



Scientific Committee on Health and Environmental Risks

SCHER

Opinion on the Chemicals and the Water Framework Directive:
Technical Guidance for Deriving Environmental Quality Standards

SCHER adopted this opinion by written procedure in October 2010

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

Scientific Committee members

Ursula Ackermann-Liebrich, Herman Autrup, Denis Bard, Peter Calow, Stella Canna Michaelidou, John Davison, Wolfgang Dekant, Pim de Voogt, Arielle Gard, Helmut Greim, Ari Hirvonen, Colin Janssen, Jan Linders, Borut Peterlin, Jose Tarazona, Emanuela Testai, Marco Vighi

Contact:

European Commission
DG Health & Consumers
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

© European Union, 2010

ISSN 1831-4775

doi:10.2772/33384

ISBN 978-92-79-12762-5

ND-AR-09-009-EN-N

The opinions of the Scientific Committees present the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The opinions are published by the European Commission in their original language only.

http://ec.europa.eu/health/scientific_committees/environmental_risks/index_en.htm

ACKNOWLEDGMENTS

Prof. Herman Autrup
Prof. Peter Calow
Prof. Wolfgang Dekant (*Chair and Rapporteur*)
Prof. Colin Janssen
Prof. Jan Linders
Prof. Jose Tarazona
Prof. Marco Vighi

Keywords: SCHER, scientific opinion, Water Framework Directive, Environmental Quality Standards

Opinion to be cited as:

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

TABLE OF CONTENTS

ACKNOWLEDGMENTS.....	3
1. BACKGROUND.....	5
2. TERMS OF REFERENCE	5
3. OPINION	7
3.1. Question 1.....	7
3.2. Question 2.....	7
3.3. Question 3.....	8
3.4. Question 4.....	8
3.5. Question 5.....	17
3.6. Question 6.....	17
3.7. Question 7.....	17
3.8. Question 8.....	21
3.9. Question 9.....	22
3.10. Additional comments on the document by SCHER.....	22
4. LIST OF ABBREVIATIONS	25
5. REFERENCES	26

1. BACKGROUND

Article 16 of the Water Framework Directive (WFD, 2000/60/EC) requires the Commission to identify priority substances among those presenting significant risk to or via the aquatic environment, and to set EU Environmental Quality Standards (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 WFD Article 16 requires the Commission to review periodically the list of priority substances. Article 8 of the EQSD requires the Commission to finalise its next review by January 2011, accompanying its conclusion, where appropriate, with proposals to identify new priority substances and to set EQSs for them in water, sediment and/or biota.

The Commission has been working on the above-mentioned review since 2006, with the support of the Working Group E on Priority Substances under the Water Framework Directive Common Implementation Strategy. The Working Group E is chaired by the Commission 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 Technical Guidance has been developed 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. The Commission intends to use the Technical Guidance to derive the EQSs for newly identified priority substances and to review the EQSs for existing substances.

2. TERMS OF REFERENCE

The Commission is referring the draft Technical Guidance to SCHER for a response to the questions below, focussing on the scientific aspects. The SCHER is not asked for a comprehensive assessment of the draft document.

The SCHER is invited to review the Technical Guidance for derivation of Environmental Quality Standards (EQSs) and to address the following **general questions**:

1. The SCHER is invited to give its opinion on the overall scientific quality of the guidance and, considering that the purpose of the document is to provide practical guidance for practitioners in deriving EQSs, whether it reflects properly the current state of technical and scientific knowledge.
2. Given the remit to EG-EQS to provide detailed practical guidance to practitioners, does the SCHER consider the contents of the guidance to be fit for purpose? We are aware that the guidance contains only a short section (section 7 on pages 147-149) on calculating quality standards for substances occurring in mixtures. The Directorate-general for the Environment is separately requesting an opinion from the SCHER on the toxicity and assessment of mixtures of chemicals, but this may not be available for several months. Therefore, the SCHER's preliminary opinion on how mixtures are considered in the draft guidance on EQS would be welcome.

3. The SCHER is invited to elaborate on its reasons for considering any aspect of the guidance inappropriate, suggesting alternative approaches, and on any aspects that it considers are missing and should be addressed.

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

4. Does the SCHER agree that the opinion offered by CSTE in 2004 has been adequately dealt with in the guidance? The EG-EQS has produced a summary of the comments made by CSTE in 2004 with responses explaining how those have been taken into account in developing the new guidance. The SCHER is invited to comment on any of the points raised in 2004 that it considers is not properly or sufficiently addressed.
5. Does the SCHER support the approach in the guidance as it relates to the use of field and mesocosm data in deriving EQSs?
6. Does the SCHER believe that the current state of technical and scientific knowledge is mature enough to support the development of legally binding standards for sediment and/or biota? If this is the case, which would be the most important criteria or considerations to take into account in deriving those standards (e.g. minimum quality criteria for underlying ecotoxicological data)? The SCHER will wish to take into account the quality assurance/control requirements set by Commission Directive 2009/90/EC. The Chemical Monitoring Activity under Working Group E under the Common Implementation Strategy for the Water Framework Directive has been drafting guidance on chemical monitoring for sediment and biota and the latest draft can be provided if requested.
7. As far as possible, the technical guidance for EQSs described in the guidance is consistent with the guidance for effects assessments performed for chemical risk assessment under REACH (as stated on page 10 of the guidance). However, in some details it deviates from the approach taken in the REACH guidance or suggests an alternative option. In particular, the process for deriving sediment standards is based on that used under REACH but with additional consideration of field or mesocosm data (page 119), Ksed-water is used rather than Ksusp-water (section 5.2.1.2), and indicative conversion factors from EFSA are provided in addition to conversion factors from REACH in Table 4-1 in the context of mammalian toxicity studies. Does the SCHER consider the deviations and alternatives appropriate?
8. Some stakeholders have asked whether data for blue-green algae should be treated the same way as data for green algae as indicated in the guidance (see section 3.3.1.1, page 50). Consideration of blue-green algae could particularly affect the derivation of EQS for, and thus indirectly the regulation of the use and discharge of, antiseptics or medicines with bactericidal activities, notably products for use in aquatic animals. Does the SCHER agree that data for blue-green algae should assume the same status in the derivation of EQS as data for green algae, as indicated in the guidance?
9. Our attention has been drawn to concerns about the use of BLMs in determining the level of protection of water bodies from metals. Does the SCHER agree that the use of BLMs as advised in the guidance provides sufficient protection from the potential effects of metals?

3. OPINION

3.1. Question 1

The SCHER is invited to give its opinion on the overall scientific quality of the guidance and, considering that the purpose of the document is to provide practical guidance for practitioners in deriving EQSs, whether it reflects properly the current state of technical and scientific knowledge.

In the opinion of SCHER, the overall quality of the document has been significantly improved compared to the guidance commented upon in 2004 (CSTEE, 2004); however, some issues remain to be resolved. Many of these issues are addressed in the comments of SCHER to the responses made by Commission Services to the previous CSTEE Opinion (see response to question 4).

For many aspects, the practical guidance is adequate and the current state of technical and scientific knowledge is adequately integrated. Specific points are addressed below.

