is using the $QS_{dw,hh}$, derived from the drinking water standard limit of 0.1 µg L^{-1} as a "overall" EQS, the correct approach?

[1] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/ba6810cd-e611-4f72-9902-f0d8867a2a6b/details

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 provided below.

Section 4 – Mode of Action

The dossier states on page 4 that glyphosate specifically targets the 5-Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS), and that "this enzyme is specific to primary producers". The latter statement is wrong.

Unfortunately, the reference that is supposed to support the text in the dossier (Rodriguez-Gil, 2021) is missing from the list of references. The reference is likely "Rodríguez-Gil, J.L., Prosser, R.S., Duke, S.O. and Solomon, K., 2021. Ecotoxicology of glyphosate, its formulants, and environmental degradation products. Reviews of Environmental Contamination and Toxicology Volume 255, pp.129-205.". This paper clearly states that the EPSPS is not confined to primary producers but that "*Plants, fungi, and bacteria, but not animals, possess EPSPS*".

Section 7 – Effects and Quality Standards

Ecotoxicological data for the derivation of the various QS and EQS values were taken from "the previous draft dossier on glyphosate in 2015" (no specific reference provided), a report from Oekotoxzentrum Centre Ecotox from 2016 (incorporating previous reports from 2011-2013), and the WFD-UKTAG report from 2010 (for which also no reference seems to be provided). Additionally, nonspecific comments received by stakeholders in 2015 are included (no further details are provided). The SCHEER is of the opinion that the data sources used for compiling the dossier need to be more carefully referenced.

The SCHEER notes that a central document providing data for the JRC dossier, i.e. the "Combined Draft Renewal Assessment Report prepared according to Regulation (EC) No. 1107/2009 and Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) No. 1272/2008" is referenced as "CLH report (2021)" with incomplete bibliographic information. SCHEER therefore suggests to amend the reference accordingly (including the URL).

The studies referred to in the dRAR should use the data point provided, rather than the authors' names.

SCHEER notes that the minimum reliability score that a study must be awarded before it is considered a key study is not provided.

Finally, SCHEER notes that only analytically verified tests are to be included in the key data collection for setting EQS values (dossier page 26).

SCHEER does not agree with the strategy to exclude the data on "isopropylammonium salt and glyphosate isopropylamine salt (IPA)" (page 26). Firstly, those two names refer to the same chemical (CAS Nr 38641-94-0, InChIKey ZEKANFGSDXODPD-UHFFFAOYSA-N). Secondly, and more importantly, the salt dissociates in the water environment to glyphosate and isopropylamine. Data on the isopropylamine salt should therefore be included in the data evaluation, after the necessary correction for differences in molecular weight.

SCHEER agrees with the decision to exclude ecotoxicity data on glyphosate formulations, especially from those that contain co-formulants with well-known toxic properties, such as several of the commonly used surface-active agents.

Section 7.1 – Acute Aquatic Ecotoxicity

The data on the acute ecotoxicity of glyphosate used for setting MAC-QS values are provided in table 10.1.1. (page 62 ff) and table 10.1.4 (page 79 ff). The key data are compiled in a table in section 7.1. (page 26 ff). SCHEER is surprised to see that all recent data, i.e. all the studies listed in table 10.1.4., are assessed as having a reliability score of 3, even those studies that tested the active substance.

All MAC-QS values are based on a dataset in which the available freshwater and marine studies are combined. The SCHEER endorses this approach, given that not enough marine data were identified to allow a meaningful statistical comparison of the (dis)similarity of the marine and freshwater datasets.

Derivation of the MAC-QS$_{fw, eco}$ using the deterministic approach

The most sensitive species and endpoint is represented by the EC_{50} of 0.844 mg L^{-1} for growth (root length), measured for the freshwater aquatic plant *Myriophyllum sibiricum*. After an application of an AF of 10, this results in a suggested MAC-QS$_{fw, eco}$ of 0.0844 mgL^{-1} (84.4 µg L^{-1}).

