Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Quinoxyfen

SCHER adopted this opinion via written procedure on 15 June 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**.
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 quinoxyfen

The SCHER is asked to consider the two generic questions in the request, as well as an additional point.

The additional point is addressed in the two documents that accompany the dossier. It concerns the question of whether Quinoxyfen should be considered to have PBT properties. It has not been possible for the Members of the Sub-Group on Review of Priority Substances to agree on this point[2]. A suggestion was made that the question be referred to the EU PBT Working Group, but this no longer exists.

The position of the industry stakeholder, Dow AgroSciences, is that Quinoxyfen is not expected to be accumulated by aquatic organisms at levels of concern or over prolonged periods of time (see first background document). The contrary position is that Quinoxyfen should be regarded as bioaccumulative and even very bioaccumulative (see second background document). The monitoring studies in DE, IT and SE referred to in section (b) of the Dow AgroSciences document can be provided if required.

DG Environment wishes to ensure that the conclusion drawn is consistent with REACH guidance and with the conclusions drawn in other risk assessment contexts (i.e. other than in the context of the Water Framework Directive) according to the same guidance.

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;

Based on the available information and the guidance given in the TGD-EQS the SCHER is of the opinion that the EQS for the substance Quinoxyfen have been derived correctly and appropriately. As stated in the EQS dossier, significant differences between freshwater and marine species cannot be demonstrated from the information available. Therefore SCHER is not convinced of the need for a different assessment factor to distinguish between fresh water and marine water and therefore the SCHER recommends to use the same EQS for fresh water and marine water: AA-EQS = 0.152 µg/L and MAC-EQS = 2.7 µg/L.

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 $QS_{freshwater,eco}$.

[2] The DT_{50} in soil cited in the EQS dossier meets the criterion for persistence, but agreement could not be reached on bioaccumulation.

3.2. Responses to the specific requests on quinoxyfen

SCHER's opinion was required for quinoxyfen bioaccumulation assessment. (The persistence assessment did not appear to have been questioned.)

a) B/vB assessment

A new bioconcentration study: « Quinoxyfen multispecies bioconcentration study in rainbow trout (*Oncorhynchus mykiss*), algae (*Pseudokirchneriella subcapitata*) and Daphnid (*Daphnia magna*) » by Rick and McClymont (2011), was provided. This study was performed separately in the 3 species. For B/vB assessment, BCF in invertebrates and algae are of poor predictability, as adsorption in small organisms is higher by body weight and then BCF measured do not reflect bioconcentration only. The new fish BCF value confirms that found in a previous study (Woodburn et al., 1995) *i.e.* around 7500, lipid normalized. Relying to REACH guidance for PBT assessment (ECHA, 2008) and recent REACH Annex XIII amendment (Commission Regulation (EU) 253/2011), the SCHER concludes that quinoxyfen is a vB compound.

b) Discussion on modeling and monitoring results

Meregalli (2010) set up a model for predicting actual quinoxyfen bioconcentration in fish, and Kramer and Rick (2011) a model for predicting actual quinoxyfen bioaccumulation in a food web including algae, daphnids, small fish and larger fish. Both took into account realistic intermittent release, available kinetics (DT50: 7 days) of the substance in the water column, and uptake/clearance kinetics obtained in testing each organism (Woodburn et al., 1995, and Rick and McClymont (2011). Predicted quinoxyfen waterborne BCF in fish was below 2000, and both waterborne and dietary BCF in fish above 2000 during about 100 days a year. The results of the monitoring studies as cited in EQS dossier are consistent with those of the modelling in not demonstrating a tendency for quinoxyfen to bioaccumulate under field conditions.

SCHER's opinion is that the above results are explained by the low persistence in water and the emission pattern to water from intermittent application of quinoxyfen in the field. These results do not allow the conclusion that quinoxyfen is vB to be dismissed.

4. LIST OF ABBREVIATIONS

AA-QS	annual average quality standard
BCF	Bioconcentration Factor
ECHA	European CHemicals Agency
EQS	environmental quality standard
MAC-QS	maximum acceptable quality standard
PEC	Predicted Environmental Concentration
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation and Authorization of CHemicals
TGD-EQS	technical guidance document- environmental quality standard
vB	very Bioaccumulative

5. REFERENCES

ECHA (2008), Guidance on (REACH) information requirement and chemical safety assessment, Chapter R11, PBT Assessment

Commission Regulation (EU) 253/2011 of 15 March 2011 amending Regulation (EC) N° 1907/2006 of the European Parliament and of the Council on the Regulation, Evaluation, Autorisation and Restriction of Chemicals (REACH) as regards Annex XIII.

VJ Kramer and DL Rick (2011), Multi-trophic simulation of Quinoxyfen exposure and bioaccumulation potential, 20 April 2011, Dow AgroSciences confidential report

Meregalli (2010), Quinoxyfen - Assessment of bioaccumulation, 7 October 2010, Dow AgroSciences confidential report

DL Rick and EL McClymont (2011), Quinoxyfen multispecies bioconcentration study in rainbow trout (*Oncorhynchus mykiss*), algae (*Pseudokirchneriella subcapitata*) and Daphnid (*Daphnia magna*), 5 April 2011, Dow Chemical Company confidential report

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

KD Woodburn, DL Rick and HD Kirk (1995), The bioconcentration of XDE-795 in rainbow trout *Oncorhynchus mykiss* Walbaum, 19 June 1995, Dow Elanco confidential report