Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

Scientific Advice on

Guidance Document n°27: Technical Guidance for Deriving Environmental Quality Standards

The SCHEER adopted this document via written procedure on 15 September 2017

ABSTRACT

Following a request from the Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reviewed the Guidance Document No. 27: 'Technical Guidance for Deriving Environmental Quality Standards' prepared by a collaborative framework (the Common Implementation Strategy) for the Water Framework Directive.

The SCHEER concludes that the overall scientific quality of the proposed changes is an improvement to the earlier 2011 version. The SCHEER has a number of comments where more practical guidance can be provided or where the current state of knowledge is still insufficient or where it is not being fully utilised.

Keywords: Water Framework Directive, environmental quality standards

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All Declarations of Working Group members are available at the following webpage:
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1. SUMMARY

A first version of the "Guidance Document n°27: Technical Guidance for Deriving Environmental Quality Standards" was published in 2011. In 2010, the SCHER provided a series of comments on the draft of the Guidance. In 2016 a newly revised draft Guidance was presented that includes substantial changes in some sections. Moreover, some of the original comments from SCHER 2010 that had not been fully addressed in the 2011 version have been addressed in the new draft.

The SCHEER has been asked to comment on the new draft Guidance focussing on the specific sections that have had major changes and to evaluate if the questions of the SCHER (2010) have been adequately addressed.

The SCHEER concludes that the overall scientific quality of the proposed changes is an improvement on the earlier 2011 version. However, the SCHEER has a number of comments where more practical guidance can be provided or where the current state of knowledge is still insufficient.

Quality assessment of data
A new approach (CRED) is proposed as an alternative to the traditional Klimisch approach for assessing the quality of toxicological data. It is opinion of the SCHEER that the CRED method represents a suitable procedure for quality assessment of data and, to some extent, may represent an improvement in comparison to the Klimisch method. However, its applicability is strictly limited to aquatic ecotoxicity studies. For the development of EQSs, other types of studies may also be relevant (e.g. sediment toxicology, molecular properties) that are not covered by the CRED method. Some detailed suggestions for the improvement of the procedure are also proposed by the SCHEER.

Deriving EQSs for metals
A stepwise procedure is described based on the application of the Biotic Ligand Models (BLMs) for bioavailability correction that proposes the application of a generic EQS, as a conservative worst case, if the available information does not allow the application of the BLMs. It is the opinion of the SCHEER that the procedure is appropriate and the problem of bioavailability has been adequately addressed. However, the SCHEER is of the opinion that the issue of using variable background concentrations that may substantially affect the derivation of EQSs for metals has not been adequately addressed in the draft Guidance.

Revisions to biota quality standards for protecting predators (secondary poisoning)
The draft Guidance proposes a new approach to account for the energy content of the food items. The SCHEER welcomes the proposal of this innovative approach. However, it is opinion of the SCHEER that, in the current literature, many uncertainties and controversial issues still exist. For a better harmonisation of the procedures, the SCHEER recommends that ECHA and EFSA provide comments on the new methodology proposed.

Revisions to biota quality standards for protecting human health
The new draft Guidance proposes two approaches to deriving the standards for protecting human health from fish and seafood consumption by using a toxicologically-based formula. Based on the information provided in the draft Guidance, SCHEER prefers the second option which uses a toxicological-based formula as first tier with an allocation factor of 20% based on the default factor used by WHO for drinking water quality (WHO, 2011). However,

additional information is required to provide clarity on how the EU food limits are defined. For example, clarification is needed whether or not hotspots (due to background or historical contamination), where high levels of contaminants have been found in fish, have been included in the derivation of maximum limits for those contaminants. The SCHEER is also of the opinion that the default allocation factor of 20% should be used as a minimum level which gives a sufficiently conservative approach to protect humans from consuming fish and seafood.

Marine Quality Standards

The new draft Guidance does not propose any substantial changes for the derivation of marine quality standards. It is the opinion of the SCHEER that, considering the present status of knowledge on the sensitivity of marine organisms, there is insufficient information for modifying the procedure. However, considering the level of uncertainty surrounding the available scientific information, the SCHEER proposes that the procedure should be adopted as an *interim* approach, and revised in due course as the knowledge base on the topic improves.

This Opinion also provides answers to a series of comments made by SCHER in 2010 and these have been individually evaluated in Table 1.

2. MANDATE FROM THE EU COMMISSION SERVICES

2.1. Background

2.1.1 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 Chemicals[1] 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 DG ENV, 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.

2.1.2. Legislative context

The aforementioned Guidance document offers clear and detailed technical guidance for developing EQSs that will meet the requirements of the WFD. It was developed from 2007 onwards by a dedicated expert group (EG-EQS) under the Water Framework Directive Working Group E (now WG Chemicals), based on an earlier methodology, and presented to the SCHER in March 2010. The Opinion of the SCHER was taken into account to produce a final version of the Guidance, which was formally validated by the Water Directive 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 in light of recent scientific developments. The work of this expert group led to a revised version of the document, which was recently 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

[1] Former Working Group E.

