



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

**Naphthalene**

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.

#### 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](mailto:Sanco-Sc8-Secretariat@ec.europa.eu)

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Prof. Peter Calow  
Prof. Wolfgang Dekant  
Prof. Arielle Gard  
Prof. Colin Janssen (rapporteur)  
Prof. Jan Linders (chair)  
Prof. Jose Tarazona  
Prof. Marco Vighi  
Prof. P. de Voogt

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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 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**.

## 2.2 Specific requests on Naphthalene

**No additional requests on naphthalene were made to SCHER.**

## 3. OPINION

Responses to the general requests:

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

The procedures for the derivation of the EQS values for naphthalene are in accordance with those prescribed the TGD-EQS (2010). However, on some issues data interpretation and expert judgement was needed. Some of these choices made can be questioned and/or are not sufficiently justified in the document.

For example, an issue which hampers the evaluation of this draft EQS-document is the fact that it frequently refers to a recent document in preparation (Verbruggen, in prep.); as such SCHER is unable to check the some of the data and/or some conclusions on assessment factors. The SCHER wishes to underline that it is the selection and interpretation of the toxicity results and the selection of appropriate assessment factors which may lead to disagreement on the final EQS values.

It is also unclear from the document if the key toxicity test results on which an application factor is applied to derive the QS are based nominal or measured concentrations( e.g. MAC derivation on 96h *Chironomus* data; nominal or measured?). Although the Klimisch score given in the tables may indicate that the values are acceptable, the SCHER cannot verify the (nominal or measured) value of the toxicity data and thus the relevance and appropriateness of the data used. The document should be re)evaluated in the context of this comment.

The draft EQS document also does not provide sufficient justification of when the data set is deemed appropriate to use the SSD approach and when not. E.g. it is proposed that the SSD should not be used for the AA-QS<sub>water-eco</sub> derivation because 'usable data on insects are missing'; yet there are chronic data (on *Tanytarsus dissimilis*), which are considered as appropriate based on the assigned Klimisch score (=2), reported in the document for this group.

Finally it unclear to SCHER why for sediment dwelling organisms a different AF is used for the freshwater and for the marine environment despite the fact that no statistical difference between the two pelagic datasets was detected. The rationale for assuming that there is a difference (or a difference can be expected) for benthic organisms is not stated.

Given the above-mentioned short-comings and reservations, SCHER cannot agree with the proposed values and is of the opinion that the influence of the above considerations on the value of the EQS should be examined prior to a final decision.

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

The critical QS proposed in the draft EQS documents is the QS<sub>water-eco</sub> (for freshwater and marine waters). It is the opinion of SCHER that this QS has been correctly identified as the most critical EQS (in terms of impact on environment/health).

### 3.3. specific question to SCHER

No specific additional requests were made.

#### **4. LIST OF ABBREVIATIONS**

AA-QS	annual average quality standard
DAR	draft assessment report
DT50	half life for degradation or dissipation
EQS	environmental quality standard
MAC-QS	maximum allowable concentration quality standard
PEC	Predicted Environmental Concentration
PBT	Persistent, Bioaccumulative and Toxic
TGD-EQS	Technical Guidance Document - Environmental Quality Standards
WFD	Water Framework Directive

#### **5. REFERENCES**

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