



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

**Position Paper on "Draft Environmental Quality Standards
for Priority Substances under the Water Framework
Directive"**

SCHEER self-mandate



The SCHEER adopted this document
by written procedure on 3 April 2023

ACKNOWLEDGMENTS

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[Register of Commission expert groups and other similar entities \(europa.eu\)](#)

This Position Paper identified several areas where there is scope for improvement and the SCHEER takes this opportunity to offer some reflections.

Keywords

SCHEER, Position Paper, Water Framework Directive, environmental quality standards

Document to be cited as:

SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), SCHEER Position Paper on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive", 3 April 2023

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ISSN

ISBN

doi:

ND

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ABSTRACT

The SCHEER was requested, according to the Mandate from DG Environment, to provide opinions on a series of draft EQS dossiers for newly proposed priority substances and on those EQS dossiers for existing priority substances that were recently updated.

The SCHEER welcomes the opportunity to provide a review of the proposed changes in EQS, and it is the SCHEER's view that independent scrutiny has been essential in this process. As a result of the review, many of the proposed EQS values were endorsed, but a number of them were either amended directly by the SCHEER or detailed comments were provided suggesting what changes would be required.

During the review of more than 40 dossiers, the SCHEER identified several areas where there is scope for improvement both within the dossiers and the Technical Guidance document (2018), many were observed in different dossiers, and the SCHEER takes this opportunity to offer some reflections on overarching and detailed issues.

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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 the other component of the draft dossier. The EQS for a number of existing priority substances have also been revised.

The EQS derivation has been carried out in accordance with the Technical Guidance Document on Deriving EQS (TGD-EQS) and reviewed by the SCHEER¹.

2. Terms of reference for the mandate

The terms of reference as sent by DG Environment reads as follow:

"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.*

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

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. The dossiers contain much more information than simply the draft EQS; the SCHEER is asked to focus on the latter."

In each Opinion, the SCHEER commented that they would provide a general discussion concerning the procedure and derivation of the EQS values and related topics and identify unresolved issues and areas where the process might be improved that are common to more than one substance and dossier. This position paper provides such a synthesis.

The SCHEER is also aware of the Proposal for a Directive of the European Parliament and of the Council (COM(2022)540), which shall amend Directives 2000/60/EC, 2006/118/EC and 2008/105/EC and has responded separately to that consultation, which is included in Section 5 of this text.

The SCHEER welcomes the opportunity to provide a review of the proposed changes in EQS, and it is the SCHEER's view that independent scrutiny has been essential in this process. Many of the proposed EQS values were endorsed as a result of this exercise, others were directly amended by the SCHEER, and for others, the SCHEER provided detailed comments suggesting what changes and additional data would be required before the proposed values could be endorsed.

While not relevant to the technical evaluation of the dossiers, the SCHEER took the view that a rationale underlying the selection of the various substances as priority hazardous substances or the deselection of others would have been beneficial and would have facilitated the identification and evaluation of cross-cutting issues, such as the grouping of substances.

During the review of more than 40 dossiers, the SCHEER identified several areas where the process might be improved, and the SCHEER takes this opportunity to offer some reflections, which are described in the following text. The document is structured into two main sections, as follows:

Section 1: Dossier structure, quality and data evaluation

Section 2: Overarching and emerging issues within the TGD

Section 1: Dossier structure, quality and data evaluation

This section provides some discussion of issues that occurred in more than one dossier that relates to the EQS derivation according to the Technical Guidance Document (TGD). Not all issues were present in all dossiers, but each issue was encountered in several dossiers.

1.1 State of dossier readiness/completeness

Several dossiers submitted to the SCHEER were preliminary and incomplete, including in sections that are central for the derivation of the EQS values. In some cases, after the submission of the original dossier, updated documents were submitted while the SCHEER evaluation was already in progress. This compromised a proper and systematic dossier evaluation. The SCHEER advises that to streamline the review process, future dossiers should be submitted for external review only when considered finalised and complete.

