



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Dioxins

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 (rapporteur)
Prof. Arielle Gard
Prof. Colin Janssen
Prof. Jan Linders (chair)
Prof. Jose Tarazona (co-rapporteur)
Prof. Marco Vighi

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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 Dioxins

The SCHER is asked to consider **the two generic questions in the request**, as well as the following **specific point** related to the second generic question.

The dossier does not currently contain corresponding water values, although it has been proposed that they be derived, at least for dioxin-like PCBs. The SCHER is asked to comment on the appropriateness of the three possible monitoring matrices (biota, sediment, water).

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;

A joint dossier covers dioxins and dioxin-like compounds (sometimes dioxins and dioxin-like compounds are referred to as "dioxins"). The dossier includes:

- seven polychlorinated dibenzo-*p*-dioxins (PCDDs) out of 75 theoretical possible congeners;
- 10 polychlorinated dibenzofurans (PCDFs) out of 135 theoretical possible congeners;
- 12 dioxin-like polychlorinated biphenyls (DL-PCBs) out of 209 theoretical possible congeners.

The justification for grouping 2,3,7,8-substituted PCDD/Fs and coplanar PCBs is based on a common mechanism of action through the Ah receptor. Additivity among the different components of the group is assumed, and thus, the environmental quality standard (EQGs) for PCDD/Fs and PCBs are intimately related and should be considered concurrently. The estimate of the toxic potency of a sample, relative to 2,3,7,8-TCDD, is defined in terms of the toxic equivalency unit (TEQ) and is the sum of the individual congener concentrations multiplied by their respective TEFs. The SCHER supports this approach.

Despite the huge amount of information generated on dioxins and dioxin-like substances during the last decades, the dossier presents a very limited basis for setting the EQS, and does not properly justify the proposed QS values for sediment and secondary poisoning.

The QS for sediment seems to be based on the US NOAA (2008) screening quick reference tables, which refers to the Canadian guidelines. The SCHER notes the disclaimer in the US screening tables "*These tables were developed for screening purposes only; they do not represent official NOAA policy and do not constitute criteria or clean-up levels*". The Committee also notes that the Canadian values are interim proposals (Interim sediment quality guidelines, ISQGs). The SCHER considers that setting an EQS under the WFD based on screening/interim values proposed in other jurisdictions, without a clear analysis of the data and methodologies applied by the other bodies, and without a proper assessment of their applicability regarding the WFD objectives, cannot be justified.

Therefore, the Committee cannot support the proposed value. A clear and scientifically sound description presenting the rationale for the proposed value should be provided in the dossier.

A similar situation is observed for the QS for secondary poisoning. The QS is derived from a NOEC referred to as being from a presentation at a scientific meeting cited by the EU Scientific Committee on Food: "Faqi A.S., Dalsenter P.R., Merker H.J. and Chahoud I. (1997). *Reproductive toxicity and tissue concentrations of low doses of 2,3,7,8-tetrachlorodibenzo-p-dioxin in male offspring rats exposed throughout pregnancy and lactation*. 25th Anniversary Meeting of the European-Teratology-Society, Cannes, France, Academic Press Inc. Cited in EC, 2001."

The SCHER notes that in reality the reference in the Scientific Committee on Food opinion is to a published paper (Faqi et al. 1998), and that both the Faqi paper and the SCF opinion are oriented on the human health effects and do not include any direct proposal regarding an ecologically relevant NOEC value of 6.9×10^{-5} mg/kg biota ww.

The effects of dioxin and dioxin-like compounds on reproduction and development seem to be a proper foundation for setting the EQS for wildlife, due to their sensitivity and ecological relevance. However, as the work from Faqi, the SCF and others has been extensively reviewed recently, (e.g. Bell et al., 2010; Bursian et al., 2011), the SCHER considers that the dossier should be updated accordingly.

Therefore, as for the QS for sediment, the Committee cannot support the proposed value. A clear scientifically sound description and rationale using the most recently derived TEQs for the proposed value should be provided in the dossier.

In addition, the Committee also notes that only the TEFs for human health (mammals) are presented in the opinion. The TEF values for birds and fish as developed by the WHO (Van den Berg et al., 1998; 2006) should also be considered, and use be made of those for the relevant taxonomic groups, as appropriate. The human health assessment should be revisited. Tolerable daily intakes based on TEQs for humans have been derived by a variety of organizations and the critical studies considered by these organizations should be used for assessment. The study used for deriving an EQS for dioxin-TEQs is based on results with 2,3,7,8-tetrachlorobenzodioxin and therefore likely to be conservative since other polychlorinated dioxins have a lower potential for toxicity. Moreover, the document would benefit from expressing all numbers in the same units to improve readability, and a short description of the process and the justification for deriving each value.

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

Although the SCHER cannot support the proposed EQS for environmental impacts, it seems acceptable to consider that the most critical EQS for this group are those associated with bioaccumulation/biomagnification. Therefore, the most critical EQS should be related to human health or wildlife secondary poisoning. The dossier directly identifies human health as the most critical EQS, and this is likely correct as human health requires a level of protection at the individual level while the wildlife protection is set at the population level. However, due to the higher level of exposure expected for some species, and the specific protection required for some endangered top predator species, SCHER cannot provide a final answer before a proper derivation of the EQS for secondary poisoning is presented.

3.2. Responses to the specific requests on Dioxins

On the specific question, the SCHER agrees on the uncertainties, difficulties and low relevance of setting EQS for the pelagic community based on waterborne exposure.

However, on the monitoring issue, the Committee proposes the following consideration.

As previously suggested (SCHER, 2010), the derivation of the EQS should consider all relevant information and should develop case specific methodologies whenever needed. In this particular case, the possibility for using biomarkers and other biological alternatives for monitoring purposes should be investigated.

The rationale for a group QS is the common mechanisms of action, through the Ah receptor. The joint effects can be considered as additive and therefore quantified on the basis of their relative potencies using the TEF approach.

There is a large number of methods, and even commercially available tools, that offer quantitative measurements of the Ah receptor mechanism and CYP4501A induction. Several of them can be used for direct measurements of environmental samples. In fact, these tools have been already used for monitoring purposes (e.g. Brack et al., 2005, 2007).

The SCHER considers that the applicability of these methods should be reviewed in the dioxin dossier. The direct measurement of the biological responses associated to the Ah receptor in water and sediment samples may provide a proper and rapid quantification of the overall potency of dioxin and dioxin-like compounds in the sample, that can be easily expressed as 2,3,7,8-TCDD toxic equivalency unit (TEQ).

Screening, tentative and even definitive EQS for surface water, suspended matter and sediments could be developed using biological responses instead of the expensive and time-consuming chemical analysis.

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
HC5	hazardous concentration for 5% of the species
MAC-QS	maximum allowable concentration quality standard
PEC	Predicted Environmental Concentration
PBT	Persistent, Bioaccumulative and Toxic
SSD	species sensitivity distribution
TGD-EQS	Technical Guidance Document - Environmental Quality Standards
WFD	Water Framework Directive

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