The SCHEER does not endorse this value for two reasons:

1. An ecotoxicity estimate based on growth impairment after an exposure of 14 d should be considered an indicator for the *chronic* toxicity of the test organism.
2. The value is based on nominal (analytically unverified) test concentrations, see Roshon (1997), page 258. This is in direct contradiction to the selection criteria as provided in section 7, where it is explicitly stated that only analytically verified concentrations are included in the data evaluation.

Also, the second most sensitive value listed in the collection of key data, the EC_{50} of 3.53 mg L^{-1} for *Chlorella pyrenoidosa* from the study by Ma (2001), seems to be based on nominal concentrations.

The SCHEER endorses the use of an AF of 10, as per the current version of the TGD.

Derivation of MAC-QS$_{fw, eco}$ using the probabilistic approach

Two SSDs are constructed. The first includes all key studies listed in the table presented in section 7.1., page 26 ff and results in an HC_{05} of 3.986 mg L^{-1}. The second SSD includes only primary producers (higher plants and algae) and results in an HC_{05} of 2.218 mg L^{-1}. The HC_{05} from the first analysis, using the full dataset, is used for the final QS derivation. The SCHEER endorses this strategy, in particular in view of the fact that the target enzyme of glyphosate (ESPS) is not confined to primary producers (see above).

An assessment factor of 10 is applied to the HC_{05} in order to derive the final QS value. The SCHEER endorses this approach, which is in line with the requirements set by the TGD.

However, the SCHEER does not endorse the suggested numerical value of the probabilistic MAC-QS$_{fw, eco}$, as the EC_{50} values from the Roshon (1997) and Ma (2001) studies (both based on nominal concentrations) are included in the dataset used for calculating the underlying SSD.

Micro-, mesocosm studies and field studies in the freshwater environment No statement regarding the availability of micro- and mesocosm studies on the acute toxicity of glyphosate is provided in the dossier. The SCHEER recommends stating this clearly, so that the reader knows that no micro- or mesocosm data are available on the acute freshwater toxicity of glyphosate.

Derivation of MAC-QS$_{sw, eco}$ using the deterministic approach

An additional AF of 10 is applied to the EC_{50} from the Roshon (1997) study, resulting in a total AF of 10x10=100. The SCHEER endorses this approach. However, the SCHEER does not endorse the final numerical value for the MAC-QS$_{sw, eco}$, due to the aforementioned inconsistencies in the data selection procedure.

Derivation of MAC-QS$_{sw, eco}$ using the probabilistic approach

An additional AF of 10 is applied to the HC_{05}, resulting in a total AF of 10x10=100. The SCHEER endorses this approach. But, as outlined above, the SCHEER does not endorse the final numerical value, due to the inconsistencies in the data selection procedure.

Micro-, mesocosm studies and field studies in the marine environment

No statement regarding the availability of micro- and mesocosm studies on the acute toxicity of glyphosate in marine systems is provided in the dossier. The SCHEER recommends stating this clearly, so that the reader knows that no micro- or mesocosm data are available on the acute marine toxicity of glyphosate.

Section 7.2 – Chronic Aquatic Ecotoxicity

The data on the chronic ecotoxicity of glyphosate used for the setting of AA-QS values are provided in table 10.1.2. (page 71 ff) and table 10.1.4 (page 79 ff). The key data are compiled in a table in section 7.2. (page 36 ff). Again, SCHEER is surprised to see that the vast majority of the most recent data, i.e. those that are listed in table 10.1.4., are assessed as having a reliability score of 3, even those studies that tested the active substance.

All AA-QS values are based on a dataset in which the available freshwater and marine studies are combined. The SCHEER endorses this approach, given that not enough marine data were identified to allow a meaningful statistical comparison of the (dis)similarity of the marine and freshwater datasets.

Derivation of AA-QS$_{fw, eco}$ using the deterministic approach

It might be worth pointing out that the most sensitive data comes from the same study that was also identified as the most sensitive study during the calculation of the deterministic MAC-QS, i.e. Roshon (1997). The only difference is that now the NOEC for the inhibition of the root growth of *Myriophyllum sibiricum* after 14 d exposure is selected as a key value.