1.2 Incomplete toxicological and ecotoxicological data

Scientific knowledge and data are being continually generated and updated. Nonetheless, in the opinion of the SCHEER, some of the dossiers produced did not take into account all of the data available in international databases and in the scientific literature at the time of dossier production. This was particularly noted for chemicals for which extensive ecotoxicological information already exists in the literature (e.g. pyrethroids and neonicotinoids). While it was not the task of the SCHEER to provide an extensive review of the international literature, there were some cases where new information was known to the SCHEER WG and which was highlighted. The SCHEER in several instances endorsed the EQSs with reservation because the supporting data from the databases and literature had not been fully updated.

The SCHEER noted that for some chemicals, e.g. certain pesticides which are no longer registered in the EU, the regulatory datasets are not made available/accessible. As a direct result, the EQS evaluation and validation for such pesticides becomes more difficult. Therefore, the SCHEER recommends that such data are retained after de-registration.

In some cases, the dossiers referred to proprietary (eco)toxicological data for which the reliability could not be examined or confirmed by the SCHEER. Where such data are critical to the EQS derivation, this situation is unsatisfactory and may erode confidence in the EQS itself. In these circumstances, the SCHEER would recommend that a mechanism be found to allow the underlying data to be disclosed.

1.3 Transparency of data collection

The SCHEER noted that the search for relevant scientific literature for data collection lacked transparency and could be better explained and justified in the dossiers. The use of an in-house tool (the "JRC Literature Evaluation Tool", LET) makes it almost impossible to extend previous literature compilations in future dossier updates.

The SCHEER recommends that the principles of systematic review, including the provision of a study protocol that explicitly explains how the references were identified, be followed for each dossier and that the protocol specifies the eligibility criteria and quality control measures.

In addition, the SCHEER suggests that more than one database be used. As an example, the use of PubMed as the main source of literature can be problematic for the purpose at hand, because this database, as the name implies, is focussed on the medical literature and may not fully capture the (eco)toxicological literature.

1.4 Reliability and relevance assessment

Individual papers from which the data are extracted are assessed for their relevance and reliability and only the data that are assessed as being sufficiently reliable and relevant were used as "key studies" or "critical data" for the estimation of EQS values. The SCHEER was asked in several cases to evaluate the reliability assessments of specific data and to independently validate the assessments made in the dossier. However, the dossiers do not always explicitly state where the balance of the lines of evidence is drawn between "reliable" and "insufficiently reliable", or "relevant" and "insufficiently relevant", respectively.

Data that are classified as "supporting studies" do not seem to have been included in the final estimation of QS values, although the TGD allows such studies to be considered. The SCHEER has previously published its memorandum on the weight of evidence approach (SCHEER 2018), which could be applied in this context, for the final QS estimate. This is allowed under the TGD but could be more explicitly described in the procedures.

1.5 Clarification needed on terms such as provisional EQS

Several EQS values are indicated in the dossiers as "preliminary", "provisional", "tentative" etc., without further explanation about the reasoning and possible differences among these terms. If they are considered as being synonymous, the SCHEER suggests the wording should be harmonised. The SCHEER is aware that EQS values will be updated and revised according to the timeframe outlined in the WFD. However, it should be explicitly clarified whether these "preliminary" EQSs are to be dealt with in the same way as the proposed EQS value which are not described as "preliminary/provisional".

1.6 Use of data from technical formulations

As a general rule, the SCHEER recommends that data from the pure active substance/ingredient should be used to derive the EQS. In addition, data on technical formulations can be used as supporting information and in exceptional cases (e.g. data-poor substances) used as stand-alone data. It must, however, be demonstrated that the identity and concentrations of all other chemicals (co-formulants, impurities, additives, reaction by-products, etc) in the formulation are known and that they do not interfere (toxicologically, chemically or physically) with the active substance / main ingredient. When these conditions are met, the SCHEER considers that the information on the toxicity of the formulation can be used for the EQS derivation.

