



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Bifenox

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.

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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 Bifenox

The SCHER is asked to consider **the two generic questions in the request**. There are no additional points, but the SCHER is asked to note that the MAC-QS derivation the industry had favoured a higher value (0.2 µg/l) based purely on the mesocosm SSD; however, the value in the dossier (0.04 µg/l) is now based on both the originally proposed AF-based EQS and the mesocosm SSD EQS, taking a weight-of-evidence approach.

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;

Bifenox is an herbicide used for "control of broad leaved weeds in post-emergence applications in winter cereals". The dossier includes a set of laboratory ecotoxicity data, covering the three taxonomic groups, and a mesocosm study. The mesocosm study addressed the effects on phytoplankton and macrophytes of a formulation containing bifenox and two additional active substances. The dataset indicates high toxicity for the three taxonomic groups.

The derivation of the MAC-QS_{freshwater, eco} is based on a weight of evidence approach, combining the information generated in the mesocosm and in the laboratory studies. The dossier concludes that the NOEC from the mesocosm cannot be directly used for the EQS derivation. The reason is that only the initial concentration is reported and significant dissipation via adsorption to the sediment is expected. The EFSA Scientific Report (2007) suggests a DT50 in water/sediment systems well below 1 day, supporting this statement; it should be noted that this DT50 refers to dissipation from water, no degradation, but nevertheless confirms a rapid reduction, within hours, in the expected waterborne exposure level following the application of bifenox. As there is a good quality laboratory study on the most sensitive species/family (laboratory and mesocosm), the dossier suggests the use of the laboratory NOEC as equivalent to the short-term mesocosm NOEC. The SCHER considers that this approach represents a proper evaluation of the available evidence. The Committee does not support the industry proposal for using directly the mesocosm data as no twa-MEC is available.

The SCHER cannot comment on the proposed AF of 3 as the only justification in the dossier is that this would be the AF used for the mesocosm NOEC, without discussing why this value is considered appropriate for covering the remaining uncertainty.

The AA-QS_{freshwater, eco} is derived using the standard approach, an AF of 10 on the most sensitive laboratory NOEC is applied as the three taxonomic groups are included in the dataset. The SCHER agrees with this proposal as the mesocosm study is based on a single application and cannot be used for assessing potential long term effects.

The dossier states that "*Significant differences between freshwater and marine species cannot be demonstrated from the information available*", however, still applies an additional factor of 10 in the derivation of the MAC- and AA-QS_{saltwater, eco}. As indicated before (SCHER, 2010) the Committee does not support this approach

and considers that potential differences between freshwater and marine ecosystems should be assessed case-by-case based on the available information and not by a generic addition of an additional factor of 10.

The bioaccumulation potential is clearly indicated by the bioconcentration factor in fish. The dossier properly justifies the selection of the BCF value and the ecological relevance of the mammalian NOEC used in the assessment. The SCHER agrees with the proposed QS value.

Issues regarding human health are adequately covered by the derived EQS.

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, the pelagic community, in terms of impact on environment/health has been correctly identified

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
twa-MEC	time-weighted averaged Measured Environmental Concentration
WFD	Water Framework Directive

5. REFERENCES

EFSA Scientific Report (2007) 119, 1-84, Conclusion on the peer review of Bifenox.

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