



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Cypermethrin

SCHER adopted this opinion at its 12th plenary on 30 March 2011

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TABLE OF CONTENTS

ACKNOWLEDGMENTS..... 3

1. BACKGROUND 5

2. TERMS OF REFERENCE..... 5

3. OPINION..... 6

 3.1. Responses to the general requests 6

 3.2. Responses to the specific requests on cypermethrin 8

4. LIST OF ABBREVIATIONS 8

5. REFERENCES 8

6. APPENDIX..... 9

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 cypermethrin

The SCHER is asked to consider the **additional points** on which it has not been possible for the Members of the Sub-Group on Review of Priority Substances to agree.

- i) In particular, there is disagreement about the EQS derived for freshwater (AA and MAC) and for sediment (AA).**
- ii) The question of whether the sediment EQS should be selected as the critical EQS is raised.**

The industry stakeholder (BASF) raises questions about the monitoring data and the feasibility of monitoring concentrations in the range of the proposed EQS. As pointed out by the rapporteur, these issues go beyond the scope of EQS derivation and are therefore also not for the SCHER to address.

BASF has provided a summary comments document (dated 3 Nov 2010) and a document on EQS derivation (dated 21 Sept 2010). It also provided an annotated version of the dossier dated 20 Sept (Cypermethrin_Dossier final Sept 2010_BASF 3rd comments.doc), but the relevant annotations have been reproduced and responded to in the rapporteur's response of 9 Nov. In its summary comments document, BASF makes reference to six other documents provided during the process. Most of these are also provided (zip file), although many of the points in them have been addressed or are raised in the summary. The first two documents are commentaries on the dossier before the EQS-derivation process began in earnest.

The rapporteur has slightly revised the 20 Sept dossier and provided a document (dated 9 November) responding to BASF's comments. Data tables (Excel file) accompany the dossier.

Additional notes:

- a) It appears that DE and the UK have derived AA-EQS (freshwater) for cypermethrin as a specific river basin pollutant that are similar to the AA-EQS proposed in the dossier.
- b) Cypermethrin is currently under review in the context of the Biocidal Products Directive. The RMS (BE) has derived a PNEC of 0.01 µg/l. It is probable that the EQS derivation is based on more studies. The BP dossier will be discussed at a Technical Meeting in March 2011.

3. OPINION

3.1. Responses to the general requests

In general the document appears quite imprecise, with many major and minor mistakes and inaccuracies, in particular in the reporting of toxicity data. This raises some doubts about the reliability of the data and, therefore, on the correctness of the conclusions, even if the procedures of the TGD-EQS are properly applied.

A detailed list of the problems observed is reported in an Appendix. Probably other inconsistencies could be observed checking more carefully original references.

Therefore, the database reported seems unreliable and the proposed EQS may be biased by this unreliability, even in the case of an appropriate application of the TGD procedure.

For the derivation of the MAC-QS_{water} for freshwater a factor of 10 has been applied to the HC5 derived from the SSD curve. The approach is appropriate, however, as mentioned before, the result may be biased by unreliability in reporting of the data.

For the marine environment an additional factor has been applied, according to the suggestions of the TGD. However, it was opinion of the SCHER (2010) that the additional safety factor of 10 as a default for marine ecosystems is not acceptable and needs to be justified case by case depending on the available data. In this case data are available for marine invertebrates (in particular crustaceans, supposed to be the most sensitive taxonomic group) and fish. So an additional factor seems not justified.

For the derivation of the AA-QS_{water} for freshwater the usual procedure of applying an assessment factor of 10 on the lowest NOEC value (0.0041 µg/L for the marine crustacean *Acartia tonsa*) was not applied because some acute LC₅₀ values are lower than this NOEC. Therefore, it was concluded that using an assessment factor of 10 on the lowest NOEC value would be insufficiently protective. The AA-QS_{water} was derived by applying an assessment factor of 50 on the lowest NOEC value resulting in 0.082 ng/L. The proposed procedure seems not justified and, as noted above, there is uncertainty about the reliability of the data.

For the derivation of the AA-QS_{sediment} for freshwater sediments, NOEC data on two sediment dwelling organisms (*Chironomus* and *Hyalella*) are available. The AA-QS_{sediment} is calculated by applying a factor of 50, according to the TGD. In this case, correct data from the literature (Maund et al, 2002) have been used.

For marine sediments, an additional uncertainty factor of 10 has been applied, so a final factor of 500 has been used. In this case too, the additional safety factor seems not justified, being data on the most sensitive organisms (crustaceans and insects) available for sediment organisms.

For the secondary poisoning, the reliability of data has not been checked. Considering the problems on aquatic data, probably a careful check is needed. The QS_{biota,secpois} has been calculated by applying a factor of 30 to the lower NOEC, according to the procedure proposed by the TGD-EQS.

In conclusion, it is the opinion of the SCHER that:

- the procedure described by the TGD-EQS has been properly applied for deriving the MAC-QS_{water} and the AA-QS_{sediment} for freshwater;
- the application of an assessment factor of 50 on the lowest NOEC value for deriving the AA-QS_{water} for freshwater is not enough justified;
- the application of an additional uncertainty factor of 10 for the marine environment is not justified;
- the procedure described by the TGD-EQS has been properly applied for deriving the QS_{biota,secpois} .
- the reliability of the data used is highly doubtful and this makes uncertain in any case the derivation of all the EQSs.