One of the major issues identified is when and how EQSs should be adapted to the different environmental conditions in the different ecoregions as well as to the conditions in the different Member States regarding water bodies and ecosystems covered. In the opinion of SCHER, the need for adaptation to the specific conditions regarding different EQSs should be more explicitly stated. SCHER also recommends more clarity regarding the aims of EQSs in the guidance. Additional information is presented in the answer to Question 7.

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.

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.

3.2. Question 2

Given the remit to EG-EQS to provide detailed practical guidance to practitioners, does the SCHER consider the contents of the guidance to be fit for purpose? We are aware that the guidance contains only a short section (section 7 on pages 147-149) on calculating quality standards for substances occurring in mixtures. DG Environment is separately requesting an opinion from the SCHER on the toxicity and assessment of mixtures of chemicals, but this may not be available for several months. Therefore, the SCHER's preliminary opinion on the how mixtures are considered in the draft guidance on EQS would be welcome.

SCHER agrees that the document serves as a useful practical guidance, but still needs further improvement. Specific points to improve the document are stated in the discussion of the responses to CSTEE comments. Regarding the problem of mixtures raised in the document, it is the opinion of the SCHER that this issue should be faced in the WFD with an approach substantially different from that included in the regulations on dangerous chemicals (e.g. REACH). Mixtures considered in

chemical regulations usually are technical formulations (e.g. PCBs, commercial formulations of pesticides, etc.) with a relatively well-known composition. Mixtures of chemicals expected to occur in water bodies are the result of all human activities developed in the watershed (urban wastes, industry, agriculture), and are characterised by an extremely complex and variable composition.

It is the opinion of the SCHER that the present knowledge on toxicology and ecotoxicology of mixtures is suitable for providing valuable suggestions for setting quality standards. Considering that the issue will be the objective of a specific opinion, a final position on mixtures in the guidance document should be postponed. In this frame, the issue of mixtures is specifically addressed in the SCHER response to question 4, comment on point 19.

3.3. Question 3

The SCHER is invited to elaborate on its reasons for considering any aspect of the guidance inappropriate, suggesting alternative approaches, and on any aspects that it considers are missing and should be addressed?

In the opinion of SCHER, the document needs to more explicitly address the issue that the REACH approach regarding risk assessment and the EQSs defined in the Water Framework Directive are different. In addition, it clearly needs to be mentioned that PNECs and EQSs have a different meaning. More details can be found in the responses to question 4, comment 1 and to Question 7.

3.4. Question 4

Does the SCHER agree that the opinion offered by CSTE in 2004 has been adequately dealt with in the guidance? The EG-EQS has produced a summary of the comments made by CSTE in 2004 with responses explaining how those have been taken into account in developing the new guidance (see Annex 3). The SCHER is invited to comment on any of the points raised in 2004 that it considers is not properly or sufficiently addressed.

Many of the points made by CSTE have been adequately addressed. Specific comments and the position of SCHER are detailed below.

Comment 1

CSTE: *There are important distinctions between **PNECs arising from risk assessments** and EQSs. These need to be made explicit (page 3 of CTSEE opinion). (See also comment 2).*

Commission Response: *Section 2 of the latest guidance explicitly refers to the relationship between EQS derivation and PNECs from existing risk assessments. PNECs arising from risk assessments would be regarded as a key source of data but would rarely be adopted without further consideration (unless the assessment was clearly comprehensive and current). See also comments 2 and 4.*

SCHER's position and Recommendations

Although the conceptual difference 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. Although the PNEC and the QS for the same compartment/receptor may be considered equivalent for substances where

sufficient information is available, there are significant conceptual differences in the iterative risk assessment process (allowing preliminary estimations of the PNECs for further refinement, if needed) established under the existing substances legislations and under REACH and the concept of a reference value. In the risk assessment process, estimated PNECs may be further refined, if needed. In contrast, a quality standard (QS) is a direct decision on the quality status, which if exceeded will not trigger further refinement (see detailed response to question 7). Therefore, SCHER recommends to perform a QS establishment after a thorough assessment has been carried out.

A second difference is that the PNECs, as formerly derived by the TGD and currently under the REACH guidance, are intended to cover a pan-European assessment, as the risk assessment or REACH registration covers the EU market. However, and particularly in the case of the EQSs derived by member states (MS) under Annex V of the WFD, the derivation of an EQS may consider the specific characteristics of the water bodies to be addressed (e.g. the EQS for the acidic Scandinavian lakes are expected to be different than those applicable to the water reservoirs and ponds of the Mediterranean region).

Finally, the uncertainty assessment of the EQS also needs to consider a key piece of information, the assessment of the biological status of the water body. This assessment (not relevant for the PNEC derivation) requires presenting and communicating the uncertainty in the QS derivation in a different way than for a PNEC. In a substance risk assessment (TGD/REACH, PPP, BP), the key element is the overall uncertainty in the PEC/PNEC or TER (considering also the uncertainty in the exposure prediction). In contrast, under the WFD, it is essential to present the uncertainty associated to each QS contributing to the overall EQS and to compare the QS (including each endpoint and its uncertainty) with the outcome of the biological status assessment for each water body, refining the EQS for that specific body according to the observed and reference ecological conditions.

In the opinion of SCHER, these aspects are not sufficiently clear in the guidance. SCHER suggests including a subchapter clarifying the main differences in the development, use and implementation of a QS versus a PNEC. SCHER is of the opinion that the PNECs included in the RARs or those derived under REACH should not be directly proposed as QS, the appropriateness of the derivation approach should be checked specifically before suggesting the use of the PNEC value as QS. The response to Question 7 presents the conceptual differences between the PNECs derived under REACH and the EQSs.

Comment 2

CTSEE: *Where standards are defined legally, caution needs to be exercised in basing standards on too little and inappropriate data. Whereas PNECs are part of a tiered approach that trigger more refined assessment, EQSs are legally binding, and trigger measures (page 3 of CTSEE opinion).*

Commission Response: *The guidance is very clear about how data should be collected and evaluated to ensure it is adequate. Section 2 highlights the uncertainties involved in EQS derivation. Ultimately, it is the policymaker's decision whether or not to implement a particular EQS. However, the assessor has a responsibility to bring to the policymaker's attention where there is high uncertainty caused by an absence of data (or a lack of data for critical taxa). A report template is provided that prompts discussion of assumptions and residual uncertainty.*

SCHER's position and Recommendations

As mentioned above, a preliminary PNEC derived from a limited data set (to be used for a preliminary estimation of risk and allowing refinement if needed) should not be

compared with the derivation of an EQS. The document should clearly state that if the information is not sufficient, an EQS should not be derived. In this case, a preliminary PNEC could be compared with the measured concentrations. The outcome should not be a decision on the ecological status, but the need for refining the PNEC in order to derive a proper QS when the preliminary PNEC is exceeded. The need for a sufficient data set is particularly essential when EQSs are derived at the EU level.

Comment 3

CSTEE: EQSs are intended to apply to long-term exposure and should rarely, if ever, be based on acute endpoints (page 3 of CTSEE opinion).

Commission Response: It is correct to say that AA-QS will be more important for water-body classification and permitting but, for the water column, we are also obliged to estimate an EQS that covers short-term exposure (the MAC-QS). Sections 2 and 3 of the guidance explain that acute data are not generally recommended for deriving long-term standards but, in order to ensure consistency with REACH, may be used in association with a large uncertainty factor if chronic data are lacking. This would result in a very high residual uncertainty that must be highlighted (see comment 2). Acute data are relevant for deriving a MAC-QS. See also response to comment 5.

