



SCIENTIFIC COMMITTEE ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS (SCHEER)

Request for a scientific opinion: Guidance document n°27: technical guidance for deriving environmental quality standards

Commission Department requesting the Opinion: Directorate-General for Environment

1.1 Background

Introduction

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 (EQSs) 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 EQSs for those substances were established (Directive 2008/105/EC or EQS Directive, EQSD). The EQSD was then revised in 2013 by Directive 2013/39/EU, which modified the EQSs for seven of the existing priority substances and introduced twelve new priority substances. Article 16 of the WFD requires the Commission to review the list of priority substances every six years, and when appropriate, to revise EQSs for existing priority substances, to identify new priority substances and to set EQSs for them in water, sediment and/or biota. The current review is underway.

The Commission has been working on the above-mentioned review since 2013, with the support of the Working Group Chemicals¹ under the Water Framework Directive Common Implementation Strategy (WFD CIS) and its dedicated sub-group for review (led by the JRC). The Working Group Chemicals is chaired by the Commission, the JRC, Romania and Italy and consists of experts from Member States, EFTA countries, candidate countries and more than 25 European umbrella organisations representing a wide range of interests (industry, agriculture, water, environment, etc.).

The guidance document (*'Guidance Document n°27: Technical Guidance for Deriving Environmental Quality Standards' - 'Guidance'*) is intended to support the derivation of EQSs for priority substances and for river-basin-specific pollutants that need to be regulated by Member States according to the provisions of the WFD.

Legislative context

The mentioned guidance document is intended to give clear and detailed technical guidance for developing EQSs that will meet the requirements of the WFD. The work to develop the document started back in 2007 in an expert group under the WFD Working Group E (EG-EQS, now WG Chemicals) and took account of a previously-used methodology for EQS derivation. The resulting draft guidance

¹ Former Working Group E.

document was presented to the SCHER in March 2010. The Opinion of the SCHER was taken into account to produce a final version of the document (hereafter the Guidance), which was formally validated by the Member State "Water Directors" under the Common Implementation Strategy process in March 2011. In 2014, a new Expert Group was set up to review the Guidance, in particular to adapt it to recent scientific developments. The work of the EG group led to a revised version of the document, which is now submitted to the SCHEER.

EQSs play a key role in assessing the chemical quality of waterbodies and are also used, indirectly, to regulate discharges to water. The Guidance is intended for deriving EQSs that will apply across Europe (i.e. Priority Substances and Priority Hazardous Substances contained in Annex X of the WFD). It is also intended to assist in the derivation of EQSs for substances identified as 'Specific Pollutants' requiring national controls, as described in Annex VIII of the WFD.

The principles for setting EQSs were set out in Section 1.2.6 in Annex V of the WFD, but the details that practitioners need to follow are lacking in this Annex. The Technical Guidance is intended to fill this gap.

There is no formal obligation to follow the Guidance. However, the European Commission believes it encompasses best practice in all aspects of EQS derivation and, therefore, strongly encourages Member States to adopt the Guidance.

Scope of the Guidance

The Guidance is intended to cover all receptors (humans, aquatic life, predators) and all media (water, sediments and biota) that might be put at risk from chemical pollution. It covers derivation of EQSs for inland surface waters, as well as for coastal and transitional waters.

Principles involved in EQS derivation have much in common with those used for risk assessment of chemicals. As far as possible, consistency with the other regimes is sought, but differences may be justified in some cases².

The Guidance focuses on the technical steps needed to develop EQSs that can be proposed by experts to policymakers for implementation. Although this is a key step in the process, other steps are necessary before an EQS can be implemented in practice, e.g. chemical monitoring guidance and advice on the design of compliance assessment regimes. These are covered in other documents.

Process and scope for the revision of the Guidance

The aim of the WG in reviewing the Guidance was three-fold:

- Adapting the Guidance to recent scientific developments, keeping in mind that the purpose of the document is to provide practical guidance for practitioners in deriving EQSs, while ensuring consistency, as far as possible, with other risk assessment regimes,
- Reviewing the comments made by the SCHER in 2010 and taking account, where possible, of those that couldn't be taken on board at the time,
- Clarifying, where necessary, the structure and content of certain sections of the Guidance.