While the SCHEER agrees with this use of this NOEC as a descriptor for the chronic ecotoxicity of glyphosate, the study by Roshon is based on nominal concentrations. Its use as a key study for the determination of the deterministic AA-QS$_{fw,eco}$ therefore contradicts the statement in section 7.1. (that only analytically verified concentrations shall be used for the QS derivation). Therefore, the SCHEER cannot endorse the numerical value of the AA-QS$_{fw, eco.}$ The next-lowest value (geometric mean of 2 NOEC values for the marine diatom *Skeletonema costatum*) is calculated from two confidential studies and is not available for scrutiny.

Derivation of AA-QS$_{fw, eco}$ using the probabilistic approach

Two SSDs are constructed. The first includes all key studies listed in the table presented in section 7.1, page 36, and results in an HC_{05} of 0.450 mg L^{-1}. The second includes only primary producers (higher plants and algae) from the same table, and results in an HC_{05} of 0.358 mg L^{-1}. The HC5 from the first analysis, using the full dataset, is used for the final QS derivation. The SCHEER endorses this strategy, in particular in view of the fact that the target enzyme (ESPS) is not confined to primary producers (see above).

An additional assessment factor of 2 is applied to the HC_{05}, resulting in a total AF of 2x5=10, which was used to derive the final QS value. The SCHEER does not endorse this approach, which is not in line with the data evaluation as prescribed by the TGD, and no

specific reasons are provided for the additional AF of 2 in the dossier. The statistical descriptors, as well as the visual inspection of the SSD as provided in figure 7.2.1. on page 39, do not give particular reason for concern. Also, the data from the mesocosm study (Relyea, 2009) do not seem to indicate the need for an additional AF.

For this reason, and because the NOEC from the Roshon (1997) study is included in the dataset used for calculating the SSD, the SCHEER does not endorse the numerical value of the AA-$QS_{fw,eco}$.

Micro-, mesocosm studies and field studies in the freshwater environment

Table 10.1.3 in appendix 1 lists results from one mesocosm study (Relyea, 2009). This study provides only a glimpse of the eco-toxicity of glyphosate in a semi-natural system, as only a single concentration was studied (0.0069 mg L^{-1}), which did not cause any toxicity. The SCHEER recommends clearly stating that this study neither supports nor contradicts the QS values calculated from the SSD.

Derivation of AA-$QS_{sw, eco}$ using the deterministic approach

The lowest NOEC (=most sensitive species & endpoint) stems from the study by Roshon (1997), which is based on nominal concentrations. Its use as a key study for the determination of the deterministic AA-$QS_{fw,eco}$ therefore contradicts the statement in section 7.1. (that only analytically verified concentrations shall be used for the QS derivation). Therefore, the SCHEER cannot endorse the numerical value of the AA-$QS_{fw, eco.}$ The next-lowest value (geometric mean of 2 NOEC values for the marine diatom *Skeletonema costatum*) is calculated from two confidential studies and is not available for scrutiny.

Derivation of AA-$QS_{sw, eco}$ using the probabilistic approach

An additional AF of 10 is applied to the HC_{05}, resulting in a total AF of 10x5=50. The SCHEER endorses this approach. But, as outlined above, the SCHEER does not endorse the final numerical value of the AA-$QS_{sw, eco}$, due to the aforementioned inconsistencies in the data selection procedure.

Micro-, mesocosm studies and field studies in the marine environment

No statement regarding the availability of micro- and mesocosm studies on the chronic toxicity of glyphosate in the marine environment is provided in the dossier. To better orientate the reader, the SCHEER recommends clearly stating that no micro- or mesocosm data are available on the chronic marine toxicity of glyphosate.

Final QS values

All QS values are either based directly on the results from the study by Roshon (1997) with the aquatic plant *Myriophyllum sibiricum* (deterministic MAC-$QS_{fw,eco}$, $MAC_{sw,eco}$, AA-$QS_{fw,eco}$, AA-$QS_{sw,eco}$) or those data are incorporated in the datasets used for establishing the SSD (probabilistic MAC-$QS_{fw,eco}$, $MAC_{sw,eco}$, AA-$QS_{fw,eco}$, AA-$QS_{sw,eco}$). Given that these data are based on nominal concentrations, whose use is supposed to be explicitly excluded (see section 7.1.), SCHEER cannot endorse the resulting numerical values. There are indications that other data are also based on nominal concentrations.