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.

2.1.3. 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 water, 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 cases[2].

The Guidance focuses on the technical steps needed to develop an EQS that can be proposed 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.

2.1.4. 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 the 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 to include, where possible, the ones 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 relied on an extensive consultation process, where the recommendations from the expert group on EQS were presented and discussed with the dedicated technical sub-group for the review of the priority substances, other Commission Directorates General, such as DG GROW and DG SANTE, experts from Agencies such as the ECHA and the EFSA, and the WG Chemicals under the CIS. The comments received were considered and addressed and the current draft revised Guidance reflects the conclusions

[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.

reached at the WG Chemicals meetings.

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

Revision	Content 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)
Section 3.5 - Metals guidance	Guidance on the derivation of bioavailability-based EQSs for metals have been clarified and developed[3].
Section 4.4 - Revisions to 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 toward an approach that explicitly accounts for the energy content of prey items in the diet.
Section 4 .5- Revisions to biota quality standards for protecting human health	Changes 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 is to be decided at a strategic level (Strategic Coordination Group under the WFD CIS).
Marine quality standards	Inclusion of comments by marine experts
Technical revisions	Various technical corrections

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

2.2. 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 views 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, to suggest alternative approaches as necessary and to 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.

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 REACH[4]. 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 poisoning[5]. 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[6] [7] [8] and Kase *et al.* 2016[9]. 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

[4] 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)

[5] 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.

[6] For information, we consulted informally our expert contacts in the EFSA and the ECHA. Our expert contacts in 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.

[7] 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 the final version of the TGD to derive the EQS for the substances identified as relevant).

[8] 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

[9] 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

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 see page 90). The final decision will have to take policy considerations into account. 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?

2.3. Additional information

In 2010, the SCHER provided a series of comments on the draft Guidance available at the time[10]. They offered comments on that Guidance but also highlighted a number of scientific issues that should be addressed in any further updates 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

[10] 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

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 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 Strategy[11], further work will be undertaken to enhance the 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 mixtures and in the 7th EAP. The Commission also aims to make sure that approaches are consistent across different legislative frameworks.[12] [13]

[11] Available at : https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

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

[13] 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

3. SCIENTIFIC ADVICE

In 2010, the SCHER was requested by the European Commission to review the draft Guidance document ('Guidance Document n°27: Technical Guidance for Deriving Environmental Quality Standards' - 'Guidance')[14]. The SCHER provided its comments and highlighted a number of scientific issues that the SCHER felt should be addressed in developing the Guidance further. As a result, some suggestions from the SCHER were incorporated in the final version of the Guidance published in 2011.

In 2016 a newly revised draft Guidance has been proposed; this incorporates new sections and has also included some of the original comments from SCHER (2010). On the whole, most sections in the 2016 draft technical Guidance remain unchanged compared to the 2011 version but some sections have been significantly revised or are new (as indicated in the table of the mandate).

The SCHEER has been requested to comment on the specific sections of the draft Guidance that were subject to major changes, as indicated in the table in section 2.1.4 of the mandate or in the table of responses to the 2010 SCHER Opinion. These sections rather than the whole draft Guidance have been reviewed by the SCHEER to answer to the questions of the Terms of Reference.

The Scientific Advice provided by the SCHEER is structured as follows: the first part (section 3.1) provides detailed comments on the main changes included in the draft Guidance (as summarised in the table of the mandate); the second part (section 3.2) answers the specific questions posed to the SCHEER in the Terms of Reference.

3.1 Comments to the main changes included in the Guidance

3.1.1 Quality assessment of data - Section 2.6 of the Guidance (and related appendix 1)

The draft Guidance (Section 2.6 (and related appendix 1)) provides some discussion of the quality assessment of data and states that "Comprehensive and quality assessed data are key inputs to QS derivation" and that "A rigorous assessment of the data is needed to ensure that data are **reliable** and **relevant**." Reliability is then defined as referring to the method used to conduct the test (including all details) and relevance refers to the extent to which the test provides useful information. The current draft Guidance document proposes the use of the CRED approach rather than the Klimisch approach previously used to assess reliability and relevance. However, it also then states that the Klimisch approach can still be used. The CRED method "aims at strengthening consistency and transparency of hazard and risk assessment of chemicals by providing criteria and guidance for reliability and relevance evaluation of aquatic ecotoxicity studies" (Kase et al., 2016).

[14] 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

In the original Klimisch paper (1997), the authors proposed three criteria in their paper namely "reliability, relevance and adequacy", and presented a systematic approach to their assessment.

"Reliability—evaluating the inherent quality of a test report or publication relating to preferably standardized methodology and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings."

"**Relevance**—covering the extent to which data and tests are appropriate for a particular hazard identification or risk characterization."

"Adequacy—defining the usefulness of data for risk assessment purposes. When there is more than one set of data for each effect, the greatest weight is attached to the most reliable and relevant."