Revision of the Guidance has involved an extensive consultation process, where the recommendations from the expert group for the revision of the TGD were presented and discussed with the dedicated technical sub-group for the review of the priority substances, , and with the WG Chemicals under the CIS

² Guidance for EQS setting of priority substances justifies more refinement than risk assessment, which is often tiered, and so refinements of the methodology in the TGD-EQS (compared to the REACH methodology) should be possible.

We also consulted informally our expert contacts in other Commission Directorates General (DG GROW and DG SANTE), and Agencies (ECHA and EFSA). The comments received were considered and addressed and the current draft revised Guidance reflects the conclusions reached at the WG meetings.

The main changes to the Guidance are summarised in the following table:

Section/topic revised	Nature of the changes
Section 2.6 (and related appendix 1) - Quality assessment of data	Advice on methods for the quality assessment of ecotoxicological data (possible use of CRED method - Criteria for Reporting and Evaluating Ecotoxicity Data) has been included.
Section 3.5 - Metals guidance	Guidance on the derivation of bioavailability-based EQSs for metals has been clarified and developed. ³
Section 4 - Biota quality standards for protecting predators (secondary poisoning)	Section 4, dealing with the derivation of biota standards for the protection of predators, has been completely revised. This reflects a move towards an approach that explicitly accounts for the energy content of prey items in the diet.
Section 4 - Biota quality standards for protecting human health	Changes have been made to the allocation of diet from fish (from 10 to 20%). Two options are under consideration at the moment (and included in the guidance): either using the food standard, where it exists, as the basis for the quality standard; or using a toxicologically-based formula - this will require decision at a strategic level (Strategic Coordination Group under the WFD CIS).
Marine quality standards	Comments from marine experts have been acted upon.
Technical revisions	Various technical corrections have been made.

The draft revised technical guidance provided to the SCHEER shows the changes resulting from the revision when compared with the current (2011) version of the Guidance.⁴

1.2 Terms of Reference

The SCHEER is invited to review the changes proposed for the Technical Guidance for Deriving Environmental Quality Standards (TGD-EQS, i.e. Guidance) and to address the following **general questions**:

1. Express its opinion on the overall scientific quality of the proposed changes, considering that the purpose of the document is to provide practical guidance for practitioners for deriving EQSs, and to conclude whether those changes properly reflect the current state of technical and scientific knowledge or not.
2. Elaborate on its reasons for considering any aspect of the changes inappropriate, suggest alternative approaches as necessary and elaborate on any aspects that it considers are missing in the Guidance and should be addressed (beyond those which the authors have committed to addressing in the longer term).

In addition, the SCHEER is invited to address the following **specific questions**:

³ Guidance on implementing metal EQSs will be provided in a separate document, to be developed under the WG Chemicals.

⁴ Comments received from the SCHER on the TGD-EQS in 2010 were taken into account as far as possible in the 2011 TGD-EQS by the drafting group (as described in the document entitled "Response to the Scientific Committee on Health and Environment regarding its scientific opinion on "Chemicals and the Water Framework Directive: Technical guidance document for deriving environmental quality standards" sent in 2010 to the SCHER, enclosed also to the current request). Annex 4 presents an update of these answers to the 2010 SCHER's comments.