1.7 Consistency in the presentation of the EQS values

The SCHEER notes that the terminology and notation used in some dossiers differed. The SCHEER recommends improving the readability of the dossiers by consistently abbreviating the different units across the dossiers, including the use of subscripts and superscripts.

It is the opinion of the SCHEER that dossiers should use two significant digits consistently across all dossiers for the final presentation of the QS values. Three or more significant digits presumes a level of precision that is in contradiction to the likely uncertainty present in the data.

1.8 The meaning of "most Critical EQS"

For each dossier, the SCHEER was asked to assess whether the "most critical EQS" had been identified, but the SCHEER is not aware of an agreed definition of this term and requests that this should be clarified. Such a definition should also be extended to include what compartment/endpoint is critical. In the opinions, the SCHEER typically selected the lowest numerical EQS, *i.e.* the hardest to achieve, and also on several occasions, identified more than one "critical EQS". However, different criteria could be used (*i.e.* the one that might be most difficult for Member States to achieve or the one that might produce the greatest harm if not respected).

1.9 The evaluation of environmental concentrations

A substantial part of the dossiers deals with risk and exposure evaluations, the latter being based entirely on measured environmental concentrations in freshwater and coastal/transitional waters of European Member States. These sections do not have any bearing on the EQS estimates, but SCHEER nevertheless recognises the relevance of these sections in the creation of the dossier.

The SCHEER identified several issues in these sections:

- The underlying empirical monitoring data are not provided as part of the dossier. In some cases, the basic information on the sample characteristics (spatial distribution, seasonality, proximity to contamination sources, etc.) is not made available. This renders an assessment of data quality, reliability and relevance impossible. The SCHEER recognises that there may be a huge variation amongst

the MSs but recommends further EU-wide harmonisation of monitoring programmes.

- In many cases, the data originate from only a small number of EU MSs, with more than 70% based on two or three countries. These data are not sufficient to allow conclusions to be drawn on EU-wide exposures and risks.
- Concentration values are often below the analytical limits of detection and quantification (LODs and LOQs), even sometimes up to 90% of the data are below the LOQs and LODs. Usually, values below the LOQ are substituted with a value of ½ the LOQ, in order to estimate exposures. The SCHEER recommends that more reliable statistical approaches be used, for example by applying Kaplan-Meier estimates for left-censored analytical data (Shoari 2018).
- In view of the limitations of the empirical monitoring data, the SCHEER suggests that exposure modelling also be performed (PEC calculation) and used as a second line of evidence. The SCHEER noted that the WFD prioritisation work initially considered measured and modelled exposure data in parallel.
- The SCHEER recommends that it would be beneficial to utilise suitable and validated models and methods to estimate PECs. An EU-wide expert group could be charged with reviewing the existing modelling options for exposure assessment.

Section 2: Overarching and emerging issues within the TGD

This section discusses those issues encountered during the dossier evaluation that relate to the Technical Guidance for Deriving Environmental Quality Standards (2018) which the SCHER (the SCHEER's predecessor) provided input to through its review of an earlier version of this Guidance in 2010 (SCHER, 2010) and the SCHEER reviewed again in 2017 (SCHEER, 2017). The SCHEER considers the 2018 version of the Technical Guidance to be a useful and well organised document. However, the intensive application of the Guidance during the SCHEER WG's two years of activity helped to identify some areas of science where the TGD may require further updating. These are highlighted below.

2.1 Assessing mixture toxicities

Relative potency factors (as an implementation of the classical mixture toxicity concepts of Concentration Addition) were applied in the new EQS dossiers for PAHs and PFAS compounds. The SCHEER supports this method for setting EQS values for groups of chemicals and recommends updating the TGD accordingly. The SCHEER also recommends providing similar RPF-based EQS values for other groups of compounds, such as estrogenic compounds (17 β -estradiol, estrone, ethinylestradiol, bisphenol A, nonylphenol, octylphenol), photosynthesis inhibiting herbicides (atrazine, diuron, isoproturon, cybutryne, terbutryn), and neonicotinoid insecticides (acetamiprid, clothianidin, imidacloprid, thiacloprid, thiamethoxam).