Reliability is then further sub-categorised into 4 categories: reliable without restrictions (R1), reliable with restrictions (R2), not reliable (R3), and not assignable (R4). Relevance and adequacy are not further defined, but for relevance three questions are suggested to assist with the evaluation. The evaluations require expert judgement but criticisms of the approach relate to the subjective element of assessment and to observed inconsistencies amongst assessors ("found to be unspecific, to lack essential criteria and guidance for both reliability and relevance evaluations, and to leave considerable room for interpretation").

The CRED approach offers an extension to Klimisch but is specifically developed for aquatic eco-toxicity studies, where Klimisch is more general.

The CRED system identifies 4 reliability categories which are the same as the Klimisch categories and in this way, past assessments which have used Klimisch could still be used. The CRED evaluation method identifies 4 relevance categories: relevant without restrictions (C1), relevant with restrictions (C2), not relevant (C3), and not assignable (C4). CRED does not address adequacy explicitly. A series of reporting recommendations are also provided, including 50 specific criteria divided into 6 categories: general information, test design, test substance, test organism, exposure conditions, and statistical design and biological response. The CRED system provides an excel spreadsheet, with three sections, reliability, relevance and reporting. Assessors are asked to address each of the 50 criterion as fulfilled, not fulfilled, not applicable, and not reported and then to assess the specific overall reliability and relevance category.

The CRED authors add a comment - "Determining reliability is not a box checking exercise, where the number of passed or failed criteria is determined to obtain a reliability category. Any method used to assess the reliability and relevance of a study should be based on sound scientific argumentation, and expert judgment is essential."

In this sense, since there is no apparent or quantitative connection between the reliability and relevance categories and the 50 specific reporting criteria, there is no avoidance of expert (and/or subjective) judgement, but the checklist approach ensures that at the very least every expert must consider and form an impression based on the same set of criteria.

Table 1 below, which is taken from Kase *et al.* 2016, summarises the differences between the two approaches:

Table 1: General characteristics of the Klimisch and the final CRED evaluation methods

Characteristics	Klimisch	CRED
Data type	Toxicity and ecotoxicity	Aquatic ecotoxicity
Number of reliability criteria	12-14 (ecotoxicity)	Evaluating 20 (reporting 50)
Number of relevance criteria	0	13
Number of OECD reporting criteria included	14 (of 37)	37 (of 37)
Additional guidance	No	Yes
How to summarize the evaluation	Qualitative for reliability	Qualitative for reliability and relevance

The CRED methodology has been developed specifically to evaluate aquatic eco-toxicological data in accordance with specific criteria, but only one criterion (Reliability #15) refers to the analytical method applied, in a generic sense. The SCHEER considers that more analytical details should be evaluated, examples include: Has the analysis been performed by an established standard method? (e.g. recommended by the OECD)? Is the stated recovery sufficiently high? (this should be stated). Has the linear dynamic range been established? Is the measured value within the linear dynamic range? Are product interferences absent?

(Assessment of) Biodegradation of the test compounds does not seem to be one of the criteria; there is a Relevance criterion (#11: In case of a formulation, other mixture, salts or transformation products: Is the substance tested representative and relevant for the substance being assessed?) and one very generic criterion for Reporting (#3b: Physico-chemical characteristics that may influence the behaviour of the compound during the study data (e.g. solubility, volatility, stability hydrolysis, photolysis, degradation), solubility, log K_{OW}, degradability, adsorption). The SCHEER is of the opinion that biodegradation of the test compound can seriously influence test results and could be incorporated in more detail.

The SCHEER would also suggest that additional points should be evaluated under Reliability, such as: was equilibrium achieved in the test set up? Is the accuracy being determined for each measuring point? Does the result of the measurement significantly exceed the detection limit of the analytical apparatus? Exposure conditions should also be added: Were the organisms cultivated by a reported standard procedure? Are the test organisms exposed to uncontaminated water before the experiment for at least 48 h? Is the water concentration not exhausted during the experiment? If relevant, is the used co-solvent non-toxic and non-degradable? Is the experiment being carried out with a single substance?

The SCHEER suggests that CRED provides an improved level of detail in terms of criteria to be considered by the assessor that did not appear with Klimisch. In general the CRED system provides an extension and substantial improvement of the methodologies to evaluate the reliability of reported aquatic ecotoxicity studies. Both Klimisch and CRED require subjective judgement, but the CRED approach provides an extensive checklist. One concern might be that with an excel spreadsheet; there might indeed be a tendency to use a 'box ticking' count to evaluate the reliability and relevance of a study. The Kase *et al.* study (2016) does however appear to support that there is more consistency in the assessment results using the CRED approach. "Our results show that the CRED evaluation method is a suitable and practical replacement for the Klimisch method. It gives more detailed guidance for both reliability and relevance evaluations, which contributed to a greater confidence expressed by the ring test participants regarding their results. (Kase *et al.* 2016)".