The dossier does not specify whether the deterministic or the probabilistic MAC-$QS_{fw,eco}$ is retained as the final value. Based on the numerical value listed in the summary table on page 3, it seems as if the probabilistic value is retained. SCHEER supports this approach in principle, assuming that the necessary re-calculation of the SSD does not fundamentally change the statistical properties of the fit to the data.

The same applies to the calculation of the MAC-$QS_{sw,eco}$.

Currently, the dossier retains the deterministic value as the final AA-QS_{fw}. The SCHEER does not support this strategy, as the probabilistic AA-QS_{fw} seems sufficiently robust to

serve as the basis for the final AA-QS_{fw} value, assuming that the necessary re-calculation of the SSD does not fundamentally change the fit to the data.

The same applies to the calculation of the AA-$QS_{sw,eco}$

Section 7.3 – Sediment Ecotoxicity

Only one study with a sediment-dwelling organism was identified (Egeler, 2021). SCHEER considers this a problematic data gap in our understanding of the ecotoxicicty of glyphosate. The study (Egeler, 2021) derives a chronic NOEC of 154 mg kg^{-1}_{dw} based on mean measured concentrations. Normalising the data to 5% organic carbon content (EU standard) and applying an AF of 100 results in a **$QS_{sed, fw}$ of 3.08 mg kg^{-1}_{dw} (rounded to 3.1 mg kg^{-1}_{dw})**. Applying an AF of 1000 results in a **$QS_{sed, sw}$ of 0.308 mg kg^{-1}_{dw} (rounded to 0.31 mg kg^{-1}_{dw}).** The SCHEER endorses both values.

Section 7.4 – Secondary Poisoning

Experimental data clearly indicate that glyphosate has a BCF of less than the critical value of 100. Also the logP of glyphosate is substantially lower than the critical value of 3. The determination of the secondary poisoning risk is therefore assessed as being not relevant. The SCHEER supports this conclusion.

Section 7.5 – Human Health

The dossier follows the conclusions of EFSA and ECHA (harmonised CLP classification) that glyphosate does not meet the criteria to classify the compound as carcinogenic substance. The SCHEER agrees but recommends closely following the developments that might result from the current work regarding the possible re-authorisation of glyphosate as a pesticide for the European market.

Based on an ADI of 500 µg kg^{-1}_{bw} d^{-1} (T_{hh}), 20% fish in the average European diet (equal to 0.00163 kg_{fish} kg^{-1}_{bw} d^{-1} for a person of 70 kg), the threshold level for human health (TL_{hh}) was calculated as $0.2*T_{hh}/0.00163 = 61.35 \times 10^3$ µg $kg^{-1}_{biota\ ww.}$ = 61.35 mg $kg^{-1}_{biota\ ww.}$. The SCHEER endorses the calculation and the final value.

Glyphosate is used as an herbicide and, therefore, the generic limit value of 0.1 µg L^{-1} for pesticides according to the Drinking Water Directive (EU) 2020/2184 applies, i.e. $QS_{dw, hh}$=0.1 µg L^{-1}. The SCHEER does not endorse the application of assumed removal rates of 20% or even 50% during the production of drinking water (which would result in values of 0.125 µg L^{-1}, respectively 0.2 µg L^{-1} for $QS_{dw, hh}$). See also the answers to specific questions posed to SCHEER below.

Critical QS values for deriving the EQS

The critical QS value for the derivation of the EQS is $QS_{dw, hh}$ = 0.1 µg L^{-1} for surface waters that are used for drinking water production, and the probabilistically determined AA-$QS_{fw,eco}$ for surface waters currently not used for drinking water production, whose numerical value remains to be estimated from an updated SSD analysis.

4. Specific questions

Is the validity of the following ecotoxicity studies included in the draft dossier correct?

