



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Perfluorooctane sulphonate (PFOS)

SCHER adopted this opinion at its 13th 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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http://ec.europa.eu/health/scientific_committees/environmental_risks/index_en.htm

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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**.

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 PFOS

No specific requests were made.

3. 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 SCHER notes that the EQS document is based on the data available from other regulatory and/or overview studies, some of which are relatively old (e.g. Environment Agency, 2004). It should be realized that a considerable number of studies have become available during recent years, including data which may be used for the derivation of EQS for sediment; these (exposure and effects) data are not included in the EQS document. SCHER notes that some references used in the document are not included in the reference list.

The MAC-QS_{water, eco} was derived using a pooled freshwater-marine acute toxicity data set, however, no evidence is provided that there is no statistical difference between the two datasets. The MAC-QS_{eco, water} for the freshwater environment is based on an acute toxicity test result using the marine mysid *Mysidopsis bahia*. For the marine environment the MAC-QS_{eco, water} is based on the same data point to which an additional assessment factor of 5 applied. The use of this additional factor 5 is justified by stating that the proposed factor of 10 can be lowered because an acute result for the marine mollusc *Crassostrea virginica* is available. SCHER fails to see how the magnitude of this applied assessment factor was derived.

For secondary poisoning, the monkey subchronic study is used instead of the rat 2-generation study, although the NOAEL for rats is lower than the NOAEL for monkeys. The argument that the monkey study gives a lower value for the EQS is not convincing, as the only reason is the use of a larger AF as this is subchronic instead of a chronic study.

Based on the available information and the guidance given in the TGD-EQS the SCHER is of the opinion that the EQS values, except for the EQS values for the marine environment, have been appropriately derived.

A considerable number of studies have become available in the recent years which may allow for the QS for sediments to be 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_{nh via fishery products} and has been correctly identified.

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 acceptable quality standard
PEC	Predicted Environmental Concentration
PBT	Persistence, Bioaccumulation and Toxicity evaluation
TGD-EQS	technical guidance document- environmental quality standard
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