2.2 Assessing bioconcentration factors (BCFs)

The Technical Guidance recommends the use of experimental data for bioconcentration or bioaccumulation factors (BCF or BAF ≥ 100) or for biomagnification factors (BMF ≥ 1) as triggers for secondary poisoning. Furthermore, the TGD suggests the use of the K_{ow} as a surrogate if experimental data are not available. However, it becomes increasingly clear that for some compounds bioaccumulation is driven by factors other than hydrophobicity, such as the protein-binding capacity of a substance, as, for example, in the case of poly- and perfluorinated substances. In these cases, a trigger based on a substance's K_{ow} is inappropriate and an experimental BCF must be provided. Therefore, the SCHEER is of the opinion that the K_{ow} is a useful surrogate for empirical

BCF, BAF or BMF data only if there is evidence that the substances bioaccumulate in lipids. The SCHEER recommends updating the TGD accordingly.

2.3 Pooling of freshwater and marine data for the estimation of sediment QS values

The TGD specifically allows for the pooling of ecotoxicity data from marine and freshwater test systems for the estimation of the $QS_{\text{sediment, marine}}$, given that there are no biological or other scientific reasons to the contrary (page 109). However, the TGD does not provide a similar provision for the estimation of $QS_{\text{sediment, freshwater}}$. The SCHEER therefore recommends updating the TGD in order to explicitly also allow the pooling of marine and freshwater data for the estimation of $QS_{\text{sediment, freshwater}}$.

2.4 Combining extrapolation methods for estimating EQS values

The TGD stipulates the most reliable extrapolation method be used from:

- the deterministic approach in which a specific assessment factor is applied to the lowest credible EC50 or NOEC value; or
- the probabilistic approach using the lower 5% percentile of a species sensitivity distribution (SSD) to which an assessment factor is applied; or
- the results from model ecosystem (e.g., mesocosms) and field studies.

However, on some occasions none of these methods may be considered sufficiently reliable on their own. In order to make full use of the available information, the SCHEER recommends that a systematic weight-of-evidence approach is used when more than one of the three methods are applied to the data (SCHEER 2018).

2.5 Taxonomic requirements for establishing a species sensitivity distribution

The TGD describes the conditions for considering a species-sensitivity distribution (SSD) as statistically sound and ecologically representative:

"the output from an SSD-based QS is considered reliable if the database contains preferably more than 15, but at least 10 NOECs/EC10s values, from different species covering at least 8 taxonomic groups."

In this sentence the concept of a "taxonomic group" is not sufficiently clear, without specifying which level of the taxonomic hierarchy (phylum, class, order or family) is assumed as being a distinct "taxonomic group".

The TGD also proposes a list of taxonomic groups that *"would normally need to be represented"*, but it is not specified what this actually means in terms of whether such a list should be compulsory or if this is simply a proposal.

Moreover, the taxonomic terminology is used improperly and includes a number of mistakes (for example: fish and amphibians are not families of the phylum *Chordata*, they are classes; common names instead of rigorous taxonomic terms are used to represent different orders and families; different levels of the taxonomic hierarchy are mixed to indicate a taxonomic group; etc.).

All of this raises the question of what actually constitutes a distinct taxonomic group. The SCHEER recommends that this section of the Technical Guidance be clarified and revised using more appropriate taxonomic terminology.

2.6 Improved estimation of probabilistic QS values (HC05 estimation)

The methods for estimating species-sensitivity distributions have advanced over the last years, improving both precision and accuracy of the estimates of the hazardous concentration for five percent of the species (HC05). In particular, it has become clear that a log-normal distribution is not always the best model to describe the data.

