Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Diclofenac

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 (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 diclofenac

The SCHER is asked to consider **the two generic questions in the request**, as well as the following **additional points** on which it has not been possible for the Members of the Sub-Group on Review of Priority Substances to agree.

In particular, the industry stakeholders (AESGP-EFPIA) do not agree that there is sufficient evidence to set an EQS at all, not least because they do not accept the reliability of one of the key studies and the significance of the endpoint. Their points are expressed in the accompanying **issue paper**.
The position of the dossier lead (DE) and several other MS is that there is already sufficient evidence to set an EQS. However, an additional study would allow refinement of this EQS. Their points are expressed in the accompanying **statement paper**. Some edits have been made to the paper since it was first drafted and forwarded to the industry stakeholders.

Documents containing **reciprocal comments** on the issue paper and the statement paper are also provided, as are two earlier industry stakeholder papers (one dating from before EQS derivation began in earnest) although they mostly duplicate the information in the other two industry documents.

The SCHER is invited to consider the respective comments and the possible value of conducting the additional study proposed in the statement paper.
Additional information on discussions held at the Sub-Group meetings can be provided, and if the SCHER Members were interested, it might be possible to hold further discussions at the next Sub-Group meeting on 14 December, in which they could participate.

Additional notes:
a) The dossier lead notes that two studies referred to as "Novartis internal data", i.e. on *Danio reri*o (relevant to MAC derivation) and on baboon (relevant to $QS_{biota,hh}$ derivation) have not yet been provided by the industry and it has therefore not been possible to validate them.
b) The dossier lead notes that the proposed AA-EQS could be refined if additional tests were conducted, e.g. a 90 day ELS with rainbow trout (covering histopathology, survival, growth and development parameters). An OECD 305 bioaccumulation test could reduce the uncertainty in the estimated whole body BCF for fish. To reduce the AF for the calculation of the QS_{biota} a chronic or at least subchronic avian test should be available. In the absence of these, the proposed **AA-$QS_{freshwater,\ eco}$** (0.1 µg/L), **AA-$QS_{marine\ water,\ eco}$** (0.01 µg/L) and **$QS_{water,\ sec\ pois}$** (0.007 µg/L) should be used.

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 dossier presents some controversial points that make difficult a precise judgment of the reliability and correctness of the results. The first point is the water solubility reported with two fully different values: 2.37 mg/L and 53.1 g/L. The second value is in disagreement with the logKow of about 4. Justification for these

differences are not provided. In the literature different values are reported, from poorly soluble (less than 1 mg/L) to highly soluble (about 1800 mg/L) as a function of the different chemical forms (Llinas et al., 2007). The issue is relevant for at least two reasons: if the solubility is in the range of a few mg/L many toxicity values (most data used for MAC and some data used for AA-QS) are unreliable because they are far above the water solubility; if the solubility is very high, the hypothesis of bioaccumulation and secondary poisoning is not supported.

The second controversial point is the dataset used for the derivation of the $MAC_{freshwater}$. A complete dataset (algae, invertebrates, fish) of acute toxicity data is reported. However, the reliability of the fish data is classified as "not assignable" (score 4), two values (quoted paper not reported in the reference list) are below 1 mg/L, while the third value available is much higher (82 mg/L) and derives from a Novartis document not supplied. For the derivation of the $MAC_{freshwater}$ the toxicity on *Lemna minor* is used even though fish are the most sensitive organisms, as confirmed by reliable chronic data. If acute fish data are not considered due to their low (or uncontrolled) reliability, it is the opinion of the SCHER that the data set is insufficient for the derivation of MAC-$QS_{freshwater}$

For the derivation of the AA-$QS_{freshwater}$ a complete dataset (algae, invertebrates, fish) of enough reliable toxicity data is available. A factor of 10 is applied to the lowest acceptable NOEC on fish. It is the opinion of the SCHER that the procedure is appropriate. For the derivation of AA-$QS_{marine\ water}$ it is the opinion of the SCHER that the application of an additional factor of 10 is not justified.

A quality standard for secondary poisoning has been calculated considering some particularly sensitive organisms (bird of the *Gyps* genus). It is the opinion of the SCHER that the AA-$QS_{secondary\ poisonong}$ is appropriately derived. However, the EQS value may be influenced by the reliability of the BCF values.

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

The SCHER considers that, in view of the uncertainties mentioned above, there are some doubts on the identification of the most critical EQS.

3.2. Responses to the specific requests on diclofenac

Different data produced independently by different authors indicate comparable chronic NOEC values for fish. It is the opinion of the SCHER that the objections made the industry stakeholders on the reliability of the data for the derivation of the AA-$QS_{freshwater}$ are not justified. The industry stakeholders state that the ecological relevance of the end point measured (histopathological damages in kidneys) for the population dynamics of fish is questionable. It is opinion of the SCHER that fish population decline due to this kind of endpoint is documented in the literature (Schwaiger et al., 2004; Triebskorn et al., 2004). However, transferring this very specific endpoint to other taxonomic groups of the community may be questionable. Therefore, it is the opinion of the SCHER that the proposal of the dossier lead of adopting the proposed **AA-$QS_{freshwater}$,** as preliminary to be refined on the basis of additional chronic fish tests is acceptable.

It is also the opinion of the SCHER that the uncertainty of the AA-$QS_{secondary\ poisoning}$ may be reduced on the basis of whole body fish BCF assessment and a chronic avian test.

4. LIST OF ABBREVIATIONS

AA-QS	annual average quality standard
EQS	environmental quality standard
MAC-QS	maximum allowable concentration quality standard
TGD-EQS	Technical Guidance Document - Environmental Quality Standards
WFD	Water Framework Directive

5. REFERENCES

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