SCHER's position and Recommendations

SCHER agrees with the general concept that, whilst an AA-QS should be based mainly on chronic toxicity data, a MAC-QS referred to intermittent short-term exposure may be based on acute data, as mentioned in chapter 3.2.1.

However, this statement seems in contradiction with the procedures described for deriving an AA-QS that allows the use of correction factors to the short-term base data set.

It must be highlighted that the procedure is not intended for a general application to chemical substances for which toxicity data may be lacking (as in REACH). It should be applied to chemicals identified as priority substances in the WFD, or to "specific pollutants that are discharged in significant quantities" as selected by the Member States. It can be assumed that for these selected chemicals more information is available. In this context, the reference to REACH seems inappropriate.

Comment 4

CSTEE: The distinction between industrial chemicals and PPPs (plant protection products) is artificial. A key difference is the way in which algal data are treated under REACH and pesticide risk assessment (page 4 of CTSEE opinion).

Commission Response: This comment refers to the previous (2005) guidance. In the latest guidance, the same principles and practices (data evaluation, extrapolation) are applied to all chemicals, irrespective of their intended use. The only point we would make is that most PPPs have a specific mode of toxic action which can help focus the assessment on certain taxonomic groups and reduce uncertainty in the final EQS.

SCHER's position and Recommendations

SCHER accepts the response.

Comment 5

CSTEE: CSTEE supports the distinction between EQSs expressed as an annual average concentration (AA-QS) and those referring to short-term transient

exposure (the MAC-QS). However, this distinction is too sharp. Explicit advice on intelligent monitoring is required (page 4 of CTSEE opinion).

Commission Response: Annex V of the WFD requires the estimation of both an AA-QS and a MAC-QS. Whilst the compliance assessment regime for implementing an AA-QS is explicit (the average concentration from measurements made over a year), assessment against a MAC-QS is not. The design of compliance assessment regimes was considered to fall outside the scope of EG-EQS but the latest guidance does refer to separate guidance on monitoring and the ISO standard on design of compliance assessment regimes.

SCHER's position and Recommendations

See SCHER's position regarding comment 3.

Comment 6

CSTEE: EQS assessment should be based on as extensive databases as possible; the SSD approach will be common (page 4 of CTSEE opinion).

Commission Response: EG-EQS agrees with this principle. At several points, the guidance explains in detail how data sources should be searched to ensure datasets are as comprehensive as possible. Principles underlying data selection and evaluation are given in Section 2. For example, data are not confined to those in existing risk assessments or conducted under specific QA (e.g. Good Laboratory Practice) regimes.

The SSD approach to extrapolation is the favoured approach where data permit. However, we recognise that sufficient data will not be available for many substances - especially for media such as sediments and biota - so the deterministic paradigm will be the only realistic option in many cases.

SCHER's position and Recommendations

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.

SCHER agrees that the guidance on the use of SSDs is now adequate. The statement that "ideally the dataset for an SSD should be statistically and ecologically representative of the community of interest" is especially welcome. This means that the SSD should be based on an unbiased sample of taxa from the ecosystem of concern. This is difficult to achieve, as experience in practice shows, but it should be stated as an aspiration and careful consideration should be given to which representatives are included. In addition, the choice of 5 as the default AF is presumed to be arbitrary – this should be made clear.

Comment 7

CSTEE: SSD approach for substances with a specific mode of action: there are two main options (1) combining the information for all species in a single curve and (2) separate analyses of different taxonomic groups (page 4 of CTSEE opinion).

Commission Response: This point applies mainly to the derivation of EQSs for protecting pelagic communities. Detailed guidance on the construction of SSDs is given in Section 3. This covers the specific case of substances with a specific mode of action (e.g. many pesticides) and invites the assessor to construct an SSD using all the available data. If there is evidence that some taxa are particularly sensitive, then

an SSD should be constructed if possible using only data for those taxa that are likely to be particularly sensitive to the substance of interest.

SCHER's position and Recommendations

SCHER agrees that this issue is adequately addressed.

Comment 8

CSTEE: Use of mesocosm data to calculate EQSs : *the aim of mesocosm studies and results should be checked on an individual basis. Interpretation should be case-by-case. It is not acceptable to always express exposure data as the time-weighted average concentration (page 5 of CTSEE opinion).*

Commission Response: *The latest guidance provides much more guidance on the use of mesocosm (and field data). Key principles are given in Section 2 and guidance on the interpretation of mesocosm data, including treatment of exposure data (e.g. for substances that disappear rapidly from the water column), is in Section 3 of the latest guidance.*

SCHER's position and Recommendations

The updated guidance has been significantly improved. Additional information is presented in the response to question 5.

Comment 9

CSTEE: *There is concern about the **added risk approach** for deriving PNECs and quality standards (pages 5 and 13 of CTSEE opinion).*

Commission Response: *The added risk approach (ARA) is a technique for allowing backgrounds to be taken into account for substances where a significant natural background is expected (e.g. many metals). It is necessary where ignoring backgrounds is likely to lead to spurious conclusions about risks to the environment. Detailed guidance about where ARA is valid and how background should be estimated are given in Section 3. The guidance suggests that any allowance for background should be made in the treatment of (compliance) monitoring data and not in the magnitude of the EQS. See also comment 16.*

SCHER's position and Recommendations

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.

If there is sufficient evidence, a similar approach as developed for metals may also be applied to other naturally occurring chemicals.

Comment 10

CSTEE: *Setting EQSs for substances that are also covered in **drinking water legislation**: need to bear in mind that drinking water standards may be more stringent than ecological standards. They should also take account of the relative*

ease of removing substances (in treatment of raw water prior to distribution) and risks to terrestrial vertebrates (e.g. livestock) (page 6 of CTSEE opinion).

Commission Response: *The guidance (Section 3) makes clear that assessments must be performed for all receptors that may be at risk; existing drinking water standards are to be used where they exist i.e. there is no intention to replace existing drinking water standards. In any case, it is beyond the remit of EG-EQS to develop methodology for the derivation of drinking water standards. The selection of an 'overall QS' takes account of all receptors, the most sensitive determining the 'overall QS'. Section 3 explains how treatment of raw water prior to distribution is factored into the decision.*

SCHER's position and Recommendations

Several aspects need to be considered in this context. Drinking water standard setting is different between member states and some drinking water limits are health-based, while others are « precautionary » or oriented to removal efficiencies or specific sources (geogenic versus industrial sources).

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.

Comment 11

CSTEE: *As a general conclusion the CSTEE believes that **specific quality standards can and should be developed for sediment and biota**. This should be based on direct assessment and monitoring of sediments and biota directly...(page 11 of CTSEE opinion).*

Commission Response: *Quality standards for biota and sediment are considered in detail in Sections 4 and 5, respectively.*

SCHER's position and Recommendations

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.

