



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Anthracene

SCHER adopted this opinion at its 12th plenary on 30 March 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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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 information¹ and the TGD-EQS;**
- 2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

¹ 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 Anthracene

SCHER is requested to comment on one additional point: "As in the case of the fluoranthene EQS dossier, there has been discussion in the Sub-Group on Review regarding the AF that should be used for the QS for marine sediment. The dossier lead has proposed using the same ratio between the AFs for freshwater sediment and marine sediment as occurs in the fluoranthene dossier (as submitted to the SCHER). This means that with an (agreed) AF of 50 for freshwater sediment, the AF for marine sediment becomes 250, cf 10 and 50 for fluoranthene.

The principle of "read-across" between the two dossiers appears to be agreed upon. However, as for fluoranthene, some experts in the Sub-Group (in this case industry and some MS) consider that the AF for marine sediment should be the same as for freshwater sediment, i.e. that the additional factor of 5 is not justified and the AF for marine sediment should be 50. Furthermore, they question whether an AF of 250 should be used at all, since it is not among the AFs recommended in the TGD (see Table 5-1). The lead argues that there are other examples where expert judgement has led to non-standard AFs, and that the additional factor of 5 covers the possibility that among the greater diversity of marine sediment species there are more likely to be species more sensitive than those for which ecotoxicity data are available.

The SCHER is asked to consider whether the proposed AF for marine sediment is appropriate, taking into account the above points and the comparability of the anthracene and fluoranthene dossiers.

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 anthracene 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, contrary to the dossier on fluoranthene, this draft EQS document does not mention/discuss the statistical analyses needed to demonstrate that the marine and freshwater toxicity data used do not differ significantly.

Another 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 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 (cf. 3.3.). In most cases SCHER can support these selections made, except for the issues discussed in 3.3.

Despite the above-mentioned short-comings and reservations, SCHER is of the opinion that, except for the issue discussed in 3.3., the EQS have been correctly and appropriately derived.

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

The most critical EQS (in terms of impact on environment/health) is the QS_{water, eco} and has been correctly identified.

3.3. specific question to SCHER regarding the AF used to derive the QS for marine sediments (cf. above)

The SCHER does not agree with the procedure and justification given for using an AF of 250 for deriving the QS for marine sediments. Given that (1) the data sets for freshwater and marine pelagic organisms are considered as 'not significantly different' (i.e. same AF used for both environments) and (2) there is no evidence that there is a significant difference in sensitivity of benthic organisms compared to pelagic species, and (3) that this deviation from the standard, agreed AFs mentioned the TGD may lead to further, unjustified deviations from standard procedure, the SCHER cannot support the EQS derived for marine sediments. The argument given by the EQS lead author, i.e. 'the AF is needed because the greater diversity of marine sediment species it is likely that there will be more species more sensitive than those tested', is one which is used frequently but which has not been scientifically demonstrated. Additionally the same argument holds for the pelagic freshwater and marine species, but here (although the size and diversity of both data sets is similar) the same AF is used for the marine and sediment environments.

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
FOCUS	FORum for the Coordination of pesticide fate models and their USe
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