Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Cybutryne

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 (EMEA), 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[1] 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 cybutryne

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 EQS for cybutryne are based on an extensive data set of toxicity data on several freshwater and marine organisms (including some typical marine taxa).
Algae and other photosynthetic organisms are the most sensitive, with acute and chronic toxicity values usually at least two orders of magnitude lower than other aquatic organisms. The calculation of EQS has been mainly focused on these organisms. It is the opinion of the SCHER that the approach is appropriate.

The MAC-QS has been calculated using three different approaches: assessment factor, SSD and micro/mesocosms. The following comments can be made:

- Assessment factor method: considering the large amount of data on the most sensitive organism, the use of an AF of 10 is justified.
- SSD method: a good SSD curve has been calculated on more than 30 toxicity data on freshwater and marine primary producers. An AF of 8 has been applied to the HC5. The criterion for using an AF of 8 is not fully explained..
- Micro/mesocosm method: good studies on marine algal communities have been considered with an AF of 5, taking into account some uncertainties in the available studies.

The values of MAC-QS calculated with the three methods are very similar (9.6, 16 and 14 ng/L respectively). The dossier proposes as MAC-QS for fresh and marine water the value calculated with the SSD method (16 ng/L) assumed as the most reliable. Considering the fit of the SSD curve, based on a large number of data of the most sensitive taxonomic group, it is the opinion of the SCHER that the value of 16 ng/L) is appropriate.

The same procedure has been applied for the calculation of the AA-QS. The following comments can be made:

- Assessment factor method: the use of an AF of 10 is justified.
- SSD method: an AF of 3 has been applied to the HC5. Enough justification is provided for the AF.
- Micro/mesocosm method: studies on freshwater and marine mesocosms have been considered with an AF of 2.

In this case too, the values of AA-QS calculated with the three methods are very similar (1.7, 2.5 and 2 ng/L respectively). The dossier proposes as AA-QS for fresh and marine water the value calculated with the SSD method (2.5 ng/L).

QSs for sediments, secondary poisoning and human health are correctly derived.

Considering the amount of information used and uniformity of the results obtained with the different procedures the SCHER is of the opinion that the EQS for the substance cybutryne are appropriate.

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

As a consequence of the position of the SCHER taken under 3.1.1, the most critical EQS (in terms of impact on environment/health) has been correctly identified.

3.2. Responses to the specific requests on cybutryne

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

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
MAC-QS	maximum allowable concentration quality standard
PEC	Predicted Environmental Concentration
PBT	Persistent, Bioaccumulative and Toxic
$QS_{human\ health}$	Quality Standard based on human health
TGD-EQS	Technical Guidance Document - Environmental Quality Standards
WFD	Water Framework Directive

5. REFERENCES