



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

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

Aclonifen

SCHER adopted this opinion at its 12<sup>th</sup> 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.

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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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**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 aclonifen .....7

4. LIST OF ABBREVIATIONS .....9

5. REFERENCES .....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 information<sup>1</sup> and the TGD-EQS;**
- 2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

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<sup>1</sup> 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 aclonifen**

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

- i) The first additional point relates to the derivation of the MAC-QS. The position of the industry stakeholder is explained in the Bayer CropScience document that accompanies the dossier. The rationale for the approach taken in the dossier, which results in a more stringent MAC-QS, is explained in the dossier itself.
- ii) The second additional point concerns the question of whether aclonifen should be considered to have PBT properties, specifically whether aclonifen satisfies the persistence criterion. This point is addressed in the dossier itself, in the Bayer CropScience document and in the document commenting upon it. The position of Bayer CropScience is that aclonifen does not satisfy the persistence criterion. The contrary position is that there is evidence from sediments and soils that the persistence criterion is satisfied. All three documents make reference to the temperature dependence of aclonifen degradation, including the question of whether/how results are normalised, and to the issue of bound residues. The two sediment studies referred to in the dossier have not been made available to the dossier rapporteur. The soil studies have been provided to the rapporteur and can probably be made available to the SCHER if necessary.

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 aclonifen have been derived correctly and appropriately.

#### **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 aclonifen**

- i) The first additional point relates to the derivation of the MAC-QS. The position of the industry stakeholder is explained in the Bayer CropScience document that accompanies the dossier. The rationale for the approach taken in*

*the dossier, which results in a more stringent MAC-QS, is explained in the dossier itself.*

In the EQS-dossier of aclonifen the reasoning of the experts of Working Group E is given based on the information on the substance in the evaluation dossier for aclonifen as a plant protection product for weed control in agriculture and horticulture. The ecotoxicological data available for aclonifen are used to establish an AA-EQS and a MAC-EQS. It happened that the AA-EQS was higher than the MAC-EQS based on assessment factors (AF) in the standard way of working according to the TGD-EQS. In such a case the MAC-EQS is set equal to the AA-EQS.

As the above mentioned procedure is standard methodology in the TGD-EQS, SCHER concludes that the AA-EQS and the MAC-EQS for aclonifen have been established correctly.

*ii) The second additional point concerns the question of whether aclonifen should be considered to have PBT properties, specifically whether aclonifen satisfies the persistence criterion. This point is addressed in the dossier itself, in the Bayer CropScience document and in the document commenting upon it. The position of Bayer CropScience is that aclonifen does not satisfy the persistence criterion. The contrary position is that there is evidence from sediments and soils that the persistence criterion is satisfied. All three documents make reference to the temperature dependence of aclonifen degradation, including the question of whether/how results are normalised, and to the issue of bound residues. The two sediment studies referred to in the dossier have not been made available to the dossier rapporteur. The soil studies have been provided to the rapporteur and can probably be made available to the SCHER if necessary.*

The SCHER understands the situation as follows: due to the position of the Working Group E not to consider the formation of bound residues as degradation but as dissipation on one hand and the determination of 12 °C as a relevant environmental temperature on the other hand the conclusion for aclonifen concerning the persistence criterion of the PBT-evaluation leads to the classification of P (persistent) or even vP (very persistent). Therefore, the second additional point has to consider two separate aspects: a) the formation and subsequently the interpretation of bound residues and b) the temperature dependence of degradation processes in environmental compartments.

a) The SCHER disagrees with the approach to consider bound residues as part of the active substance still remaining in the compartment of consideration, based on the following arguments:

- According to Stephenson et al. (2006), bound residues should be defined as "residue associated with one or more classes of endogenous macromolecules that cannot be disassociated by extraction or digestion without alteration." The definition does not specify the environmental compartment under consideration. Therefore, the definition applies to all compartments. The main compartments where the formation of bound residues are encountered will be soil and water/sediment systems.
- For pesticides in both these compartments, standard degradation studies are required to fulfil the registration dossier for plant protection products, preferably carried out according to OECD Test Guideline 307 (soil) and 308 (water/sediment). Both TGs may be used for the determination of the half life of the substance (DT50 for degradation) and for the determination of the transformation pathway, including the formation of bound residues as one of the constituents in the degradation pathway.
- In the evaluation of plant protection products in the framework of 91/414/EEC and its revision Regulation 1107/2009, the formation of bound residues is considered part of the degradation process of the active

substances, based also on the definition of bound residue, in which the key wording is "without alteration".

- The extraction processes to be used to release the substance from its soil or sediment matrix have to be so powerful that neither the soil nor sediment matrix, nor the substance itself will remain undamaged. In addition, the environmental circumstances in the soil or sediment are not subject to such rigorous changes that the substance may be released.

Therefore, the SCHER agrees with this approach. The way bound residues seem to be evaluated in the case of aclonifen in the framework of the WFD is therefore considered to be in disagreement with the method used in the new Regulation for plant protection products. Finally, the degradation rate in sediment has been set arbitrarily to a DT50 of 1000 days to account for the unavailability of 2 separate half lives, one for the water phase and one for the sediment phase, based on the high sorption value of aclonifen to soil and sediment. This half life should not be used for the persistence analysis as it is an arbitrary value and no literature data are available on the half-life in sediments. Finally no characterisation of persistence can be performed on a missing value.

- b) SCHER does not agree with the temperature correction to 12 °C of measured DT50 data in laboratory tests, based on the following reasoning:
  - The PBT-criteria are not defined including a temperature correction to an ambient average temperature of 12 °C in moderate climates, but simply at test temperature.
  - The temperature dependence of chemical processes is well known. The Arrhenius-equation indicates about a factor of 2 for each 10 °C difference as a first approximation. Most studies performed by industry to fulfil registration requirements for substances are carried out under laboratory conditions and descriptions in test guidelines generally recommend room temperatures of about 20 °C.

In conclusion, the SCHER is of the opinion that having considered all relevant information provided to the SCHER these data do not lead to a P-classification of aclonifen.



#### **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
MAC-QS	maximum allowable concentration quality standard
PEC	Predicted Environmental Concentration
PBT	Persistent, Bioaccumulative and Toxic
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

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