EC50 and NOEC for root growth of *Myriophyllum sibiricum* after an exposure of 14 d (Roshon, 1997).

Both the EC_{50} and NOEC are based on nominal concentrations and the studies have been assessed as being reliable and relevant. Their use, however, is in contradiction to the statement in section 7.1., which stipulates that only data based on analytically verified concentrations shall be used for the QS determination. Should these nominal concentrations be used, then the criteria stipulated in the dossier (section 7.1) would need to be changed.

Glyphosate is stable to hydrolysis at environmentally relevant pH and temperature values (EFSA, 2015). A study by Mallat and Barcelò (1998) determined half-lives for glyphosate between 60 and 100 h when exposed to direct sunlight. Biodegradation can be ruled out as the experiments by Roshon were conducted under sterile conditions. In summary, the concentration of glyphosate might decrease over the total exposure duration of 14 d, but, most likely, not by much.

It should be pointed out that the ecotoxicity of all known glyphosate degradation products (especially AMPA) is significantly lower than the ecotoxicity of the parent compound. The NOEC and EC_{50} values determined by Roshon might therefore be considered a worst-case estimate. Effect estimates based on analytically measured concentrations would in all likelihood indicate a higher toxicity of glyphosate.

The study by Wenzel (2012, cited in Deutschland 2013, In Oekotoxzentrum, 2016) that was indicated as a possible alternative is not cited in the list of references and was therefore not available to SCHEER for further analysis. However, the corresponding entry in table 9.1.1. indicates that the endpoint used in this study was the growth of the whole plant, which is different from the endpoint root growth as used in the study by Roshon. In fact, the study by Roshon indicates that the growth of the plant as a whole is less sensitive than root growth (Roshon, 1997, table 66, page 264). Therefore, the study by Wenzel (2012) cannot be considered a suitable replacement for the study by Roshon (1997).

Acute and chronic data on *Danio rerio* from Anonymous study cited in Deutschland 2013 (In Oekotoxzentrum, 2016) and Dias Correa Tavares 2000 (cited in CLH, 2016).

As a general remark: SCHEER would very much appreciate if the data that form the basis for the derivation of QS values would be properly referenced, directly in the dossier. An indirect 3-tiered reference to an anonymous study is not useful. Furthermore, no specific reasons for the raised concern are provided in the request to SCHEER, which makes a targeted re-analysis of the data difficult.

The referred anonymous study does not seem be available for scrutiny and SCHEER therefore cannot comment on whether the data are sufficiently reliable.

The dossier lists an acute EC_{50} of 123 mg L^{-1} for mortality in *Danio rerio* after an exposure of 96h (table with key data on acute toxicity, page 29), citing CLH (2016). SCHEER was unable to identify the referenced study in CLH (2016).

The study summary for the chronic study on the toxicity to *Danio rerio* provided in CLH (2016) does not spark concern, beyond the fact that also this study is based on nominal

concentrations. It might be worth noting that the NOEC of the study was set by the evaluating authors to 1 mg L^{-1} (10% mortality at the LOEC of 3.2 mg L^{-1}), although statistical significance was only reached at a concentration of 5.6 mg L^{-1} (16.7% mortality), which would result in a NOEC of 3.2 mg L^{-1}. SCHEER supports this approach, as a 10% mortality should be considered biologically relevant, in view of a control mortality of 0% (also test concentrations of 0.32, 0.56, and 1.0 mg L^{-1} did not cause any mortality).

Data for *Chlorella saccharophila*, *Scenedesmus acutus* and *Desmodesmus subspicatus* from the study by Vendrell et al. (2009).

Vendrell et al. (2009) recorded concentration response curves for four algal species (*Scenedesmus acutus, Scenedesmus subspicatus (*now re-classified as *Desmodesmus subspicatus), Chlorella vulgaris and Chlorella saccharophila*). The authors analysed the resulting data using the endpoint "area under the growth curve", using a standard Probit analysis for describing the resulting concentration-response curves. Unfortunately, no plots of the concentration-response curves are provided in the paper. There are no indications of any particular problems with the resulting EC_{50} values, which is why SCHEER would, in principle, recommend using those data for the determination of MAC-QS-values (but see the last comment, below).