3. Does the SCHEER agree that the Opinion offered by SCHER in 2010 has been adequately dealt with in the Guidance? The Working Group produced a summary of the comments made by SCHER in 2010, with responses explaining how those comments were taken into account when developing the new Guidance. The SCHEER is invited to comment on any of the points raised in 2010 that it considers were not properly or sufficiently addressed (bearing in mind the commitment to consider some of them in the longer term).
4. As far as possible, the Guidance is consistent with the principles of chemical risk assessment under REACH (as stated on page 15 of the Guidance). However, in some details it deviates from the approach taken in REACH or suggests an alternative option. In particular, the methodology for deriving the quality standard for the protection of top predators from secondary poisoning is a refinement of the dietary approach under REACH⁵. According to the new methodology, the endpoints of dietary toxicity tests are expressed on the basis of caloric content of the food instead of its fresh weight. This accounts for differences in energy content between different food items, before converting them to the biota standard, based on fresh weight. This refinement of the methodology is expected to produce more robust estimates of thresholds for secondary poisoning⁶. Does SCHEER have comments on this refinement of the methodology? Does SCHEER support its inclusion in the Guidance?
5. The CRED method (Criteria for Reporting and Evaluating Ecotoxicity Data) has been introduced as an alternative to the Klimisch method, in particular to transparently assess the reliability and relevance of aquatic ecotoxicity data. The Guidance recommends its use, especially for key studies^{7 8}. Related information on CRED guidance and a comparison between Klimisch and CRED is available in Moermond *et al.* 2016^{7 8 9} and Kase *et al.* 2016¹⁰. Does the SCHEER have comments on the CRED method, and does the SCHEER support its introduction as an option for assessing the reliability and relevance of ecotoxicological data? Does the SCHEER have any comment on how CRED compares with Klimisch in terms of suitability for the purpose?
6. As regards the derivation of the quality standard for the protection of human health from contaminants in seafood, two options are under consideration at the moment: either using the food standard, where it exists, as the basis for the quality standard; or using a toxicologically-based formula. These two options are described in more detail in the Guidance (in particular

⁵ This refinement is related to two parameters: the ratios of body weight to daily food intake as tabulated in Table R.10-12 in REACH Guidance document R.10 and the default factor 3 to account for caloric content and field metabolism as described in footnote 9 on page 45 of R.10. (Guidance Document R.10 available at: http://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf)

⁶ As mentioned in the TGD-EQS, the scientific basis for the methodology is explained in:

- Verbruggen E.M.J (2014). New method for the derivation of risk limits for secondary poisoning. RIVM Letter report 2014-0097. Bilthoven, The Netherlands, National Institute for Public Health and the Environment (RIVM): 50.

- Van Herwijnen R., Verbruggen, E.M.J (2015) Water quality standards for uranium Proposal for new standards according to the Water Framework Directive. RIVM Letter report 270006003/2014. Bilthoven, The Netherlands, National Institute for Public Health and the Environment (RIVM): 92.

⁷ For information, we consulted informally our expert contacts in the EFSA and in the ECHA. Our expert contacts in the ECHA commented that CRED extends rather than contradicts the Klimisch system. They underlined that any steps to make CRED more obligatory should account for consistency between (a) legislative frameworks and (b) assessment of ecotoxicity and toxicity data. They also advised that the scope of CRED should be extended to evaluating toxicity data as well as ecotoxicity data. Our expert contacts from EFSA noted they consider a consistent evaluation of reliability and relevance as the key issue, and do not recommend Klimisch or other scoring systems as the selection tool.

⁸ The CRED has also been used, with adaptations (such as weighing of the criteria), for ecotoxicity database management, e.g. by the Intelligence-led Assessment of Pharmaceuticals in the Environment (iPiE) project (<http://i-pie.org>) by the NORMAN association (in their ecotoxicity database, the NORMAN EMPODAT database) and by the JRC for sorting the ecotoxicity information available for the whole universe of substances, in order to inform the selection of new priority substances (this information will then need to be reviewed in details according to the final version of the TGD to derive the EQS for the substances identified as relevant).

⁹ Moermond C, Kase R, Korkaric M, Ågerstrand M (2016): CRED: Criteria for reporting and evaluating ecotoxicity data. Environmental Toxicology and Chemistry. DOI 10.1002/etc.3259. Available at: <http://onlinelibrary.wiley.com/doi/10.1002/etc.3259/full>

¹⁰ Kase R, Korkaric M, Werner I, Ågerstrand M (2016): Criteria for Reporting and Evaluating ecotoxicity Data (CRED): Comparison and perception of the Klimisch and CRED methods for evaluating reliability and relevance of ecotoxicity studies. Environmental Sciences Europe. 28:7; DOI: 10.1186/s12302-016-0073-x. Available at: <http://enveurope.springeropen.com/articles/10.1186/s12302-016-0073-x>

see page 90). The final decision will have to take into account policy considerations. The arguments for each of the two options will be presented to the Strategic Coordination Group under the Common Implementation Strategy for the WFD. Does the SCHEER have scientific comments on the suitability of using one or other of the two approaches preferentially under the WFD, bearing in mind that where there is no food standard, the intention would be to use the toxicologically-based formula, leading to standards based on different approaches?

