



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Dicofol

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.

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 (rapporteur)
Prof. Colin Janssen
Prof. Jan Linders (chair)
Prof. Jose Tarazona
Prof. Marco Vighi
Prof. Pim 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**.

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 Dicofol

The SCHER is asked to consider the two generic questions in the request.

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;

The Dicofol data set is incomplete because it is a pesticide that has not been registered by producers, who have ceased its manufacture. So only old studies are available, and some of them have been invalidated in the EQS report, due to lack of analytical control. Particularly, there is no NOEC in invertebrates, which are the most sensitive taxon, according to validated acute values. Therefore, neither MAC-EQS nor AA-EQS could be derived for pelagic and benthic organisms in freshwater and marine waters. SCHER agrees with this, as it was demonstrated further that the most critical EQS could indeed be derived from secondary poisoning data, as explained below.

As there are enough chronic mammalian/birds data, derivation of EQS for secondary poisoning was possible (biota and human health through fish consumption). The SCHER is of the opinion that $QS_{\text{biota, sec.pois (ww)}}$ has been derived according to the TGD-EQS procedures, using recommended AF (90) and a 90 day NOAEL in rat.

The $QS_{\text{biota, hh}}$ for fish consumption is based on the NOAEL from a one-year dog study which is considered of adequate quality by the US EPA. In contrast, the QS for secondary poisoning of top predators uses a 90-day rat study as basis. This study gave the lowest NOAEL from a range of studies covering chronic toxicity and reproductive and developmental toxicity. NOAELs were 3 to > 20 fold higher. When integrating the available database, the results on toxicity testing do not show specific effects on endpoints potentially related to "endocrine disruption". Therefore, the decision to not use an additional factor for potential endocrine effects is additionally justified. The assessment factor of 300 used for extrapolation from the dog study is not justified in the document; based on the toxicity profile, an AF of 100 is considered adequate by SCHER since a 2-year feeding study in rats gave a NOAEL of 0.22 mg/kg bw/day. This study served as a basis for defining an acceptable daily intake by WHO.

The QS for drinking water corresponds to the general precautionary standard used for pesticides

The SCHER agrees with the BCF value chosen for back calculation of corresponding EQS in water from $QS_{\text{biota, sec.pois}}$. However, the SCHER considers that the publication by Kelly et al. (2007a and b) has been misinterpreted, and that the BMF1 used in the EQS dossier has therefore been wrongly derived. BMF2 could also be derived from Kelly et al. (2007a and b), and the SCHER therefore disagrees with the choice of the default value of 10 used in the EQS dossier. Therefore SCHER is of the opinion that $QS_{\text{biota, sec.pois}}$ in freshwater and marine waters have not been correctly back calculated.

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

The SCHER considers that the most critical EQS in terms of impact on environment/health has been correctly identified, namely the QS_{biota} .

3.2. Responses to the specific requests on Dicofol

i) The SCHER is asked to consider the two generic questions in the request.

For the substance Dicofol there are no additional requests to the SCHER. Therefore, no further action is needed from the SCHER.

4. LIST OF ABBREVIATIONS

AA-EQS	annual average environmental quality standard
AF	Assessment Factor
EQS	environmental quality standard
MAC-EQS	maximum acceptable environmental quality standard
NOAEL	no observed adverse effect level
TGD-EQS	technical guidance document- environmental quality standard
QS _{biota, hh}	Quality Standard based on human health
QS _{biota, sec. pois.}	Quality Standard based on biota secondary poisoning
QS _{biota, sec. pois. (ww)}	... (weight/weight)

5. REFERENCES

Kelly B.C., Ikonomidou M.G., Blair J.D., Morin A.E. and Gobas F.A.P.C. (2007a). "Food Web-Specific Biomagnification of Persistent Organic Pollutants." Science **317**(5835): 236-239.

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