



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Fluoranthene

SCHER adopted this opinion at its 12<sup>th</sup> 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 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 Fluoranthene

### **SCHER is requested to comment on one additional point:**

*Section 7.1.2: page 23: Calculation of AA-QS<sub>marine water, sed</sub> -choice of AF*

In the dossier, an AF of 50 is used for calculation of the marine sediment AA-QS on the grounds that "for marine sediment, acute studies are available for annelids, molluscs, crustaceans and echinoderms but for crustaceans only for the chronic dataset (see table at top of page 23). Therefore, an assessment factor of 50 is applied to the lowest value of 41 mg.kg<sup>-1</sup><sub>dw</sub> for derivation of AA-QS<sub>marine water, sed</sub>."

However, there appears to be another possibility, i.e. that some of the "acute" dataset could be used alongside the chronic data for crustaceans, and that the AF for marine sediment would then be 10 rather than 50. The argumentation for this can be summarised as follows:

"The marine studies with benthic annelids, crustaceans and echinoderms appear chronic rather than acute; exposure duration is at least 10 days. The AF of 10 covers all observed effects, even the individual observations for species for which more than one study is available. With 8 species with a reliable NOEC or EC10 of which 4 are marine species (2 taxa), and additional information in the form of (sub)chronic EC50s for marine species from additional taxonomic groups, an AF higher than 10 could not be justified. This is confirmed by the water data for which there are many marine data available, but they do not show an increased sensitivity compared to freshwater species."

Against this argument, the point is made that the LC50 of 18 for the molluscs from the acute dataset is at the low end of the range of data in the chronic dataset (which are NOECs or LC10s - lowest value = 9), suggesting that the chronic dataset may not cover the most sensitive species. The uncertainty would justify an AF of 50.

The SCHER is asked to consider the above argumentation and comment on the choice of AF.

## 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 fluoranthene are in accordance with those prescribed in 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 (cf. 3.3.). 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.). The SCHER had no access to this document and was 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. Furthermore, SCHER notes that under section 7.1.2 of the draft EDS the normalisation to 10% organic carbon is not according to the TGD (which notes that normalisation to 10% should be done). The consequences of this difference should be assessed.

Notwithstanding 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 critical QS proposed in the draft EQS documents is based the QSbiota-hh for the protection of human health via consumption of fishery products. 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). The top predator value seems to have been correctly derived according to the TGD. The SCHER does not support a linear extrapolation of animal tumour incidences down to human exposures, but, like EFSA, prefers a Margin-of-Exposure approach.

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

As for anthracene, the SCHER does not agree with the procedure and justification for calculating the AA-QS for marine sediments. The SCHER supports the second approach mentioned under 2.2., i.e. that "the marine studies with benthic annelids, crustaceans and echinoderms appear chronic rather than acute; exposure duration is at least 10 days. ../.." . The SCHER notes that this argument was also used in the naphthalene dossier to justify the size of the AF. The counter-argument given, i.e. the chronic data may not cover the most sensitive species... and thus an AF of 50 is needed, is not supported by the scientific fact. Indeed, the fact that an acute LC50 is close to (but higher than) the lowest NOEC is reassuring, since photo-active substances such as fluoranthene are characterised by their high acute toxicity.

The SCHER is of the opinion that a AF of 10 should be used, i.e. the second approach mentioned under 2.2.

#### **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