7. As regards the derivation of the quality standard for the protection of human health from contaminants in seafood, the default allocation has been increased from 10 to 20% (see formula on page 92). The value of 10% had been chosen for consistency with the default value used under the WHO guidelines for drinking water, but this has been increased to 20%. Although the 20% (nor indeed the 10%) value isn't conservative for hydrophilic substances, it has been considered as conservative for hydrophobic or bioaccumulative substances - i.e. the substances for which a biota quality standard for the protection of human health is actually derived. (Other substances, and other protection goals, in particular the protection of pelagic organisms from direct toxicity, will in any case require a more stringent quality standard.) For substances for which the biota quality standard protecting human health is the strictest quality standard (and therefore the final EQS), the revised TGD-EQS now recommends taking a food basket approach whenever possible, or at least refining the allocation factor based on the characteristics of the substances. Does the SCHEER consider these changes appropriate?

1.3 Additional information

In 2010, the SCHER provided a series of comments on the draft guidance available at the time¹¹. They offered comments on that guidance but also highlighted a number of scientific issues that should be addressed in any further developments of the Guidance. The Working Group provided answers to these comments and indications about how they would be taken into account in the Guidance to be published in 2011. These answers were sent to the SCHEER in November 2010. They have now been updated to reflect the changes made in the current review (see table below).

In addition to the specific comments on the Guidance addressed in the table below, a number of other issues highlighted by the SCHER in 2010 require longer-term consideration and/or are policy rather than technical issues, such as the need to consider questions about the integration of different approaches for effects assessment, the possibility of a minimum data requirement for EQS setting and/or of proposing a preliminary EQS where the assessment factor is high, the mechanisms for enabling data-gathering during the EQS-setting process, and the relationship between good ecological status and the protection afforded by EQS compliance. DG Environment has worked on several of these issues and will give them further attention in the coming years.

As regards the relationship between good ecological and chemical status and the protection afforded by EQS compliance, it is important to note that the level of protection granted by the EQS should be consistent with the requirements of WFD Annex V Section 1.2.6, while the normative definitions of ecological status (including biological quality elements) are given in WFD Annex V 1.2.1-1.2.4. Ecological status aims at identifying effects, while EQSs aim at identifying a risk. For this reason, some margin can be expected between concentrations giving rise to demonstrable impacts and those posing a risk to flora and fauna. Under the 2016-2018 Work Programme for the WFD Common Implementation

¹¹ SCHER (Scientific Committee on Health and Environmental Risks), Opinion on Chemicals and the Water Framework Directive: Technical Guidance for Deriving Environmental Quality Standards, October 2010.
https://ec.europa.eu/health/sites/health/files/scientific_committees/environmental_risks/docs/scher_o_127.pdf

Strategy¹², further work will be undertaken to enhance our understanding of the links between ecological and chemical status.

As regards the uncertainty linked to the derivation of an EQS based on a limited ecotoxicity dataset, SCHER's concern has been taken into account in the selection of the Watch List substances: where the uncertainty related to the EQS was too high (assessment factor (AF) of 1000), the substance was not selected for inclusion in the final list but the need for additional ecotoxicological data was pointed out. (The Watch List mechanism was introduced by Directive 2013/39/EU amending Directive 2008/105/EC or EQS Directive, to gather monitoring data for substances that may pose a significant risk at EU level but for which monitoring data are insufficient.) In the current priority substances review, an assessment of uncertainty (reflected in the AF) is also provided as supporting information for the short-listed substances.

Finally, under the 2016-2018 Work Programme for the Common Implementation Strategy, possibilities of new approaches to chemical risk assessment and management will be explored, taking into account the risk coming from mixtures of pollutants present in the environment. This will imply looking at the use of alternative/emerging monitoring tools such as passive samplers or effect-based tools. This is part of the Commission's wider effort to better take into account the risk from chemicals mixtures, as outlined in the Commission Communication on mixtures¹³ and in the 7th EAP¹⁴. We will make sure that approaches are consistent across different legislative frameworks.