Comment 12

CSTEE: ***Reporting concentrations of substances in samples of whole water (i.e. containing suspended particulate matter): reporting concentrations in the water column only ignores exposure through ingestion by sediment organisms (page 11 of CTSEE opinion).***

Commission Response: *Risks to benthic organisms are covered by EQSs for sediments (Section 5).*

The conduct and analysis of most ecotoxicity tests means that water column EQSs are estimated on the basis of dissolved concentrations. However, to assess compliance with the EQS, some MSs prefer to retain the option to monitor chemical contamination using whole water (containing suspended particulate matter) rather than filtered samples. This possibility is allowed for by showing (Section 3) how EQSs expressed as dissolved concentrations may be recalculated so they can be expressed as 'whole water' EQSs.

SCHER's position and Recommendations

SCHER agrees that this addresses part of the concern expressed by CSTE (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.

Comment 13

CSTE: For a small number of **lipophilic substances**, CSTE strongly recommends that the required ecotoxicity data be generated (page 11 of CTSEE opinion).

Commission Response: It is beyond the remit of EG-EQS to undertake or commission ecotoxicity testing. Nevertheless, we recognise that a lack of data for some substances will lead to a high level of residual uncertainty. This must be highlighted in the report, ideally identifying what further tests would be most beneficial and the likely impact on the choice of assessment factors if uncertainty was to be reduced. In the longer term we hope that the REACH programme will stimulate the generation of new data.

SCHER's position and Recommendations

Lipophilic substances are particularly relevant for secondary poisoning and for sediment EQs. Relevant parts of the Technical Guidance are now dedicated to the issues of lipophilic substances. SCHER considers the issue to be adequately covered.

Comment 14

CSTE: The use of partition coefficients to derive **sediment quality criteria** for a generic sediment is not appropriate for EQs that are derived for site-specific assessments (page 11 of CTSEE opinion).

Commission: The EQs developed using this guidance will be applied across MSs and, even within a MS, sediments are likely to cover a wide range of physico-chemical conditions. Sediment EQs must therefore take this into account to ensure the most vulnerable sites are not put at risk. It is beyond our remit to develop site-specific EQs. The guidance in Section 5 shows how ecotoxicity data should be normalised to the organic carbon content of the test sediment to eliminate some of the site-specific variability in partition coefficients.

SCHER's position and Recommendations

SCHER accepts the response and considers the issue adequately covered. However, normalisation to the organic carbon content of the test sediment may not be an appropriate standardisation method in the case of polar or ionic organic species.

Comment 15

CSTE: A distinction needs to be made between **estimating EQs in fresh and marine waters** (extra assessment factors) (page 12 of CTSEE opinion).

Commission: We agree that the greater biodiversity of marine environments, compared to freshwater environments, encourages the use of larger assessment factors when deriving marine EQs. Section 3 sets out the different assessment factors to be used which are, by and large, a factor of 10 larger in the marine situation.

Section 3 explains that, where there is evidence that freshwater and marine data can legitimately be combined, then this is done. Separate derivations are always done for metals though. Even where data can be combined, different assessment factors will be used for the reasons outlined above.

SCHER's position and Recommendations

The document includes a justified assessment for the evaluation and comparison of freshwater and marine data. However, SCHER still has concerns on how the assessment is treated in the PNEC derivation. In the opinion of SCHER, the use of different approaches for freshwater and marine ecosystems should be scientifically justified on a case-by-case basis. The justification for the “additional factor of 10” presented in the REACH guidance (either higher –generic assumption– or lower –e.g. Baltic Sea– biodiversity than in the generic freshwater systems) can also be applicable to the specific ecosystems for which the EQS is derived under Annex V of the WFD. With the exception of echinoderms, all other taxa that can be used for avoiding this additional factor of 10 are also relevant for the freshwater environment. Therefore, SCHER does not accept the additional safety factor of 10 as a default for marine ecosystems as generally justified. The additional assessment factor needs to depend on the available data and thus requires a detailed assessment of the individual situation.

Comment 16

CTSEE: Setting EQSs for transitional waters: *if values are proposed that are different to those used for inland waters, the difference should be justified. The relevance of organisms in transitional waters to freshwaters or salt waters should be considered (page 12 of CTSEE opinion).*

Commission: *The latest guidance (Section 3) explains how separate EQSs are recommended for freshwaters and salt waters. EQSs for transitional waters per se are not estimated. Transitional (e.g. estuarine) waters with a low salinity, supporting communities that are closely related to freshwater ecosystems, the freshwater EQS is more appropriate. As a default, we recommend a salinity of 5‰ as the cut-off unless other evidence suggests a different cut-off is appropriate for a particular location.*

SCHER’s position and Recommendations

If different EQSs are recommended for fresh and salt waters, specific assessment for transitional waters should be conducted. The main factors responsible for the difference should be identified (i.e. differences in species sensitivity, relevance of sensitive taxonomic groups or the effect of water quality conditions (pH, conductivity, main ions, etc.); and considered for setting the proper EQS within the gradient of estuarine conditions.

Comment 17

CTSEE: Background concentrations for metals: *opinion is divided about the added risk approach (ARA). With a total risk approach (TRA), it is possible for EQSs to be estimated that fall below the natural background. ARA assumes that the background does not affect the ecology, and that we only need concern ourselves with the anthropogenic metal addition. Current knowledge about the geographic distribution of metal background concentrations is insufficient to correctly implement the ARA (page 13 of CTSEE opinion).*

Commission: *EG-EQS recognises the limitations of the ARA but also understands that it may be impossible to implement an EQS that does not take account of background levels, especially when the EQS is at, or lower than, the natural background. Databases of background concentrations are now emerging and are at a stage where they can usefully inform the implementation of EQSs. The approach we have adopted (Section 3) is to derive an EQS under maximum bioavailability conditions and to deal with backgrounds as part of the compliance assessment step (i.e. implementation). See also comment 9.*

SCHER's position and Recommendations

As mentioned under comment 9, SCHER supports the proposed tiered approach which combines TRA and ARA in a pragmatic yet scientifically defensible manner.

Comment 18

CSTEE: For metals, the bioavailable fraction in the environmental compartment and the bioavailable no-effect concentration should be considered (page 14 of CTSEE opinion).

Commission: EG-EQS recognises the limitations of setting EQSs for metals that are based on 'total' concentrations. A significant portion of the guidance is concerned with the derivation of EQSs for metals. Reflecting recent advances in the underlying science, detailed guidance is given on the use of availability and bioavailability models so that the resulting EQSs (Section 3) provide a more accurate assessment of the risks from metal exposure. The associated data requirements are also detailed.

SCHER's position and Recommendations

SCHER is of the opinion that the methods and procedures for metals described in Section 3 reflect the state of the science to deal with metal availability and/or bioavailability. As such, SCHER support the proposed tiered system and the associated data requirements.

Comment 19

CSTEE: Grouping of chemicals is advocated if simultaneous exposure to several members of a group is likely to occur, and several members of the group have a common mode of action/target site. For groups of chemicals, use the TEF or worst case approach (pages 16-18 of CTSEE opinion).

Commission: Section 7 provides guidance on deriving EQSs for groups of substances. Section 6 covers a variety of 'read across' and non-testing methods (e.g. QSARs) to help fill data gaps. The preferred approach is not to adopt a worst-case approach (i.e. to base the group EQS on the most hazardous constituent and assume other constituents are equally toxic) as this would lead to overly stringent EQSs and a high incidence of false positives.