However, the EC_{10} estimates seem less reliable, with data for 2 of the 4 species resulting in negative EC_{10} estimates. Also the confidence intervals for the EC10 estimates of the other two species include negative concentrations. This is an indication that the concentration-response fit is not reliable in the range of low-effect concentrations. The SCHEER therefore recommends omitting these data from the collection of key data describing the chronic toxicity of glyphosate.

It should be noted that the data from the Vendrell study also refer to nominal concentrations (see comments above).

Is the MAC-$QS_{fw,eco}$ derived correctly using the deterministic approach?

In principle, the MAC-$QS_{fw,eco}$ is derived correctly. The SCHEER agrees to the merging of freshwater and marine data and to the used AF of 10.

However, the SCHEER does not endorse the currently suggested numerical value for the MAC-$QS_{fw,eco}$ for two reasons:

1. An ecotoxicity value relating to growth impairment after an exposure of 14 d should be considered an indicator for the *chronic* toxicity of the test chemical.
2. The value is based on nominal (analytically unverified) test concentrations, see Roshon (1997), page 258. This is in direct contradiction to the selection criteria as provided in section 7, where it is explicitly stated that only analytically verified concentrations are included in the data evaluation.

   Also the second most sensitive value, the EC_{50} of 3.53 mg L^{-1} for *Chlorella pyrenoidosa* from the study by Ma (2001), seems to be based on nominal concentrations.

Is it correct to include the mesocosm study for the selection of the AF in the probabilistic derivation of the AA-QS?

The mesocosm study by Relyea (2009) is mentioned on page 40 of the dossier, but is not used for adjusting the AF during the probabilistic derivation of the AA-$QS_{fw,eco}$. In general, due to the fact that only a single concentration was tested in the Relyea study, not much can be gained from this study in the context of QS setting. Therefore, the SCHEER is of

the opinion that this mesocosm study should not be included in the derivation of the AA-QS.

Could be properly justified the additional AF of 2 AF in the probabilistic derivation of the AA-QS?

JRC suggests using an additional AF of 2 during the derivation of the AA-QS. This is not supported by SCHEER, as no specific reasons are provided to justify a deviation from the standard approach as outlined in the TGD. Statistics as well as a visual inspection of the SSD fit do not indicate any particular concern. This, however, might need to be re-evaluated if the underlying dataset is adjusted (see comments above).

Is using the $QS_{dw,hh}$, derived from the drinking water standard limit of 0.1 µg L^{-1} as a "overall" EQS, the correct approach?

According to the current version of the TGD from 2018, the EQS for freshwater represents the lowest value from the different QS values (see section 2, especially figure 4 on page 18). In this context, the TGD specifically stipulates that "*$QS_{dw,hh}$ can only be adopted as the lowest QS_{water} for waters intended for drinking water use*".

Applying the drinking water standard of 0.1 µg L^{-1} for pesticides (Directive (EU) 2020/2184) as an estimate for $QS_{dw,hh}$ is in line with the approaches outlined section 3.7 of the TGD.

The SCHEER supports the strategy to set an EQS value for water bodies used for drinking water production at 0.1 µg L^{-1} ($QS_{dw,hh}$), and a second, higher EQS for water bodies not used for drinking water production (based on a re-calculated AA-$QS_{fw,eco}$). A re-classification of water bodies currently not used as drinking-water sources to drinking water sources would be possible after an appropriate waiting time, given that glyphosate is not classified as a persistent pollutant.

5. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
AMPA	Aminomethylphosphonic Acid
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
bw	body weight
EC	Effect Concentration
EFSA	European Food Safety Agency
EPSPS	5-Enolpyruvylshikimate-3-Phosphate Synthase
EQS	Environmental Quality StandardsHC Hazardous Concentration
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
QS	Quality Standard
RAR	Renewal Assessment Report
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document for deriving EQS
TL	Threshold Level
WFD	Water Framework Directive
ww	wet weight

6. REFERENCES

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