Comment from the SCHER	Updated response
<p>SCHER recommends including guidance on assessing dermal exposure of humans during swimming. Currently, nothing is stated on this potential exposure route. Its relevance should be considered on a case-by-case basis.</p>	<p>Although there are methods to take into account dermal exposure (e.g. Albering et al (1999), Environ. Health Persp. 107(1)), in our judgement this exposure route has a negligible contribution compared to e.g. the contribution from fish consumption (see same publication). Therefore this route hasn't been considered in the updated guidance. This has been mentioned explicitly on page 20 of the draft revised TGD.</p>
<p>In the WFD, industrial compounds as well as pesticides are subject to EQS. In the current document, the difference in the risk-assessment approach is only mentioned incidentally. There should be more explicit reference to the different approaches and the TGDs behind them. SCHER is of the view that there should be more attempts to integrate the different approaches in this TGD. Under the WFD, risk assessment methodologies in PPP-guidance and those for industrial chemicals come together. This should provide further stimulus for the harmonisation of risk assessment approaches in the EU.</p>	<p>The EQS Technical Guidance makes reference to other risk assessment regimes, including those covering industrial chemicals and pesticides (Section 2.8 of the guidance). We have referred to the underpinning technical guidance for these schemes (see in particular section 1.3 "Links to chemical risk assessment"). However, the more ambitious aim of integrating different approaches for effects assessment lies outside the agreed remit for EG-EQS. Also, there may be limitations to the harmonisation between risk and effects assessment schemes that can be achieved, as highlighted in the SCHER's response to Q3 and Q4 (see previous answer to SCHER in document enclosed).</p> <p>The on-going fitness check on chemical legislation will consider whether different pieces of legislation should be further harmonised, and the relevance of hazard versus risk-based approaches.</p>

¹² Available at : <https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp>

¹³ Communication from the Commission to the Council. The combination effects of chemicals, Chemical mixtures. Brussels, 31.5.2012, COM(2012) 252 final.

¹⁴ Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020. 'Living well, within the limits of our planet'. Text with EEA relevance. OJ L 354, 28.12.2013, p. 171-200 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013D1386>