SCHER's position and Recommendations

In principle, the assessment of the effects of mixtures requires the knowledge of the mode of action of the components. The most commonly accepted models for predicting effects of mixtures are the CA (Concentration Addition) approach, applicable to chemicals with the same mode of action, and the IA (Independent Action) approach, applicable to chemicals with different mode of action.

The concept of TU (Toxicity Units), proposed in the Technical Guidance, refers to the CA approach and should be applied to chemicals with the same mode of action.

However, there is sufficient evidence supporting the conclusion that the differences between CA and IA are relatively small (Backhaus et al., 2004; Faust et al., 2003; Finizio et al., 2005; Junghans et al., 2004) and that the CA approach may be assumed as a reasonable worst case (Junghans et al., 2006; Verro et al., 2009).

The CA and IA approaches do not account for the possibility of synergism that, with the present knowledge, cannot be predicted with the available models and must be considered case by case.

It is the opinion of the SCHER that the CA approach may be assumed as a temporary interim method for deriving EQs for mixtures.

The problem of mixtures is now under specific consideration by the European Commission. It could provide some more precise elements for deriving EQs for mixtures.

3.5. Question 5

Does the SCHER support the approach in the guidance as it relates to the use of field and mesocosm data in deriving EQs?

SCHER considers that the approach suggested for using these data is appropriate. In particular, SCHER welcomes the requirement for applying all three methodologies (lab data with assessment factors, SSDs and mesocosm/field data) for setting proper EQs. Additional information on how to incorporate these three elements in a weight of evidence approach, and on using additional information, e.g. information on the mode of action whenever available, will be beneficial.

In addition, the information obtained from the assessment of the ecological status should be considered as field studies and used for assessing the appropriateness of the criteria. Although SCHER is aware of the difficulties in comparing biological and chemical status (biological status provides an integrated multi-response to all different stress factors), large inconsistencies in both directions (less than good status which cannot be explained by any other parameter and good status in water bodies in which EQs are largely exceeded) should trigger specific assessments for these water bodies.

3.6. Question 6

Does the SCHER believe that the current state of technical and scientific knowledge is mature enough to support the development of legally binding standards for sediment and/or biota? If this is the case, which would be the most important criteria or considerations to take into account in deriving those standards (e.g. minimum quality criteria for underlying ecotoxicological data)? The SCHER will wish to take into account the quality assurance/control requirements set by Commission Directive 2009/90/EC. The Chemical Monitoring Activity under Working Group E under the Common Implementation Strategy for the Water Framework Directive has been drafting guidance on chemical monitoring for sediment and biota and the latest draft can be provided if requested

In general, SCHER concludes that the current state of scientific and technical knowledge is sufficiently mature to develop legally binding standards. Development needs to account for the reservations made in response to question 3. SCHER considers the normal criteria (such as the Klimisch criteria) (Hulzebos et al., 2010) in the evaluation of studies as sufficient for the scientifically sound derivation of legally binding standards,.

In principle, SCHER supports transparency and monitoring by QA, but does not have the time to look into all relevant documents in detail.

3.7. Question 7

As far as possible, the technical guidance for EQs described in the guidance is consistent with the guidance for effects assessments performed for chemical risk assessment under REACH (as stated on page 10 of the guidance). However, in some details it deviates from the approach taken in the REACH guidance or suggests an alternative option. In particular, the process for deriving sediment standards is based on that used under REACH but with additional consideration of field or mesocosm data (page 119), Ksed-water is used rather than Ksusp-water (section

5.2.1.2), and indicative conversion factors from EFSA are provided in addition to conversion factors from REACH in Table 4-1 in the context of mammalian toxicity studies. Does the SCHER consider the deviations and alternatives appropriate?

Coherence with REACH guidance: It is important to keep coherence with other guidance documents, e.g. the guidance documents on aquatic ecotoxicology and mammalian toxicity as used in the evaluation of PPPs (EC, 2001, 2002; EFSA, 2008, 2009), but the aims and processes are very different. Under REACH, there are generic needs for generating data but also an overall responsibility of industry to demonstrate safety for the identified uses. The assessment is iterative and refinement in the risk assessment can be avoided by recommending risk management measures. The process for the implementation of EQSs is different.

SCHER considers that the conceptual differences between the EQSs developed under the WFD and the PNECs estimated under REACH have significant conceptual differences that require a better description in the document. Environmental Quality Standards (EQS) and Predicted No Effect Concentrations (PNEC) are related expressions intended to express a chemical environmental concentration which, based on the available information, is considered to represent a low-risk condition (low likelihood for adverse ecological effects if the concentration is not exceeded).

From a scientific perspective, both the EQS and the PNEC should be considered as estimations for the ecological threshold concentration, defining the boundary between contamination (the chemical is present but not causing adverse effects) and pollution (defined as the contamination level at which the chemical is producing adverse effects on the structure and/or function of the ecosystem). It should be noticed that the current level of knowledge does not allow the estimation of the real boundary between contamination and pollution for individual chemicals; and moreover that this boundary is not necessarily a single value, as it is expected to be related to the specific characteristics of each ecosystems and affected by many other parameters including the presence of other chemicals. Risk assessment methods are used for dealing with this complexity in the regulatory context. Based on the available information and the remaining uncertainty, EQSs, PNECs and other equivalent concepts have been proposed and derived. Both, EQSs and PNECs are expected to be equal to or higher than the "true" contamination/pollution boundary. However, because of the regulatory context of the WFD versus REACH (and the previous chemical legislation) there are significant differences in the concepts defining these values.

An EQS is a legally binding threshold value, with a legal definition under the WFD:

"Environmental quality standard" means the concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment."

It is expected to offer an overall protection for the different relevant receptors. As described in the guideline document, an EQS may be established after deriving different QSs for specific compartments/taxonomic groups, and then aggregating the different QSs into a sufficiently protective EQS. If the EQS is exceeded in a water body, mandatory actions should be taken for reducing the concentration of that particular chemical. In contrast, a PNEC is not a legally binding value, and there is no legal definition for the PNEC under the REACH Regulation, it just described it as a tool for the chemical safety assessment

"...and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC)."

The only objective when deriving a PNEC is to ensure that the risks of the substance are adequately controlled.

“For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

– the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, ...”

The process is iterative, the only action required if the predicted exposure exceeds the PNEC is to refine the risk characterisation, and multiple options are available (refinement of the exposure, refinement of the PNEC, application of risk management measures, etc.).

As a consequence, an over-conservative PNEC is fine, and will not be refined unless needed. Under REACH, if different Chemical Safety Assessments are conducted for the same substance, the proposed PNECs may be different, as the needs for refinement are associated to the use patterns and conditions.

The Figure below presents an overview of the overall process of collecting and assessing existing information on the intrinsic properties of a substance under REACH, including identification of needs to generate new data. It also describes the process of chemical safety assessment additionally required for substances produced/imported in amounts of more than 10 tons per year.