Appendix 1 of the draft Guidance offers the specific directions that all retrieved literature is read and evaluated with respect to its relevance and reliability. The assessment may be performed according to the scheme developed by Klimisch *et al.* (1997) or CRED (Moermond *et al.*, 2016 and Kase *et al.* 2016). "Either method may be used to quality-assess data to be used in EQS derivation, but CRED is recommended for: (a) potentially critical or contentious studies and (b) where studies are borderline reliable with restrictions, or regarded as 'not reliable'. When using CRED in such cases, it is important to use the CRED template (Appendix 4) for recording judgements of reliability and relevance. This helps promote transparency in the conclusions about the reliability and relevance and in general about the defensibility of a particular study".

The SCHEER is of the opinion that the CRED approach provides some improvements to the Klimisch method, but that the criteria require to be extended and currently relate to too narrow a suite of parameter data (i.e. are applicable to aquatic ecotoxicological data only). The SCHEER is of the opinion that for EQS, not only aquatic ecotoxicological parameters but also parameters, related to sediment toxicology and those that are key to PEC derivations, should be evaluated in a similar systematic manner such as described in (Laane *et al.,* 2012).

3.1.2 Deriving EQSs for metals - Section 3.5 of the Guidance

Metals have several specific characteristics that made ecological risk assessment and definition of EQS completely different in comparison with organic contaminants and, in particular, with organic xenobiotics:

- they are natural elements naturally present (in some cases ubiquitous) in the environment with background concentrations extremely variable; the levels of background concentrations may substantially affect the responses of natural biological communities to metal increase due to anthropogenic emissions;
- some of them are essential micronutrients; therefore, small concentrations of these metals are required for the survival of living organisms;
- they may be present in the environment in different chemical forms, depending on physical and chemical environmental conditions; as a consequence, environmental conditions strongly affect the chemical form of metals, their bioavailability and, as a consequence, their toxic effect.

In the frame of Council Regulation (EEC) 793/93 of 23 March 1993 on *Evaluation and Control of the Risks of Existing Substances,* a number of Opinions on Risk Assessment Reports (RAR) for metals were developed by the SCHER in 2007 and 2009 (SCHER, 2007; SCHER, 2009a, b, c). All the opinions highlighted the need for addressing these issues in the ERA.

The draft Guidance highlights that different EQSs should be developed, depending upon environmental conditions. However, complete information for the reliable estimation of bioavailability is not always available. Therefore, a decision tree scheme and a stepwise approach are proposed.

Step 1 is the derivation of a generic EQS.

If suitable models for estimating bioavailability cannot be applied, the generic EQS must be used. In principle, the SCHEER considers that the approach is adequate, assuming that the

generic EQS represents a default worst case to be applied in case of lack of information needed for a refined assessment. However, the procedure for the derivation of the generic EQS (section 3.5.3.1) should further clarified and the role of the generic EQS as worst case should be explicitly mentioned.

In particular, it should be further clarified if the generic EQS is derived on the basis of the total or dissolved metal. If the generic EQS represents the worst case, it should be based on the total metal, considering that:

- the estimation of the dissolved metal requires some information that is not always available;
- the dissolved part of a metal is, in many cases, also bioavailable.

This may create some confusion and overlap between the generic EQS and the bioavailability-corrected EQS.

Finally, the environmental metal concentrations to be compared with a generic EQS should be clarified. Considering that it should be a worst-case approach, concentrations must be totally metal.

Step 2 is the selection of a model for estimating bioavailability. The correction for bioavailability allows more realistic EQSs to be derived. However, one must be aware that the corrected EQSs are less conservative than the generic ones. Therefore the approaches used must be based on sound and reliable data and procedures.

Three options are proposed: i) speciation models, ii) empirical regression models which relate water chemistry to metal toxicity, iii) Biotic Ligand Models (BLMs). The three options are not equivalent and not comparable. The first is strictly chemically-based, not related to particular species or taxonomic groups. The second is limited to some specific relationship developed for particular conditions. The draft Guidance does not report any reference for this approach. The SCHEER considers that the BLM approach is the most suitable and scientifically supported and documented. Proposing three different options may lead to different criteria for the derivation of EQSs. Therefore, in order to ensure uniformity and comparability, the SCHEER concludes that it would be better to propose only one model for the normalisation of data as a function of environmental parameters. In this case, the BLM is to be preferred.

This also seems to be the approach followed in **Step 3** (suitability of models across species) that mainly refers to BLM.

Step 4 is the normalisation of data as a function of water conditions. In this case too, the normalisation procedure is well described in the literature for BLM.

Finally, **Step 5** is the derivation of a bioavailability corrected EQS. The SCHEER judges the procedure to be adequate.

Referring to the bioavailability correction for salt water (section 3.5.4.1), the main positions of the draft Guidance are:

- for high salinity waters a correction is relevant only for DOC content;

- for transitional waters with intermediate salinity, a correction for inorganic composition should be considered; however, present knowledge (e.g. BLM for saline water) is relatively poor.

The SCHEER agrees with the statements on data requirements (section 3.5.5).

Unlike the issue of bioavailability which is addressed adequately in the draft Guidance, the problem of the variability of background concentrations is mentioned in some chapters but its possible effects on the definition of EQS are not addressed in detail.