However, this is the basis for the vast majority of the dossiers, in which the SSD relies entirely on the use of the log-normal function that is implemented in the ETX software. In contrast, more modern approaches for the SSD calculation are used (partly) in the diclofenac and BPA dossiers. The SCHEER recommends applying similar approaches consistently where at least several models should be comparatively fit to the data at hand and the best-fitting (based on Akaike Information Criteria) should then be selected for the final HC05-estimation. Additionally, confidence intervals for the fit should be consistently provided for the model SSD and the resulting HC05 to allow comparison. Such an approach is, for example, provided by Thorley (2018) and implemented in the freely available "SSDTools" package for the R programming language or directly as a website for the calculation of SSDs (<https://bcgov-env.shinyapps.io/ssdtools/>).

The SCHEER recommends updating the TGD accordingly so that it provides specific recommendations for an improved SSD modelling.

2.7 MAC-QS for pesticides

Pesticide contamination is typically characterised by peaks of concentration related to seasonality, application times, etc. Therefore, concentration peaks, which may be considered as exceptional events for many contaminants, are typical for pesticide exposures. Consequently, the MAC-QSs for pesticides may have a different ecological relevance compared to other types of chemical contaminants. Therefore, it is the opinion of the SCHEER that special consideration should be given to the data used in the estimation of the MAC-QS for pesticides.

2.8 Assessment factors to be used for the estimation of the sediment QS values

Two conflicting tables with assessment factors (AFs) are currently presented in the TGD for the deterministic derivation of QS_{sediment} values, in table 11 on page 101 and table 13 on page 110. The tables provide different AFs to be applied if there are three long-term sediment tests with species representing different living and feeding conditions available: table 11 provides an AF of 10, while table 13 provides an AF of 50. Based on the context, the SCHEER assumes that table 11 is meant to apply only to freshwater sediments and recommends clarifying the TGD accordingly.

3. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
AF	Application Factor
BAF	Bioaccumulation Factor
B[a]P	Benzo[a]pyrene
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
EC	Effect Concentration
EFSA	European Food Safety Agency
EQS	Environmental Quality Standards
HC05	Hazardous Concentration for five percent of the species
MAC-QS	Maximum Acceptable Concentration Quality Standard
MS	Member State
LOD/Q	Limit of Detection/Quantification
PAH	Polycyclic Aromatic Hydrocarbons
PEC	Predicted Environmental Concentration
QS	Quality Standard
SSD	Species Sensitivity Distribution
TGD	Technical Guidance Document
TL	Threshold Level
WFD	Water Framework Directive
WG	Working Group Chemicals

4. REFERENCES

SCHEER Memorandum on weight of evidence and uncertainties 2018 Available at https://health.ec.europa.eu/publications/memorandum-weight-evidence-and-uncertainties-revision-2018_en

SCHEER Scientific Advice on Guidance Document n°27: Technical Guidance for Deriving Environmental Quality Standards (2017). Available at https://health.ec.europa.eu/system/files/2018-03/scheer_o_012_0.pdf

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5. SCHEER response to WFD consultation

Comments on the Commission's proposal for amending the WFD/GWD/EQSD

The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) provides Opinions on questions concerning emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues.

The SCHEER would like to take the opportunity to provide feedback on the Proposal for a Directive of the European Parliament and of the Council (COM(2022)540), which shall amend Directives 2000/60/EC, 2006/118/EC and 2008/105/EC. SCHEER has already provided Opinions to the suggested Environmental Quality Standards (EQS) for the new priority substances and the new priority hazardous substances, as well as for the partially updated EQS values for several existing priority substances. For these, the reader is referred to SCHEER's website at https://health.ec.europa.eu/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer/scheer-opinions_en.

1 General Comments

- The Commission's proposal implements important new elements and tools that have been developed over the last years. The SCHEER welcomes the adjustment of the legal framework to technical and scientific progress.
- The SCHEER is aware of the documents on CIRCABC² that provide information on the substance deselection criteria and the dossier development. However, to the best of SCHEER's knowledge, no background document is provided by the Commission that lays out the details of the Commission's proposal, including, but not limited to, the rationale and details of the substance prioritization. The SCHEER considers this problematic, as the lack of documentation renders the overall assessment of the Commission's proposal challenging.