3.2. Responses to the specific requests on cypermethrin

Besides the problems underlined in the previous section, it is unclear what kind of disagreement about the EQS derived for freshwater (AA and MAC) and for sediment (AA) is highlighted by the Members of the Sub-Group on Review of Priority Substances. In particular, it is the opinion of the SCHER that the procedures used for deriving the MAC-QS_{water} and AA-QS_{sediment} for freshwater are appropriate.

Considering the physical and chemical properties of the substance, in particular the very low solubility and the very high lipophilicity, the sediments represent the compartment with higher potential exposure. However, in water bodies characterised by high concentrations of suspended solids, cypermethrin may largely adsorb on the particulate matter producing relevant risk if the total (not only the dissolved) component of the chemical is considered.

Therefore, it is the opinion of the SCHER that both sediment and water EQSs should be taken into account

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
WFD	Water Framework Directive

5. REFERENCES

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

EC (2005), Review report for the active substance cypermethrin finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 February 2005 in view of the inclusion of cypermethrin in Annex I of Directive 91/414/EEC. SANCO/4333/2000 final. 15 February 2005

Maund, S.J., Hamer, M.J., Lane, M.C.G., Farrelly, E., Rapley, J.H., Goggin, U.M. and Gentle, W.E. (2002) Partitioning, bioavailability, and toxicity of the pyrethroid insecticide cypermethrin in sediments. *Environmental Toxicology and Chemistry* 21, 9-15

6. APPENDIX

The data reported in the tables of acute and chronic effects (section 7.1 pages 8-10) are inconsistent with those reported in many original references quoted. Checking only some original references, more easily achievable, the following inconsistencies have been observed:

- Many data are quoted from EC 2006 (EFSA DAR on zeta-cypermethrin). The following imprecision have been noted:
 - The 96h EC50 on *Gammarus pulex* is reported as a geometric mean of four different values. It is not true, it is the result of a single test.
 - Toxicity data on *Ciprinus carpio* and *Scardinius erithroptalmus* and *Pimephales promelas* are reported in the table but these species are not mentioned in the DAR. The references quoted in the complete data tables are useless.
 - The 96h EC50 on *Oncorhynchus mikiss* is reported as a geometric mean of 10 different values. In the DAR only 4 values are reported, also considering the results of two tests on the formulations (10% cypermethrin).
 - If data on the formulations are used, the DAR reports long term NOEC for *Oncorhynchus mikiss* (21d), *Daphnia magna* (21d) and *Chironomus riparius* (28d). These data are not used while, in other cases, data on formulations are reported.
 - A 21d toxicity on *Daphnia magna* is reported (quoted as EC 2006) but it is not the same reported in the DAR. In the complete data tables is quoted as Linders;60 (reference unavailable).
 - The 21d NOEC on *Pimephales promelas*, (quoted in the table as EC,2006) is quoted in the complete data tables as Thorpe, 1983 (reference unavailable).
- The value of 0.129 µg/L as 96hEC50 for *Acartia tonsa* refers to eggs. The original paper (Barata et al., 2002) reports a value of 0.108 for adults and 0.005 for nauplii.
- Acute toxicity data for sediment dwelling organisms *Ampelisca abdita* and *Eohaustorius estuaries* do not correspond to those reported in the original paper (Anderson et al., 2008) that are more 10 times lower. Even applying the normalisation for the standard sediment, as proposed by the TGD, the results are different. Moreover the data are indicated as also reported by Willis & Ling (2004) and this is not true.
- Toxicity for *Acartia tonsa* is quoted from Willis & Ling (2004). However these authors also report data for other three copepods much more sensitive. Some of these data (e.g. *Temora longicornis*:48h EC50 0.12 µg/L) are quoted as Wilson & LeBlanc (1980), but the reference is not reported.
- Data on 10d NOEC on *Chironomus tentans* (Maund et al, 2002) do not refer to marine water but to freshwater sediments.
- The 10d NOEC for *Hyaella atzeca* reported in the same paper (Maund et al, 2002) is not those reported in the table (3.25 µg/kg) or in the footnote. The paper reports a NOEC range between <1.8 and 2.3 µg/kg. In this case too, data do not correspond even applying the normalisation for the standard sediment.
- A 24h NOEC for survival of *Chironomus tentans* cannot be assumed as a chronic effect. Moreover, in the paper of Muir et al. (1985) there is no mention on a 0.99 µg/L NOEC. The paper reports survival in sediments at 5 ng/g.
- The origin of the 96h NOEC of 0.0041 µg/L for *Acartia tonsa* is unclear. The figure is not reported in the original paper (Barata et al., 2002). Moreover, in the complete data tables, a value of 0.0041 µg/L is reported as 32d LC50.

Some additional minor comments are listed below.

Section 5.2 Abiotic and biotic degradation (page 4). Data on hydrolysis are reported at different pHs (3, 7, 11). However, some relevant European documents from which all these data are probably derived (e.g. EC, 2005) report also data at pH 8 (5-21 d, depending on isomer ratio), much more relevant for fresh and marine water than pH 3 or 11. It would be relevant reporting also this value.

6.1 Measured concentrations (page 7). The table of data is unclear. The footnote mention that "*Most measurements show concentrations below the LOQ*". However, it is unclear if the reported means represent the average of data above the LOQ. If this is the case it would be useful reporting the percentage of positive records.

Figure 1, page 11. The units on the x axis are not reported. Reasonably, they should be $\mu\text{g/L}$.

References in section 5.1. It would be better quoting the reference Anonymous (2002) as Tomlin (2002) as in the June version. So the origin of the data would be more clear. The Anonymous (2002) is not mentioned in the reference list.