In section 3.5.4 the possible effects of high background concentrations are mentioned but it is also affirmed that "*These considerations lie beyond the scope of this Guidance*". This statement is surprising.

The SCHEER states that the effect of variable background concentrations on the definition of EQS for metals is a relevant issue and should be better addressed in the draft Guidance. The influence of background was more specifically addressed in the old version of the Guidance. If it is the intention of DG Environment to address the issue in another Guidance document, the SCHEER welcomes this intention.

Finally, a number of formal and editorial amendments are needed to improve section 3.5:

- The numbers of the tables and the figures do not correspond between text and captions.
- Most papers quoted in the section 3.5 are not reported in the Reference Section.
- Many statements need to be supported by adequate references. For example: first paragraph section 3.5.1; last paragraph section 3.5.1; regression models at page 60.

3.1.3 Revisions to biota quality standards for protecting predators (secondary poisoning) - Section 4.4 of the Guidance

One of the major changes proposed in the new draft Guidance is the revision of the methodology for protecting predators. The rationale behind the proposed approach is documented in a report from the Dutch RIVM (Verbruggen, 2014). In the previous Guidance document (EC 2011) two other methods were described. One is the diet-based approach (also used in the EU TGD (EC, 2003) and REACH guidance (ECHA, 2010)) and the other is a dose-based approach. The approach described in the new draft Guidance (2016) is based on the same principles as the previous Guidance but accounts for the energy content of the food items and, as a result, default assessment factors to convert from laboratory diet to natural diet in the fields are avoided (Verbruggen, 2014).

Regarding the latest TG document, the SCHEER concludes that the major change with respect to secondary poisoning is that instead of using (i) concentrations in the diet (TGD-EC, 2003) of the animal and accounting for different food intake rates by applying an assessment factor of 30 (10x3, 10 for interspecies differences and 3 for differences in caloric content between lab food and prey species in the field) or (ii) daily doses (as proposed by EFSA), the energy content of the food is accounted for. In other words, the derivation is no longer based on the concentration of the substance in the food, but on the amount of the substance per unit of energy that is consumed per day. Verbruggen (2014) claims that by using this method "more realistic limits for substances will be set".

Verbruggen (2014) concludes that "The only necessary correction factor is for differences in caloric content between dietary items in the field and the diets provided in the lab studies" (Ch. 2.7). Hence, normalisation to calorific content would render use of conversion factors

no longer needed". The SCHEER concurs with the conclusion that differences in calorific content can be solved by the normalisation proposed. However some of the assumptions should have been discussed in more detail:

(1) The approach proposed by Verbruggen (2014) is based on the assumption that the food intake of predators is entirely governed by their energy demand. As Crocker *et al.* (2002) have pointed out, animals may feed not only to fulfil their energy requirements but also to satisfy their need for protein (e.g. for nestlings) or minerals.

(2) Normalisation to calorific content requires that data on energy content, moisture content and lipid content are available for different food categories. Such data have been calculated for four categories of food items (bivalves, fish, vertebrates and earthworms; Verbruggen, (2014), and compared to generic values reported by RIVM (Smit, 2005) and EFSA (EFSA, 2009). A good agreement was observed between the calculated and generic values. The view of the SCHEER is that large differences are likely to exist between energy contents of items within each food category (in particular for fish), so that a large uncertainty may be introduced by using the proposed calculated values. Moreover, the validation/comparison given is partly based on food items used for human consumption (EFSA data): the relevance for wildlife has not been discussed.

(3) One possible criticism of the new methodology is that animals living in the wild may not consume energy amounts per day that are similar to the amounts consumed by laboratory test animals. As Verbruggen (2014) argues (Ch 2.6), higher metabolic rates and food intakes occur in the field, leading to exposure to higher doses. However, Verbruggen continues, "biotransformation and excretion may also be increased", and "If driven by partitioning, enhanced metabolic rate will influence the time for the substance to reach steady state, but not its final body residue". The SCHEER observed that no reference is given for the assumption of covarying biotransformation and excretion rates, and that the conclusion that a final body residue will not change as a result of different food intakes is not supported by literature data yet.

(4) According to Verbruggen (2014) a higher food intake rate due to reduced assimilation efficiency of food (the true energy value of a food is given by the assimilation efficiency, i.e. the energy content of the food minus the energy value of the faeces) in the field situation will not result in a higher uptake of substances. This assumption is based on the notion that "substances cannot move from lipids enclosed in non-digestible food particles to the intestinal wall during their residence time in the gut". Further, it is argued that a lower assimilation efficiency of food is balanced by at least equally lower assimilation efficiency of substances from that food (Hendriks *et al.* 2001). Verbruggen concludes "Hence higher food intake due to lower assimilation efficiency will not result in higher uptake of substances".

