



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

5-6 rings Polycyclic Aromatic Hydrocarbons (PAH)

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.

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

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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 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 PAH

The introductory section of the EQS dossier explains why the food standard for Benzo(a)pyrene has been proposed as the basis for the standard for a sub-group of four of the five PAHs, and a separate standard for the non-carcinogenic Benzo(g,h,i)perylene. The SCHER may wish to comment particularly on whether measuring Benzo(a)pyrene as the marker for the three other carcinogenic PAHs in the group is appropriate.

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 PAH are in accordance with those prescribed the TGD-EQS (2010). The SCHER welcomes the discussion on the pro- and cons of the various approaches which could be used to derive an QS for these five substances. The SCHER agrees with this analysis, with the final procedure selected and with the possible limitations (p.4) of the procedure, i.e. ‘..the current proposal is based on the strict application of the TGD recommendation to use existing standards, might, in some cases, be less conservative than the current approach where the sum of certain PAHs is considered’.

Regarding human health endpoints, the draft document transparently describes the options for deriving quality standards for the 5-6 ring PAHs with a clear characterization of advantages and limitations of the different options. Carcinogenicity is correctly identified as the endpoint of concern for all members of the group except benzo(g,h,i)perylene. Potency considerations made are supported by the available literature. The decision to use food limits for benzo(a)pyrene as a basis for deriving QS is scientifically well justified and acceptable to SCHER regarding human health related endpoints.

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 document is based on the QS_{biota-hh} for benzo(a)pyrene (derived from the maximum level in Foodstuffs – Reg. 1881/2006/EC). 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).

For benzo(g,h,i)perylene the QS is driven by the AA-QS_{water-eco}. The SCHER is of the opinion that this is the most critical QS.

3.3. Response to the specific question regarding the use of the food standard for Benzo(a)pyrene as the basis for the standard for a sub-group of four of the five PAHs

The SCHER agrees with the approach and use of the food standard for Benzo(a)pyrene as the basis for the standard for a sub-group of four of the five PAHs, and a separate standard for the non-carcinogenic Benzo(g,h,i)perylene. The SCHER supports the use of Benzo(a)pyrene measurement as a marker for the three other carcinogenic PAHs in the group.

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