



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Heptachlor

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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## 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 heptachlor

There are no specific requests on heptachlor

## 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;

Although the dossier distinguishes heptachlor and heptachlorepoxide and provides some distinctly differing physicochemical properties as well as BCFs and BMFs, it does not clearly state if the toxicity values obtained from the literature are for heptachlor itself or for the epoxide. The dossier derives a "Environmental Quality Standard for heptachlor including heptachlor epoxide". It remains unclear if, when implementing the QSs derived, concentrations monitored in the environment should be evaluated based on the sum of heptachlor and its epoxide, or on the most abundant one of the two.

The proposed AA-QS and MAC-QS for freshwaters and marine waters and for sediments are very low and probably close to or below current analytical limits of detection.

For the derivation of the MAC-QS<sub>freshwater</sub> and the AA-QS<sub>freshwater</sub> a dataset of acute toxicity data on a single species from each trophic level (algae, invertebrates, fish) of sufficiently reliable quality (i.e. Klimisch 1 or 2 categories) is available in the dossier. The dossier does not indicate explicitly if other, less sensitive data are available, nor if any other data sets have been evaluated, e.g. with regard to their data quality. For marine algae, freshwater invertebrates, sediment invertebrates, and freshwater fish according to the dossier there is "*no available information*". The USEPA Ecotox database (<http://cfpub.epa.gov/ecotox>) alone provides 45 acute toxicity data for marine fish and >119 data for freshwater fish. It remains unclear to SCHER whether these data were considered, and, if they were, why they were not included and/or evaluated.

Similarly, only a single value for chronic toxicity in a marine fish is available in the dossier, whereas more data can be found in the database quoted above. A factor of 100 is applied to the lowest acceptable LC<sub>50</sub> (for a marine invertebrate) to derive the MAC-QS<sub>freshwater</sub>. A factor of 1000 is applied to the same LC<sub>50</sub> to derive a AA-QS<sub>freshwater</sub>. It is the opinion of the SCHER that the procedure for derivation of these QSs is appropriate. For the derivation of MAC-QS<sub>marine water</sub> and AA-QS<sub>marine water</sub> it is the opinion of the SCHER that the application of an additional factor of 10 is not justified, as explained in an earlier document (SCHER 2010), the more so since the most sensitive organism on which the proposed AA-QS is based is a marine species.

For the selection of the BCF value several relatively high values reported in the literature were rejected; some for acceptable reasons (exposure to contaminated water and food simultaneously), some for less convincing reasons (96h exposure considered insufficient for evaluating bioaccumulation, but a longer exposure duration is likely to result in an even higher concentration in the organism, and hence a higher BCF than the value of 21300 obtained in that test could be expected).

However, since these values were invariably higher than the one selected for the derivation (14400), some doubt exists on the representativity of the BCF value selected for deriving secondary poisoning-related QSs. The actual value of the QS derived could be lower than the one proposed, but is unlikely to be lower than a factor of 2 than the value currently proposed.

SCHER can accept the proposed BMF1 (i.e. 2.26) and BMF2 (19.8) values, noting however that these originate from a single study, whereas other studies were (probably rightly) rejected as a result of errors in equations or because they had not been normalised to trophic levels in the original publication.

The derivation of the QS for human health is based on the carcinogenicity effects observed in mice which are considered to cover potential endocrine disrupting effects because in a study with dogs no other effects than hepatic and developmental ones were observed which were not attributable to endocrine disruption. This was also the reason why no additional assessment factor was applied.

The calculation of AA-QS for freshwater from the  $QS_{\text{biota human health}}$  is based on the same BCF value (14400), the selection of which was discussed above. Therefore the proposed AA-QS may still be too high.

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

Whether or not the most critical EQS has been derived cannot be judged by SCHER on the basis of the information provided in the dossier. The  $QS_{\text{biota hh}}$  is properly evaluated to be the most critical EQS when using the data provided in the dossier, but the SCHER considers that (i) more information should be provided if and why other acute and chronic toxicity data have been rejected for evaluation and (ii) that, because of the uncertainties mentioned above (in particular the selection of the BCF value), there are some doubts on the proposed value of the MAC and EQS.

**4. LIST OF ABBREVIATIONS**

AA-QS	annual average quality standard
EQS	environmental quality standard
MAC-QS	maximum acceptable quality standard
TGD-EQS	technical guidance document- environmental quality standard
BMF	
BCF	

**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