The SCHEER is of the opinion that this may not hold for substances bound to proteins rather than lipids, such as some heavy metals (e.g. cadmium) and polar organics (e.g., perfluorinated alkylated substances). Crocker *et al.* (2002) have summarized and presented assimilation efficiencies for various avian and mammalian species and different food types. While the SCHEER realizes that there are probably too limited data on substance-specific assimilation efficiencies (Jongbloed *et al.* 1994), the SCHEER is of the opinion that not accounting at all for assimilation efficiencies is an unnecessary simplification and suggests applying assimilation efficiencies where possible.

(5) Two main factors determine daily energy expenditure of animals: body size and endothermy vs. exothermy. The RIVM report considers mammals and birds and does not take into account exothermic species. Exothermic species, however, consume much less energy than endothermic species (Speakman, 1997), and therefore the SCHEER states that it can be assumed that protection goals for endothermic species will also protect exothermic species.

(6) Recently, Burkhard *et al.* (ES&T 47, 2013), have proposed a normalisation of tissue residues to protein content when dealing with trophic magnification factors. The SCHEER would welcome comments from DG-ENV on such proposals in the light of the energy content normalisation proposed for deriving EQS for secondary poisoning.

The SCHEER is in favour of new methodologies being developed for secondary poisoning such as the proposal to normalise contaminant concentrations to the calorific content of the food. However, the scientific evidence for the new methodology is very sparse compared with the documentation that is available for the diet-or dose-based methodologies that are being used by EFSA and ECHA in current risk assessments. The SCHEER concludes that uncertainties that may be introduced with the new methodology cannot yet properly be evaluated due to a lack of scientific information. Because harmonisation of procedures would enhance the transparency of risk assessment methodologies in the EU, the SCHEER would welcome comments from both ECHA and EFSA on the new methodology proposed.

3.1.4 Revisions to biota quality standards for protecting human health - Section 4.5 of the Guidance

The draft Guidance proposes two conceptually different options (Option A and Option B) for the definition of EQs for protecting human health as follows:

Option A uses European Legal Food Limits established for contaminants in foodstuffs according to Commission Regulation (EC) 1881/2006 as a first tier for setting the $QS_{biota,\ hh\ food}$ and a toxicological assessment only if such value is not available. For example: The EQS dossier for PAHs mentions that "No internationally recognised approach exists for determining the uptake of contaminants from fishery products by humans (...). Therefore, when standards have been derived through legislation [e.g. Reg. 1881/2006/EC], the $QS_{biota,\ hh\ food}$ should refer to the maximum allowable concentration in $\mu g.kg^{-1}$ wet weight in the specific tissue or sampling material." (EC, 2011).

Option A proposes that no changes be introduced into the procedure, which has the advantage of allowing existing methodology to be applied to derive EQS, so no leverage is needed and there will be consistency among values derived by previous dossiers.

The approach adopted by the EU Legal Food Limit (i.e. MLs) is based on monitoring data collected from various sources assuming a certain quality standard, if possible refined by food basket consumption data. In Option A, some toxicological analysis is performed as second tier by comparing with toxicological reference values (TDI, ADI or other), if available, but no toxicologically-based formula is used to directly calculate the $QS_{biota,\ hh\ food}$. Toxicological considerations are used as background information; however the draft Guidance does not always provide sufficient information for the SCHEER to be able to determine how the protective levels to humans have been estimated (section 7.3 of EQS dossiers).

Option B uses a toxicologically-based formula as first tier to derive the $QS_{biota,\ hh\ food}$ (expressed as $\mu g \cdot kg^{-1}$biota) from the Toxicological Level (TL) hh (expressed as $\mu g \cdot kg^{-1} bw \cdot d^{-1}$) with an allocation factor of 20% based on the default allocation factor from the WHO guidelines for drinking water quality (WHO, 2011). Refinement of the 20% default value is possible if the $QS_{biota,\ hh\ food}$ calculated using this value is lower than the legal food limit (if one is available). In this case, the $QS_{biota,\ hh\ food}$ should use actual data for human

fish consumption and if it is confirmed that fish has a higher uptake level, the $QS_{biota,\ hh\ food}$ can be calculated using a higher allocation factor than the default 20% however it should not exceed 60%. In any case, it is advised to use the default allocation factor of 20% as a minimum level which gives a sufficiently conservative approach in terms of human protection from consuming fish and seafood. Such a food basket approach is in line with the approaches of WHO (2011) and EFSA (2010, 2011).

On one hand, the SCHEER does not consider the 20% allocation factor drawn from the WHO drinking water quality guidelines to be scientifically based and does not believe that it represents the fish contribution to the overall food consumption. On the other hand, the SCHEER notes that default values are frequently used in the chemical risk assessment methodology due to lack of data, being the only pragmatic way to make such assessments. SCHEER would welcome the use of a more substantiated allocation factor when additional information becomes available and when the draft Guidance is updated again in due course.

Option B also uses a default value for fish consumption of 0.00163 kg fish/kg bodyweight/day that corresponds to the 95th percentile of the daily intake of fish and seafood by adults from the general public in Europe, weighted according to the number of adult inhabitants in each country, retrieved from the EFSA database (0.114 kg d^{-1}). As this value is traceable and very similar to the current default value of 0.115 kg d^{-1} for daily fish consumption by humans used under REACH, for the sake of harmonisation and unless there are food basket data to refine this value, the SCHEER also supports the use of 0.115 kg/day for the calculation of $QS_{biota,\ hh\ food}$ under the WFD.