² <https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/73b2d635-4cb1-4d7d-975c-da1b5db594d8> [accessed 03 March 2023]

2 Priority Substances and Priority Hazardous Substances in the context of the WFD

- The proposed definition of priority hazardous substances (Art 1(2c) of the Commission's proposal) does not specifically include endocrine disruptors (ED), or substances that are identified as PMT/vPvM substances (Persistent, Mobile and Toxic; very Persistent, very Mobile substances). The SCHEER recommends those three hazard classes be specifically included in the final text of the Directive, in line with the previously published draft for the amendment of Regulation (EC) No 1272/2008 (Ares(2022)6485391). The SCHEER considers this another step towards the objective of "one substance, one assessment".
- Some of the priority substances are labelled as "uPBT" substances (ubiquitous, persistent, bioaccumulative and toxic) in Annex V of the Commission's proposal. No definition of the term "ubiquitous" or "uPBT" is provided. Given that all priority substances are, by definition, "substances which present a significant risk to or via the aquatic environment in a high proportion of Member States." (Art1(2b) of the Commission's proposal), the difference between an "ordinary" priority PBT substance (such as any of the cyclodiene pesticides) and an "ubiquitous" PBT substances is unclear. Furthermore, it is unclear, whether the classification as a "uPBT" has any consequences for management or in a legal context.

3 Priority Substances and Priority Hazardous Substances in the context of the GWD

- A generic quality standard (QS) of 0.1 µg/L is suggested for individual pesticides in groundwater, as already established in Directive 2006/118/EC (GWD). The SCHEER would like to emphasize that the 0.1 µg/L value was established in the 1980s, with a view of the chemical-analytical sensitivity at the time. More than 40 years later, this value should now be checked against modern analytical methods and, more importantly, against the toxicological knowledge at hand. The Commission's proposal does not provide arguments why a default value of 0.1 µg/L is sufficiently protective for human health and the groundwater ecosystem. An identical default value for all pesticides treats these substances, which are usually toxicologically well characterized, as unknown chemicals, which violates a basic principle of chemical hazard and risk assessment, *i.e.* to make best use of the available data while ensuring an adequate level of protection. As such, the approach contradicts the fundamental approaches that are employed in *e.g.* the Technical Guidance Document for Deriving EQS values³.
- The SCHEER recommends a specific amendment be provided in the final Directive that a groundwater QS must not be higher than the corresponding EQS for surface waters.

³ EU Commission, 2018. Technical Guidance for Deriving Environmental Quality Standards.

- Non-relevant pesticide metabolites (nrMs) are also assessed using generic QS values, of 0.1, 1, 2.5 or 5 µg/L, for data-poor, intermediately well researched and data-rich nrMs. The SCHEER supports, in principle, the application of a tiered approach, but is of the opinion that the current implementation, as provided in the Commission's proposal, is not sufficiently consistent.
- The SCHEER has recently argued⁴ that a value of 0.1µg/L for an individual nrM is indeed sufficiently protective for human health and therefore supports this value. However, the SCHEER also emphasized that there is currently insufficient data to conclude on whether this value is indeed sufficiently protective for the groundwater ecosystem and advised the introduction of an additional assessment factor for that purpose.
- It is unclear to the SCHEER why the QS values for data-rich nrMs are not derived directly from the empirical data, just like for any other substance.
- It is also unclear why four numerical values are suggested for three nrM classes.
- The Commission's proposal suggests increasing the QS of an nrM with increasing data availability. However, it is unclear why the QS for a data-rich nrM should be increased (indicating a lower hazard), even if it would be empirically demonstrated for the nrM in question that it is highly toxic.

