



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

"CHEMICALS AND THE WATER FRAMEWORK DIRECTIVE:  
DRAFT ENVIRONMENTAL QUALITY STANDARDS"

Lead

SCHER adopted this opinion at its 13<sup>th</sup> plenary on 25 May 2011

#### 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.

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**TABLE OF CONTENTS**

ACKNOWLEDGMENTS.....3

1. BACKGROUND .....5

2. TERMS OF REFERENCE.....5

3. OPINION .....6

    3.1. Responses to the general requests .....6

    3.2. Responses to the specific requests on lead.....7

4. LIST OF ABBREVIATIONS .....7

5. REFERENCES .....7

## 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 is now aiming to present its proposals to Council and the Parliament by June 2011.

The Commission has been working on the abovementioned review since 2006, with the support of the Working Group E (WG E) on Priority Substances under the Water Framework Directive Common Implementation Strategy. The WG E is chaired by DG Environment 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.). A shortlist of 19 possible new priority substances was identified in June 2010. Experts nominated by WG E Members (and operating as the Sub-Group on Review of Priority Substances) have been deriving EQS for these substances and have produced draft EQS for most of them. In some cases, a consensus has been reached, but in some others there is disagreement about one or other component of the draft dossier. Revised EQS for a number of existing priority substances are currently also being finalised.

The EQS derivation has been carried out in accordance with the draft Technical Guidance on EQS reviewed recently by the SCHER. DG Environment and the rapporteurs of the Expert Group that developed the TGD have been considering the SCHER Opinion and a response is provided separately.

## 2. TERMS OF REFERENCE

### 2.1 General requests to SCHER

DG Environment now seeks the opinion of the SCHER on the draft EQS for the proposed priority substances and the revised EQS for a number of existing priority substances. The SCHER is asked to provide an opinion for each substance. We ask that the SCHER focus on:

- 1. whether the EQS have been correctly and appropriately derived, in the light of the available information<sup>1</sup> and the TGD-EQS;**
- 2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

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<sup>1</sup> The SCHER is asked to base its opinion on the technical dossier and the accompanying documents presented by DG Environment, on the assumption that the dossier is sufficiently complete and the data cited therein are correct.

Where there is disagreement between experts of WG E or there are other unresolved issues, we ask that the SCHER consider **additional points**.

Where there is disagreement between experts of WG E or there are other unresolved issues, the additional points to be considered by the SCHER are identified in the cover note(s), and additional documents are provided where necessary.

## 2.2 Specific requests on lead

The SCHER is asked to consider the two generic questions in the request.

## 3. OPINION

### 3.1. Responses to the general requests

#### 1. whether the EQS have been correctly and appropriately derived, in the light of the available information and the TGD-EQS;

The lead dossier takes into account the SCHER opinion (SCHER, 2009) on the voluntary risk assessment report on lead (LDAI, 2008). The opinion highlighted the relevance of the effects of dissolved organic carbon (DOC) on the bioavailability of lead.

On these bases, a procedure is proposed for correcting the standard EQS as a function of the site specific DOC content.

It is opinion of the SCHER that the procedure proposed, in absence of a more complete BLM, is appropriate.

The MAC-QS has been calculated from SSD derived on a wide data-set containing information on 28 marine and freshwater species representing 8 taxonomic groups. An assessment factor of 4 is applied to the HC5 and justifications are provided for the choice.

For the derivation of the AA-QS<sub>freshwater</sub> a careful selection of toxicity data referred to soluble lead supported by information on physicochemical conditions (DOC, hardness, pH) has been performed. An AF of 2 is applied to the HC5 and justifications are provided for the choice.

For the derivation of the AA-QS<sub>marine water</sub> a data set of 9 chronic values for marine species from five taxa (insufficient for the development of SSD) has been integrated with the freshwater data used for the derivation of the AA-QS<sub>freshwater</sub>. However, some of the freshwater values are different from those previously used. The reasons for these differences are not clearly explained. An AF of 3 is applied to the HC5 and justifications are provided for the choice.

It is opinion of the SCHER that, in principle, the procedure is appropriate. However, two issues should be clarified:

- the reasons for the difference of values some freshwater species must be provided;
- the reason for not using for both AA-QS the same enlarged database should be explained.

The procedure for the derivation of the EQS<sub>sediment</sub> is quite confusing. For freshwater two approaches are proposed:

- the application of an AF of 3 or 4 to HC5 obtained from an SSD based on 6 sediment chronic toxicity data not bioavailability corrected;

- the SEM/AVS deterministic approach by applying an AF of 10 to the lowest unbounded bioavailable NOEC.

For marine sediment, a database of 8 marine and freshwater values, not bioavailability corrected, is used and an AF of 3 or 4 is applied to the SSD HC5. It is opinion of the SCHER that the SSD approaches are not clearly described and supported. Therefore, the SEM/AVS deterministic approach should be preferred.

For secondary poisoning, a PNEC for higher vertebrates (bird and mammals) is correctly derived. However, it is opinion of the SCHER that the variability of data on bioaccumulation factors (BAF), ranging within two orders of magnitude for fish, leads to too high uncertainty for the derivation of an EQS.

## **2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

On the basis of the above comments, it is opinion of the SCHER that, notwithstanding the need for some clarifications, the EQS for the aquatic environment has been correctly identified.

On the contrary, it is opinion of the SCHER that the data used to derive the secondary poisoning EQS are not appropriate.

### **3.2. Responses to the specific requests on lead**

For the substance lead there are no additional requests to the SCHER. Therefore, no further action is needed from the SCHER.

## **4. LIST OF ABBREVIATIONS**

AA-QS	annual average quality standard
AVS	Acid Volatile Sulfides
BAF	bioaccumulation factor
EQS	environmental quality standard
MAC-QS	maximum acceptable quality standard
SEM	Simultaneously Extracted Metal
TGD-EQS	technical guidance document- environmental quality standard

## **5. REFERENCES**

LDAI Lead Risk Assessment Working Group. 2008. EU Risk Assessment Report. Voluntary Risk Assessment on lead.

SCHER (Scientific Committee on Health and Environmental Risks). 2009. Scientific opinion on the voluntary risk assessment report on lead and its compounds; Environmental Part. 13 January 2009. ([http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_111.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_111.pdf))

SCHER (Scientific Committee on Health and Environmental Risks) (2010), Opinion on Chemicals and the Water Framework Directive: Technical Guidance for Deriving Environmental Quality Standards, 16 September 2010