The $QS_{biota,\ hh\ food}$ is therefore calculated:

$QS_{biota,\ hh\ food}$= 0.2 TL hh/0.00164 based on available reference values (TDI, ADI, etc.)

The available EU Legal Food Limit (Maximum Levels) is used in this Option as second tier or as complementary source.

Additional remarks:

1. The SCHEER considers that the EU Food Limit as Maximum Level (ML) represents a level that is technically achievable and reflects the prevalence of compounds in food coming from residues/contaminants rather than a safe value from a human-toxicological point of view.
2. The SCHEER also considers that the terms used in the draft Guidance "EU Legal Food Limit", "EU Food Limit", "Food Limit", "Food Standard" are inconsistently used in the text (section 4.5); the document could benefit from presenting this information more clearly and putting this in context with the applicable Regulation(s). The document should reference more clearly the type of Food Limit it is actually referring (i.e. MLs) and how this limit is calculated (i.e. a rationale for its derivation).

Based on the information provided in the draft Guidance, the SCHEER prefers Option B. However, additional information is required to ensure clarity on how the EU food limits are defined. For example, where high levels of contaminants have been found in fish, clarification is needed whether or not hotspots (due to background or historical contamination) have been included in the derivation of maximum limits for those contaminants.

3.1.5 Marine Quality Standards

For the derivation of marine quality standards, there are no substantial differences between the new draft and the old version of the Guidance.
It is opinion of the SCHEER that, in the recent literature, there are not sufficient evidence for changing the position on the differences between sensitivities of freshwater and marine organisms. Because of the much higher biodiversity in marine ecosystems, an additional assessment factor of 10 is currently being used. There is no information available in the literature that higher biodiversity will also correspond to more sensitive taxa, therefore, the scientific basis for this additional assessment factor is weak.
Suitable toxicity data on marine organism are sometimes scarce and in many cases, the only possibility for deriving marine QS is using data on freshwater organisms. This is why in the proposed procedure the derivation of marine QS is more complex than for freshwater (see table 4 for the pelagic community and table 13 for sediments). In the absence of specific data, the uncertainty is covered by the increase of the AF. In particular, if only acute data on three freshwater organisms are available, an additional factor of 10 is used, reaching a total AF of 10000.
The SCHEER accepts the approach proposed in the draft Guidance for the time being. This does not necessarily mean that the SCHEER agrees with the absolute value of the assessment factor, since there is high uncertainty due to limited scientific information. Therefore, the SCHEER proposes that the procedure should be adopted as an *interim* approach. A substantial improvement in the knowledge on the topic should lead to a revision of the procedure in due course.

3.2 Answers to the questions of the terms of reference

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.

The SCHEER concludes that the overall scientific quality of the proposed changes represents an improvement to the 2011 version. However, the SCHEER has provided in section 3.1 a number of comments where more practical guidance can be provided or where the current state of knowledge is still insufficient (e.g. energy normalisation for secondary poisoning) or where it is not fully utilised (e.g. metals).

2. Elaborate on its reasons for considering any aspect of the changes inappropriate, to suggest alternative approaches as necessary and to 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).

Some sections of the draft Guidance have been significantly revised or are new (as indicated in the table of the mandate). The SCHEER has been requested to comment on the specific sections of the draft Guidance that were subject to the main changes in the new version and not tasked with commenting on the whole document.
Where the SCHEER considered changes inappropriate, the reasons have been explained in section 3.1. The SCHEER has provided suggestions about aspects that were considered missing.

3. Does the SCHEER agree that the Opinion offered by SCHER in 2010 has been adequately dealt within the Guidance? The Working Group Chemicals 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).

Comment from the SCHER	Updated response	Answers of the SCHEER
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.	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.	The SCHEER agrees that the dermal exposure route is negligible in the majority of cases, however, there are examples where this may not be the case As raised in earlier comment, we recommend to evaluate on a case-by-case basis and to provide guidance on how to consider dermal exposure where relevant.
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.	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).	The SCHEER acknowledges that the harmonisation of risk assessment approaches in the EU is not task for the Technical Guidance. Nevertheless, in a document where EQS (i.e. levels of no risk for the environment) are established for different types of substances, mentioning and explaining the reasons in support of the differences of various approaches for assessing risk in different EU regulations would be useful. It is opinion of the SCHEER that the changes made in section 1.3 (see next point) go, at least partly, in this direction.
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	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.	It is the opinion of the SCHEER that Section 1.3 of the new draft Guidance appropriately clarifies the issue of comparison (analogies and differences) between an EQS and a PNEC.