4 Assessment of Mixtures

- For PAHs and PFAS, the sum-EQS is based on relative potency factors (RPFs). This approach implements the state of the art of mixture ecotoxicology, i.e. the model of "Concentration Addition", the typical first tier of mixture assessments. The SCHEER supports this approach and therefore recommends to also provide similar RPF-based EQS values for the groups of estrogenic compounds (17β-estradiol, estrone, ethinylestradiol, bisphenol A, nonylphenol, octylphenol), photosynthesis inhibiting herbicides (atrazine, diuron, isoproturon, cybutryne, terbutryn), and neonicotinoid insecticides (acetamiprid, clothianidin, imidacloprid, thiacloprid, thiamethoxam).
- No rationale is provided for the establishment of generic sum-EQS values for pesticide mixtures based on total concentrations (0.5 µg/L, for surface as well as for groundwater). The SCHEER recommends the possibilities of setting RPF-based EQS values also for heterogeneous pesticide mixtures be explored, taking into account the

⁴ SCHEER: Final Opinion on Groundwater quality standards for proposed additional pollutants in the annexes to the Groundwater Directive (2006/118/EC), 18 July 2022

recommendations of the State of the Art Report on mixture toxicity⁵, the previous mixture opinion by SCHER, SCENIHR and SCCS⁶, and the EFSA Guidance⁷

- The proposal does not provide the reasons why a sum EQS / QS of 0.5 µg/L for arbitrary pesticide mixtures is considered to be sufficiently protective. The SCHEER emphasizes that the EQS values for the vast majority of pesticides identified as priority substances, are lower, sometimes by orders of magnitude. That is, an EQS / QS of 0.5 µg/L would be insufficiently protective even if only an exposure to a single entity is considered – which would then also hold true if mixtures of these substances are considered.
- The same arguments also apply to the generic sum-EQS for pharmaceuticals (0.25 µg/L) and non-relevant pesticide metabolites (0.5-12.5 µg/L, depending on data availability) for groundwater.

5 Effect-based methods (EBMs)

- The Commission's proposal suggests, for the first time, to allow for the possibility to express EQS values not only as concentration values, but also by using effect-based methods (EBMs). The SCHEER supports this amendment of the WFD in view of scientific and technical progress, but the current implementation poses some unanswered questions for its implementation.
- The SCHEER recommends not to confine the use of EBMs to (xeno)estrogens, but to also explore the possibilities of using EBMs for other groups of compounds, such as the photosynthesis-inhibiting herbicides.
- Specifically, the Commission's proposal suggests amending Art 8a of the WFD to *"require Member States to carry out effect-based monitoring to assess the presence of estrogenic hormones in water bodies, in view of possible future setting of effect-based trigger values "*. Given that the suitability of EBMs for characterizing the estrogenicity in various water types has already been demonstrated repeatedly (e.g. Könemann 2018, Simon 2022)⁷, it is unclear what would be gained from yet another data collection exercise.

⁵ Kortenkamp, A., Backhaus, T., Faust, M., 2009. State of the Art Report on Mixture Toxicity (No. 070307/2007/485103/ETU/D.1).

⁶ SCHER, SCENIHR, SCCS: Toxicity and Assessment of Chemical Mixtures, 2012

⁷ EFSA Scientific Committee, More, S.J., Bampidis, V., Benford, D., Bennekou, S.H., Bragard, C., Halldorsson, T.I., Hernández-Jerez, A.F., Koutsoumanis, K., Naegeli, H. and Schlatter, J.R., 2019. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. *EfSA journal*, 17(3), p.e05634. DOI: <https://doi.org/10.2903/j.efsa.2019.5634>

6 River-basin specific pollutants

- The evaluation of river-basin specific pollutants (RBSPs) has so far been part of the ecological status assessment of a water body. The Commission's proposal now suggests to include RBSPs in the chemical status assessment - together with the EU-wide priority substances. This approach increases the logical consistency of the WFD and is therefore fully supported by the SCHEER.