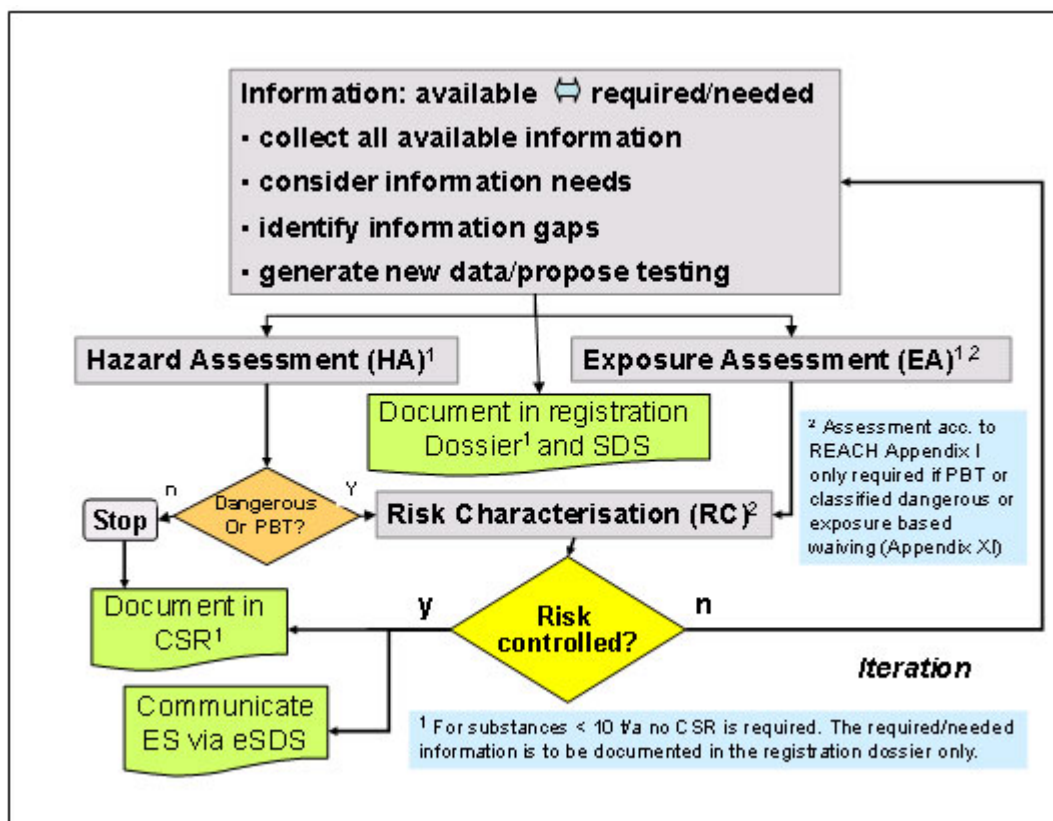


Figure from REACH guidance document: Overall process related to information requirements and chemicals safety assessment under REACH.

The first steps for the derivation of EQSs and PNECs are similar:

- assessment of the available ecotoxicological information and
- application of deterministic methods based on assessment factors or methods based on SSDs, in order to estimate a value based on the available information and remaining uncertainty.

However, after these first steps there are significant differences in the next approach.

The WFD (Point 1.2.6. of Annex V) requires the following additional assessments when setting EQSs:

(ii) where data on persistence and bioaccumulation are available, these shall be taken into account in deriving the final value of the environmental quality standard;

(iii) the standard thus derived should be compared with any evidence from field studies. Where anomalies appear, the derivation shall be reviewed to allow a more precise safety factor to be calculated;

(iv) the standard derived shall be subject to peer review and public consultation including to allow a more precise safety factor to be calculated.

This additional assessment allows options for refinement of the value obtained through the application of the standard factors or SSDs that should be considered before setting the legally binding EQS.

SCHER considers that these refinements should also consider the specific characteristics of the water bodies to which the EQS will be applied, setting different numeric values for different types of water bodies whenever justified by the available information. Different approaches are possible, e.g. based on water-body physical-chemical characteristics, ecoregions, ecotypes, etc.; and SCHER recommends including the relevant options in the guidance document. This is particularly relevant for the EQSs to be derived by the Member States under Annex V of the WFD, as those should be applied to specific water bodies.

SCHER is of the opinion that, at the minimum, the guidance should provide information for checking the need for accounting differences among ecoregions and ecotypes within each ecoregion. If needed, different numeric values for ecoregions, ecotypes or combinations of both characteristics should be considered. When the toxicity and/or bioavailability of a chemical substance in the aquatic environment are affected by water or sediment characteristics, these differences should also be considered. Whenever possible, the effect should be quantified and the EQS numeric value presented in the form of a mathematical equation accounting for that effect, or, if the information is not sufficient, as ranges related to the characteristics of the water bodies to which each numeric value should be applied.

The Committee also suggests exploring the possibilities offered by the additional information generated under the WFD in order to consider the suitability of the proposed EQSs. SCHER recognises the complexity of this issue, and that it is not directly related to the guidance document but to medium and long-term research activities for supporting the implementation of the WFD. When the EQSs are exclusively based on information from laboratory tests the information collected from the assessment of the ecological status of the water bodies could be taken into account in this refinement. A similar principle applies when the EQSs are derived from mesocosms and field studies with different characteristics from those to which the EQS will be applied. It is suggested to explore options for using the assessment of the ecological status of the different water bodies as evidence from field studies

and whenever feasible, to use the refinement contemplated by Annex V, Point 1.2.6., Subpoints ii) to iv) as described above. This approach could be implemented through periodic reviewing processes of the EQSs based on the collected information.

A similar approach could be applied when the information available for the derivation of the QS is insufficient. Instead of EQSs, the derivation of preliminary values should be considered. Measured concentrations could be directly compared to the toxicity endpoints, establishing the margins of exposure, these values should be compared with the additional information obtained for the water bodies under the WFD and then the proper application factors should be considered for setting the final EQS.

In relation to the specific differences, with the REACH guidance, SCHER consider that it is particularly relevant to consider the characteristics of the water bodies when selecting $K_{\text{sed-water}}$, $K_{\text{susp-water}}$ or any other coefficient. Generic values should be used only when the information justifies that they are relevant for the specific water bodies.

Regarding Table 4.1, the Committee considers that the transformation of NOAEL values expressed as dose into NOECs expressed as concentration in food increases the uncertainty of the assessment; moreover, this transformation is not needed under the WFD. SCHER is of the opinion that the risk for secondary poisoning should consider the species relevant to the water bodies to be assessed. The EFSA documents mentioned in the guideline offer sufficient information for estimating the body weight to daily food intake ratio for the relevant species, as indicated in chapter 4.4.4.2. Thus, the Committee suggests deleting Table 4.1 and chapter 4.4.4.1, and updating chapters 4.4.3 and 4.4.4. The assessment factors mentioned in Table 4.4 should be applied to the NOAEL values, considering carefully if the information on mammals could be extrapolated to birds when no information on avian species is available. Chapter 4.4.4.2 should be modified accordingly.

3.8. Question 8

Some stakeholders have asked whether data for blue-green algae should be treated the same way as data for green algae as indicated in the guidance (see section 3.3.1.1, page 50). Consideration of blue-green algae could particularly affect the derivation of EQS for, and thus indirectly the regulation of the use and discharge of, antiseptics or medicines with bactericidal activities, notably products for use in aquatic animals. Does the SCHER agree that data for blue-green algae should assume the same status in the derivation of EQS as data for green algae, as indicated in the guidance?

Considering the ecological importance of blue-green algae, it is opinion of the SCHER that they should be included among the organisms relevant for the derivation of EQS for surface water ecosystems.