use of the PNECs from the RARs of existing substances. SCHER does not agree with this position.		
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 to be included in the Guidance.	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.	The text on data sources, in the main text as well as in Appendix 1, has not been modified in the new version of the Guidance. The SCHEER agrees with the concern expressed in the comment from the SCHER that derives from a frequent use, in ecotoxicological literature, of endpoints for which ecological relevance is controversial or has not been proven. In section A1.3.3.14. two lists of endpoints have been provided. The first list suggests endpoints that are equally relevant at population level which is not actually the case. The SCHEER welcomes differentiations in relevance from the authors. The second list refers to those endpoints "*where effects at population level are unclear*". The SCHEER agrees that these endpoints are less relevant for the population.
Derivation of metal EQSs 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 CSTEE 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.	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 and the CIS Work Programme includes a project to provide guidance on this topic.	The issue of EQS for metals has been extensively commented on in section 3.2 of this Opinion.
Drinking water standard setting	We have added a sentence	The SCHEER is of the opinion that

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.	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.	there is no scientific basis to use a default value as an analogy to the drinking water intake. Therefore, the SCHEER recommends that, where possible, this value is refined based on human food consumption data (e.g. food basket studies or EFSA data base).
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.	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. 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 sediment QS should be highlighted for policymakers.	The text of Section 5 has not been modified in the new version of the Guidance, therefore, the comment from the SCHER is still valid. The SCHEER acknowledges that the uncertainties related to the equilibrium partitioning approach are mentioned in section 5.2.1.2. (not at the beginning of section 5.2.). The doubts arise from the first paragraphs of section 5.2 and from Figure 10 (formerly 5.1) where EqP appears at the same hierarchical level of sediment ecotoxicity data, giving the impression that they have comparable relevance. It is the opinion of the SCHEER that it should be clear and explicitly mentioned that EqP is a necessary choice only in case of absence of suitable and reliable ecotoxicity data on sediment organisms. The SCHEER therefore suggests revising Figure 10 of the draft Guidance in such a way that in a first tier the availability of sediment toxicological data should be evaluated and only if not available or not suitable, the EqP approach should be applied.
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.	There appears to be two issues here. 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. The second point refers to the level of protection afforded by sediment standards when these	It is opinion of the SCHEER that the first issue has been adequately addressed. The need for a more explicit mention on the uncertainties of the EqP approach has been highlighted above.

	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.	
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.	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.	The SCHEER acknowledges the response and the intention to consider the issue. The SCHEER looks forward to provide its opinion on the next version of the Guidance.

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 REACH[15]. 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 poisoning[16]. Does SCHEER have comments on this refinement of the methodology? Does SCHEER support its inclusion in the Guidance?

[15] 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)

[16] 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.

The SCHEER agrees with the conclusion that differences in calorific content can be solved by the normalisation proposed and that this could be a substantial improvement in deriving EQSs. As the methodology used to derive the standards differs from the procedures used by ECHA and EFSA, the SCHEER would suggest exchanging views with them on the methodology used. Moreover, the scientific basis for a normalisation of the caloric content should be strengthened. For details on this issue, see section 3.1.3.

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 are available in Moermond *et al.* 2016[17] [18] [19] and Kase *et al.* 2016[20]. 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?

The SCHEER concludes that the CRED approach provides some improvements of the Klimisch method; but that the criteria require to be extended and currently relate to too narrow a suite of parameter data (i.e. are applicable to aquatic ecotoxicological data only). The SCHEER is of the opinion that for EQS, not only aquatic ecotoxicological parameters but also parameters, related to sediment and human toxicology and those that are key to PEC derivations, should be evaluated in a similar systematic manner. For details on this issue, see section 3.1.1.

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 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

[17] For information, experts in 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. Experts 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.

[18] 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 the final version of the TGD to derive the EQS for the substances identified as relevant).

[19] 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

[20] 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

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?

The SCHEER is of the opinion that option B should be adopted so that toxicological assessments are considered in the first instance and consistently as far as possible, and that food limits are used only in the absence of data. The SCHEER would appreciate clearer definitions of terms such as EU food limits and how these are derived. Additional information should be provided on the approach to be followed if the toxicological value exceeds food limit. For details on this issue, see section 3.1.4.

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?

The SCHEER considers that there is no scientific basis to use a default value as an analogy to the drinking water intake. Therefore, the SCHEER recommends that, where possible, this value is refined based on human food consumption data. For details on this issue, see section 3.1.4.

4. MINORITY OPINIONS

None.

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6. LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
AF	Assessment Factor
ARA	Added Risk Assessment
BLM	Biotic Ligand Model
CIS	Common Implementation Strategy
CRED	Criteria for Reporting and Evaluating Ecotoxicity Data
CSTEE	Scientific Committee on Toxicity Ecotoxicity and Environment
DOC	Dissolved Organic Carbon
EAP	Environment Action Programme
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EQS	Environmental Quality Standard
ERA	Ecological Risk Assessment
JRC	Joint Research Centre
ML	Maximum Limit
QS	Quality Standard
RAR	Risk Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (Netherlands National Institute for Public Health and the Environment)
SCHER	Scientific Committee on Health and Environmental Risks
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TL	Toxicological Level
WFD	Water Framework Directive
WHO	World Health Organisation