<p>Although the conceptual difference [between a PNEC and an EQS] is presented in the introduction (2.3) and in other parts of the guidance document, there are still indications in the draft that consider the concept of an EQS and a PNEC as similar. Some of the text may also be interpreted to suggest a direct use of the PNECs from the RARs of existing substances. SCHER does not agree with this position.</p>	<p>The rapporteurs agree with this point and have expanded Section 1.3 "Links to chemical risk assessment" to more explicitly deal with the distinction between PNECs arising from a risk assessment and EQSs derived for use under the WFD.</p>
<p>SCHER agrees that there is now adequate guidance on data sources and on judging the reliability and relevance in the selection of data for use in the derivation of EQSs. Judging reliability is thoroughly addressed in Appendix 1. On relevance, SCHER welcomes the emphasis on "effects that can be linked to population sustainability". However, not all the endpoints listed contribute equally to population effects and some cautionary statement to that effect should be included in the guidance.</p>	<p>We have reviewed the endpoints cited in relation to population sustainability. The guidance identifies endpoints where effects at population level are unclear (section A1.3.3.14. Test endpoint). This has been a significant topic of debate in the derivation of EQSs for some substances.</p>
<p>Derivation of metal EQSs</p> <p>SCHER notes that the suggested implementation of the added risk approach used in the TGD for deriving EQS values (draft, 23-2-2010) and the ARA approach on which CSTEED commented is different. The tiered procedure for setting QS described in the TGD incorporates corrections for both bioavailability and metal background concentrations (Fig. 3.1.) As such, the ARA approach - with an alternative bioavailability correction - is suggested to be used in cases where the total risk approach (TRA) cannot be used. Considering (1) the integrated (TRA and ARA) tiered nature of the approach and (2) the guidance given to derive scientifically defensible background concentrations, SCHER supports the proposed procedure to derive EQSs for metals.</p>	<p>There has been a comprehensive review and redrafting of the guidance on setting EQSs for metals. This includes clearer guidance on the use of an added risk approach, especially when the EQS is based bioavailable concentrations of metals. We continue to question the value of an EQS when derivation leads to a level so low that it is within normal backgrounds. In practice, it can be very difficult to separate 'natural' backgrounds from those caused by man's activities (such as mining) which may have given rise to elevated concentrations over very long periods. Under such circumstances, we would expect the assessor to look at the levels of residual uncertainty (and refine background level estimations) and whether such an EQS is actually viable. This is an important consideration when implementing EQSs for metals. The CIS Work Programme includes a project to provide separate guidance on implementing metal EQSs.</p>
<p>Drinking water standard setting</p> <p>It should be mentioned that only a fraction of the ADI, TDI, or RfD is usually allocated to drinking water intake. The percentage of ADI, TDI, or RfD allocated to consumption of drinking water depends on other sources of exposure to the chemical under consideration.</p>	<p>We have added a sentence explaining that the default fraction of 20% (previously 10%) of the human toxicological threshold to allocate for drinking water intake may be adjusted. This should be done based on available data, e.g. food basket studies.</p>
<p>Section 5 clearly describes the options for deriving quality standards for sediment dwelling benthos (summarised in Fig 5-1). The uncertainties associated with the equilibrium partitioning approach are stated in 5.2.1.2. However, SCHER is of the opinion that these should be described up front at the start of 5.2 to give users a clear indication of problems associated with the partitioning approach and an indication that additional ecotoxicity testing is the favoured approach to reduce such uncertainties.</p>	<p>The uncertainties related to the equilibrium partitioning approach are mentioned at the beginning of section 5.2. We agree that additional ecotoxicity testing would be useful to reduce uncertainties if it results in a sufficiently robust dataset (in particular, not only short term test data). Under the WFD, regulators have no power to demand additional ecotoxicity data, so the TGD currently gives recommendations on how to use the existing data for EQS derivation.</p> <p>In particular, the TGD highlights the fact that in a risk assessment scenario, an indication of risk based on EqP would normally trigger further ecotoxicity testing, but that this is not always possible under EQS derivation, and that in that case the uncertainties linked with the</p>

	sediment QS should be highlighted for policymakers.
<p>SCHER agrees that (the guidance) addresses part of the concern expressed by CSTEE (uptake by ingestion was missed). However, water column concentrations in test vessels might still not reflect sediment exposures and hence result in inappropriate sediment quality standards. Further consideration should be given to this.</p>	<p>There appear to be two issues here.</p> <p>The first is relevant to the derivation of water column standards (as opposed to sediment standards). The guidance includes a section on translating a water column standard to a whole water value (including suspended particulate matter) because the monitoring schemes used in some MSs are based on this. We have tried to accommodate existing practice wherever possible.</p> <p>The second point refers to the level of protection afforded by sediment standards when these are based on equilibrium partitioning (as opposed to direct sediment toxicity testing), where ingestion of hydrophobic substances may be underestimated. The guidance currently recommends highlighting the high degree of uncertainty linked with the use of EqP (and also with the use of small toxicity dataset) in the factsheets, for the information of the policymakers.</p> <p>For information, work on sediment and trend monitoring is included as a specific activity in the 2016-2018 Work Programme of the WG Chemicals.</p>
<p>Assuming evidence of high toxicity for sediment dwelling organisms as a trigger criterion seems not suitable. Toxicity data for sediment dwelling organisms are scarce. Moreover, there is no scientific evidence for a different sensitivity between sediment dwelling and other aquatic organisms. The equilibrium partitioning method assumes a comparable sensitivity between these organisms. Taking “evidence of high toxicity for aquatic organisms” as a trigger would probably be more effective. A quantitative threshold should be established.</p>	<p>This couldn't be discussed in details in the EG-EQS because of the focus on, and significant modifications to other parts of the guidance. We will give it consideration in the following reviews of the guidance.</p>

2. Deadline: September 2017

The SCHEER approved this mandate at its Plenary meeting on 2 February 2017.