Many chemicals, such as substances without specific mode of action on algae or bacteria (narcotic-type or baseline effect) have comparable effects on the two groups of organisms. For chemicals with specific mode of action on photosynthetic organisms (e.g. herbicides), there is no evidence in the literature of significant differences in sensitivity between blue-green and green algae. Therefore, it is opinion of the SCHER that, for chemicals without specific bactericidal activity, data for blue-green algae should assume the same status in the derivation of EQS as data for green algae.

From the evaluation of veterinary drugs (Ando et al., 2007; CVMP, 2008), it is clear that blue-green algae tend to be more sensitive than green algae to chemicals with bactericidal activity.

Therefore, information on blue-green algae is essential for setting EQS for these kinds of chemicals.

3.9. Question 9

Our attention has been drawn to concerns about the use of BLMs in determining the level of protection of water bodies from metals. Does the SCHER agree that the use of BLMs as advised in the guidance provides sufficient protection from the potential effects of metals?

The number of studies that describe and demonstrate the development, validation and application of BLMs for various species and metals has grown considerably during the past decade. As such, the amount of scientific information which demonstrates the reliable use of these models for regulatory purposes is at least comparable to that on other (exposure and effects) models or approaches currently used in the EU. It is the opinion of SCHER that the two main concerns stated in the 'European Workshop on Metals in the Environment' report (Annex 5), i.e. (1) 'geochemical conditions not covered by the approaches' and (2) 'the relative importance of other pathways other than the free ionic form of metals', are sufficiently documented in open literature and/or addressed in the TGD document. Indeed, the TGD clearly states that the models should only be applied within their development/validation domains, thus elevating concern 1. Additionally, chronic BLMs (p. 74 TGD), i.e. which implicitly include the dietary exposure route, have been developed and validated for a number of species and metals. This fact together with dedicated studies demonstrating the rather small contribution of dietary metal to the overall toxicity value, suggests that concern 2 can be considered to be of minor importance.

Consequently, SCHER is of the opinion that the use of BLMs as advised in the guidance provides sufficient protection from the potential effects of metals.

3.10. Additional comments on the document by SCHER

General Comments

The list of abbreviations in the draft TGD needs checking.

The document has many typing errors and linguistic mistakes.

The way the word "food" is used in the document it generally refers to animal feed. Therefore, "food" should be replaced by "feed" throughout the document except in the case of "food chain".

The SI-system of units has been adopted in the EU. Therefore, throughout the document, SI-notations of units should be used; delete the dot (.) in units.

Specific Comments

Page 8 – Figure 0-1 (in the text is quoted as 1-1). The figure is unclear and more explanations in the caption would be welcome.

Page 14, biota are relevant mainly for chemicals with a potential for bioaccumulation.

Page 14 – Figure 2-2: SCHER does not agree with this scheme. "Benthic" is not synonymous of "sediment-dwelling". Mussels are benthic animals and depend on water. If, in this scheme, the meaning is "sediment-dwelling", better using the proper term. Moreover, not all sediment-dwelling organisms are sediment-eating (detritivorous). Particularly in the sea, some sediment-dwelling animals are predator. In the last row "4" may be a mistake (is it "X"?).

Page 15 – Figure 2-3: The figure too is unclear. In the upper part there is probably something wrong. In particular, the arrows are confusing (two unclear arrows from the box “Water”, no arrows from the “Human health” box). This needs to be clarified. Moreover, other parts are unclear. Probably the subscripts are confusing and need to be revised, see also comment to page 38.

Page 15, Figure 2-3: again, human health, dermal contact when swimming?

Pages 17-18: 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.

Line 408: The modes of toxicity are often not known and may vary for different “receptors”. This should be made clear.

Line 500: something is missing. The sentence is not finished.

Line 524 ff: Use of C&L as first approximation is acceptable, but detailed assessments of available toxicity studies, dose-response, and estimated exposures are needed to conclude on risk. In addition, C&L does not cover all possible endpoints relevant for risk assessment. It should be also considered that with the new provision on C&L under the CLP Regulation most of the hazard classes mentioned in the document are not subject to harmonized classification at the EU level, and the only information available will be related to the self classification decided by industry and notified through the C&L inventory, which cover substances as put on the market, not pure chemicals. As the substance name convention under REACH require to use the name of the main constituent if it is over 80% substances with the same name may have different classifications. Thus SCHER recommends using specific toxicity triggers instead of classification criteria.

Page 22, line 570: Figure 2-4 is quoted, but apparently not present in the text.

Page 23, lines 604-605: The meaning of the first sentence of the chapter is unclear. Partition coefficients are extremely important, but their usefulness is not limited to changing units. SCHER suggests to delete the first sentence and to better explain the relevance of partition coefficients.

Line 623: Dose-response is essential to assess endocrine activity, use of pure hazard (changes in endpoint regarded associated with effects on the endocrine system at any dose) is inappropriate for risk assessment.

Line 640: SCHER does not agree that a threshold cannot be defined for “non-genotoxic” carcinogens. Only “genotoxic” carcinogens may act by a non-threshold mechanism.

Line 643: 70 years exposure? Normally as a lifetime 40 years is assumed.

Line 679-680: what is meant by this sentence as in PPP standard tests are used?

Line 681: GLP data only have high reliability, they have not always been reviewed by a “competent” authority. Data from studies following OECD guidelines under GLP are of highest quality, but still need to be transformed to tolerable intakes

Lines 705–709: Sentence is not logical

Page 29, Line 753 and 756: in both items “five ecotoxicological endpoints” are mentioned. In the second case it should be “toxicological”.

Page 32, line 839: the reason is obvious, always enough (at least 3) chronic endpoints are available for pesticides.

Page 32, line 841: this statement is not clear. Also under WFD not always all compartments are needed for QS setting (see page 14).

Page 37 – chapter 2.11.3: Total or dissolved? The issue could be matter of discussion.

Page 38, line 1007: “ $QS_{\text{water,eco}}$ ” : is “eco” necessary? There are no other “ QS_{water} ”, so “eco” could be confusing. Indeed, there is some confusion in figure 2.3, were some subscripts should be changed.

Page 44, lines 1153-1158: It is not clear how the deterministic approach may include more sensitive species than the SSD approach. If toxicity data are available for sensitive species use for the deterministic approach, they may also be used for SSD

Page 44, line 1159 – 1160: for a pesticide, including insecticides, always sufficient data are available for the water column. What is mentioned seems a very rare case.

Lines 1159-1165: The equilibrium partitioning method has been developed for extrapolating toxicity data from the aquatic base set to sediment dwelling organisms and is based on some assumptions and approximations. The validity of these assumptions in the reverse application of the method is doubtful. The base set should be provided in any case.

Line 1178, Table 3.2: Is the default of 1 000 to lowest toxic effect in any test organism after short term exposure appropriate?

Page 45, line 1191: In my view this sentence can be deleted. It is also mentioned on page 50, line 1326 and in the first case the sentence does not seem to fit in the context.

Line 1201: remove “endocrine disruption”. It is just one mode of action resulting in adverse effects

Page 50, line 1332: In eutrophication, blue-green algae are considered a nuisance as causing smell problems. Blue-green algae should be considered as unwanted species. Is this part of the biological indicators of the WFD?

Page 55, line 1489: in a case of half-lives of hours such a substance is not considered the active ingredient and a QS does not seem to be relevant.

