



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Zinc

SCHER adopted this opinion at its 16<sup>th</sup> plenary on 22 March 2012

#### 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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## 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 Document on EQS (TGD-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. The SCHER should 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, the SCHER should consider **additional points**.

## 2.2 Specific requests on Zinc

The SCHER is asked to consider **the two generic questions in the request**, as well as the following specific (additional) **points**.

The UK rapporteur has presented its proposed EQS alongside others for comparison. It proposes an AF of 1 – see section 7.1.4 for discussion.

Members of the Sub-Group on Review of Priority Substances have not been able to agree on the AF value. The SCHER is invited to comment separately on the derivation of the **HC5** and on the **AF**.

As pointed out in section 7.1.4 of the dossier, a new mesocosm study is being performed and so far only the preliminary results are available. The UK concludes that they appear to support an AF of 1.

The following is the view of RIVM regarding the UK derivation:

*For zinc, a lot of data are available and more data are included compared to the EU RAR. BLM models have been developed for zinc and applied in the derivation of the quality standards. The derivation of the quality standard is quite a complex topic. UK has made an extensive review and most of the EQS derivation is well documented. This EQS derivation also gives the reference conditions explicitly, something which served as a starting point and is of utmost importance when accounting for bioavailability with BLMs.*

*It should however be realized that no extensive peer reviewed process has been performed to develop these new EQS values as was done at TCNES for the EU RAR. For example, the existing mesocosm studies were one of the key factors (maybe the key factor) to apply an assessment factor of two instead of one. However, the new mesocosm study is not yet available. Therefore, it cannot be assessed whether it is indeed valid and whether it can replace the results of the previous mesocosm studies. For example, the results of the mesocosm study are probably not yet expressed for the reference conditions.*

*Also the field data are not convincing in this either. The lowest threshold value for the most sensitive ecological metric is 8.6 µg/L, which is almost a quarter lower than the proposed standard of 10.9 µg/L. In view of the fact that 'biological metrics may not necessarily respond to the loss of a single zinc-sensitive taxa' an assessment factor of 2 on the SSD seems more appropriate than a factor of 1.*

*With regard to the exposure concentration, the translation of total concentration in dissolved concentrations remains a topic of discussion.*

If the final results of the new mesocosm study become available in time, these will be made available to the SCHER.

## 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 AA-EQS (Annual Average Environmental Quality Standards) are expressed as Added Risk and represent conditions of high bioavailability and so should be protective of sensitive areas. SCHER agrees on the way the AA - EQS for freshwater has been derived (10.9 µg/l bioavailable Zn, added risk). However, SCHER does not agree with the marine AA-EQS, because it has been derived using the same dataset as used in the the EU Risk Assessment Report (RAR v. 2006) where it is stated that "although there are sufficient NOEC (No Observed Effect Concentration) values available for saltwater organisms to apply statistical extrapolation and a 5<sup>th</sup> percentile value for saltwater was calculated in this RAR, the 5<sup>th</sup> percentile value for saltwater is considered to be too unreliable for saltwater PNEC<sub>add,aquatic</sub> derivation, because the saltwater NOEC values (from Janus, 1993), were not updated and not checked for reliability based on the criteria that have been used in this RAR for the freshwater values".

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

The SCHER is of opinion that the most critical EQS (surface water) has been correctly identified.

**3.2 Responses to specific requests on Zinc**

**Comments on HC5 (Hazardous Concentration for 5 % of species) derivation**

The HC5 has been derived according to the TGD (Technical Guidance Document) for deriving EQS under the WFD. The derivation relies on a number of data sufficient for proper statistical calculations, takes properly into account differences in zinc bioavailability and is protective of most of the sensitive EU water bodies. The HC5 proposed is considered correct by SCHER.

**Comments on AF**

SCHER have used a total risk approach for assessing validity of Zn EQS proposed by the EQS rapporteur, since in practice, "one cannot simply distinguish the 'natural' part from the anthropogenic part", as pointed out in the draft EQS dossier. A number of mesocosm studies were not taken into account as supporting evidence in the EU RAR (2008) because of weaknesses in the experimentation. The new microcosm study performed by Rand et al. (2012) also experienced a number of flaws (i.e. high background concentration probably due to use of different sources of water, and low relevance of the environmental conditions such as pH and temperature for the sensitive areas in Europe). However, the results of the above studies are consistent with the results of recent field monitoring studies (Simpson et al. 2010) and can be used in a weight-of-evidence approach. The AA-EQS for freshwater proposed in the EQS dossier is below the thresholds derived from the (extensive) SSD approach and mesocosm studies and those for surface water high/good status values observed in field studies. The SCHER considers that the very large amount of data and different lines of evidence represent a considerable reduction in uncertainty compared with the state of knowledge in the EU RAR (2008). The conceptual difference between a PNEC (as derived in an EU RAR) and an EQS, as expressed previously by SCHER (2010) should also be taken into account.

The SCHER considers that the EQS proposed by the rapporteur takes appropriate account of the above observations.

#### 4. LIST OF ABBREVIATIONS

AA-EQS	annual average environmental quality standard
AF	assessment factor
EQS	environmental quality standard
HC5	hazardous concentration for 5 % of species
NOEC	no observed effect concentration
PNEC	predicted no effect concentration
RAR	risk assessment report
SSD	species sensitivity distribution

#### 5. REFERENCES

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