Page 57, line 1544: In Giddings et al (2002), the AF to be applied is extensively discussed and may vary between 2 and 5.

Page 57, line 1558: another question could be added: what is considered the representativity of mesocosm and field studies?

Page 62, line 1687: it should be kept in mind that in performing the RA the PEC will be diluted with an extra factor of 10 in the marine environment. So, effectively the higher AF for marine water has no effect on the RA.

Page 66, line 1789: it is not clear what is meant by non-persistent. Is non-persistent identical to less than the P-criterion in the PBT assessment?

Lines 2455-2456: the meaning of the sentence is unclear. It means that organic carbon is not present or that the information is lacking? In the first case the procedure is correct. In the second case, it should be mentioned that assuming the concentration as fully dissolved is a default worst-case assumption.

Line 2537: What about plant protection products? WHO defines health based values, but the EU uses a precautionary approach which is not warranted

Page 96, line 2557: is a human body weight of 70 common in the EU? Why not harmonise with WHO at 60?

Line 2560 ff: Benchmark doses should be included. SCHER considers the 10% allocation of the TDI acceptable as a default, but it should be mentioned that this depends on exposure from other sources. ADI, TDI and RfD are essentially similar.

Line 2570: No guidance on how to calculate tolerable concentrations for animal carcinogens is presented. The whole section can be simplified by just saying expert judgement is needed.

Line 2638-2644: Biota standard: SCHER still recommends using concentration in organism.

Line 2703: The text addresses secondary poisoning and lines 2703 – 2708 are of low relevance to this endpoint.

Lines 2709 - 2719: SCHER agrees that studies covering most of the lifespan of rodents are most appropriate. Short-term studies may be used when adding additional uncertainty factors such as proposed by the US-EPA and WHO.

Page 103, line 2722: "Standard Agency" should be "Safety Authority".

Table 4-1: What is the basis for this table? The default values used have many uncertainties since they depend on the toxicokinetics (peak blood concentrations of a chemical will be different when administered by gavage as compared to food) of the chemical under study.

SCHER recommends to account for the relative part of the human diet which is covered by the organism of concern to help in deriving concentration standards as proposed in lines 2869ff.

Line 2813: How is the assessment factor of 3,000 to account for extrapolation from LC50 to effects after long-term exposure justified?

Line 2877: The TDI covers sensitive subgroups.

Lines 3094-3099: the meaning of the figure is unclear. It needs a caption and should be referenced in the text.

Line 3278, Table 5.2: is the term QSAR appropriate? They are "property-property", not "structure-activity" relationships.

Page 138, line 3548: a reference should be added on the SEM-AVS approach.

Page 156, line 3998: "Standard Agency" should be "Safety Authority".

Page 245, line 6549: "Standard Agency" should be "Safety Authority".

4. LIST OF ABBREVIATIONS

AA-QS	Annual average concentration
ADI	Acceptable Daily Intake
ARA	Added Risk Approach
BLM	Biotic Ligand Model
CA	Concentration Addition
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EQS	Environmental Quality Standards
EQSD	EQS Directive (Directive 2008/105/EC)
EU	European Union
IA	Independent Action
MAC-QS	Short-term transient exposure
MS	Member State(s)

NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
PCB	Polychlorinated Biphenyls
PEC	Predicted Environmental Concentration
RfD	Reference Dose
TDI	Tolerable Daily intake
TRA	Total Risk Approach
TER	Technical Evaluation Report
TU	Toxicity Units
PNEC	Predicted No Effect Concentrations
PPP	Plant Protection Products
QS	Quality Standards
RAR	Risk Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SSD	Species Sensitivity Distribution
WFD	Water Framework Directive (WFD, 2000/60/EC)

5. REFERENCES

- Ando, T., Nagase, H., Eguchi, K., Hirooka, T., Nakamura, T., Miyamoto, K., Hirata, K., 2007. A novel method using cyanobacteria for ecotoxicity test of veterinary antimicrobial agents. *Environ Toxicol Chem* 26, 601-606.
- Backhaus, T., Faust, M., Scholze, M., Gramatica, P., Vighi, M., Grimme, L.H., 2004. Joint algal toxicity of phenylurea herbicides is equally predictable by concentration addition and independent action. *Environ Toxicol Chem* 23, 258-264.
- CSTEE, 2004. Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment on "The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof", adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004.
- CVMP, 2008. Committee for Medicinal Products for Veterinary Use. Revised guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL8 MEA/CVMP/ERA/2005-Rev1, London, 17 November 2008.
- EC, 2001. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC (doc. SANCO/3268/2001). http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc10_en.pdf. (accessed on 07 November 2010)
- EC, 2002. Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (doc. SANCO/4145/2000-final).
- EC, 2002. Guidance Document on Terrestrial Ecotoxicology in the context of Directive 91/414/EEC (doc. SANCO/10329/2002). http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc09_en.pdf (accessed on 07 November 2010)
- EFSA, 2008. Risk Assessment for Birds and Mammals - Revision of Guidance Document under Council Directive 91/414/EEC (SANCO/4145/2000 – final of 25 September 2002) [1] - Scientific Opinion of the Panel on Plant protection products and their Residues (PPR) on the Science behind the Guidance Document on Risk Assessment for birds and mammals. <http://www.efsa.europa.eu/en/scdocs/doc/734.pdf> (accessed on 07 November 2010).
- EFSA, 2009. Risk Assessment for Birds and Mammals - on Request from EFSA, Question No EFSA-Q-2009-00223, first published on 17 December 2009. <http://www.efsa.europa.eu/de/scdocs/doc/1438.pdf> (accessed on 07 November 2010).

- Faust, M., Altenburger, R., Backhaus, T., Blanck, H., Boedeker, W., Gramatica, P., Hamer, V., Scholze, M., Vighi, M., Grimme, L.H., 2003. Joint algal toxicity of 16 dissimilarly acting chemicals is predictable by the concept of independent action. *Aquat Toxicol* 63, 43-63.
- Finizio, A., Villa, S., Vighi, M., 2005. Predicting pesticide mixtures load in surface waters from a given crop. *Agriculture, Ecosystems & Environment* 111, 111-118.
- Hulzebos, E., Gunnarsdottir, S., Rila, J.P., Dang, Z., Rorije, E., 2010. An Integrated Assessment Scheme for assessing the adequacy of (eco)toxicological data under REACH. *Toxicol Lett* 198, 255-262.
- Junghans, M., Backhaus, T., Faust, M., Meyer, M., Scholze, M., Grimme, L.H., 2004. Predicting the joint algal toxicity of chemical mixtures using a mechanism-based two stage prediction (TSP). In: *Studies on combination effects of environmentally relevant toxicants*. PhD Thesis, University of Bremen, Germany, 78-108.
- Junghans, M., Backhaus, T., Faust, M., Scholze, M., Grimme, L.H., 2006. Application and validation of approaches for the predictive hazard assessment of realistic pesticide mixtures. *Aquat Toxicol* 76, 93-110.
- Verro, R., Finizio, A., Otto, S., Vighi, M., 2009. Predicting pesticide environmental risk in intensive agricultural areas. II: Screening level risk assessment of complex mixtures in surface waters. *Environ Sci Technol* 43, 530-537.