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SCIENTIFIC COMMITTEE ON PLANTS

SCP/ETHOXY-Bis/002
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OPINION ON THE EVALUATION OF ETHOXYSULFURON [AE F095404] IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion adopted by the Scientific Committee on Plants, 7 June 2001)

A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF ETHOXYSULFURON [AE F095404] IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET.
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B. TERMS OF REFERENCE

In September 2000, the Scientific Committee on Plants adopted a preliminary opinion[1] on ethoxysulfuron on a question related to the toxicology assessment which was referred to the Committee before the whole evaluation is finalised. The ECCO[2] peer review has now been completed and another question is referred to the Committee.

The Scientific Committee on Plants (SCP) is requested to respond to the following question in the context of the Commission's work on the implementation of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

"Can the Committee confirm that the risk to aquatic organisms has been adequately addressed?"

C. OPINION OF THE COMMITTEE

The Committee concludes that assessment of the risk of ethoxysulfuron to aquatic organisms is lacking in several respects, in particular with respect to sediment-dwelling organisms. Only risks to aquatic organisms occupying adjacent water bodies have been assessed, whereas risk to aquatic organisms within the paddies have not been considered. Assessment of the risks to aquatic organisms from the metabolites of ethoxysulfuron is incomplete. Assumptions used for calculating predicted environmental concentrations deviate in some respects from previous rice paddy scenarios dealt with by the Committee, and this may have important implications for risk mitigation requirements to prevent unacceptable effects on non-target aquatic plants. The Committee recommends that a consistent approach, based on realistic worst-case assumptions, be used to address risk to aquatic organisms associated with rice paddies. Further, the general significance of various in-crop organisms for pesticide risk assessment should be clarified for rice paddies.

[1] http://europa.eu.int/comm/food/fs/sc/scp/out76_ppp_en.pdf
[2] European Commission Co-ordination.

A. TITLE

SCIENTIFIC REPORT ON THE EVALUATION OF ETHOXYSULFURON [AE F095404] IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET.

B. TABLE OF CONTENTS

C. BACKGROUND

Ethoxysulfuron is a new active substance (a.s.) in the context of Council Directive 91/414/EEC[3]. The draft Commission Directive for the inclusion of ethoxysulfuron in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market was submitted to the Committee for opinion. The Committee had been supplied with the documents listed below.

Ethoxysulfuron is a herbicide of the sulfonylurea family, with a broad spectrum pre- and post-emergence activity. In Europe, its current intended use is on rice at a maximum rate of 60 g a.s./ha with only one application/ year.

Source documents made available to the Committee:

1. Ethoxysulfuron: Terms of reference, submitted by DG Health and Consumer Protection, 23 January 2001 (SCP/ETHOXYbis/001).

2. Ethoxysulfuron: Evaluation table - Doc. 7460/VI/98 rev. 8 (17.10.2000), submitted by DG Health and Consumer Protection, 23 January 2001 (SCP/ETHOXYbis/003).

3. Ethoxysulfuron: List of End points, 22 December 2000, submitted by DG Health and Consumer Protection, 23 January 2001 (SCP/ETHOXYbis/004).

4. Ethoxysulfuron: Good Agricultural Practices, submitted by DG Health and Consumer Protection, 23 January 2001 (SCP/ETHOXYbis/005).

5. Ethoxysulfuron: Danish comments on full report and evaluation table, submitted by DG Health and Consumer Protection, 23 January 2001 (SCP/ETHOXYbis/006).

[3] OJ N° L 230, 19. 8.1991, p. 1.

6. Ethoxysulfuron: Draft evaluation report (Monograph) prepared by Italy in the context of the inclusion of the following active substance in Annex I to Council Directive 91/414/EEC, (Volumes 1 to 3) – December 1997.

D. SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED

Ethoxysulfuron degrades in the aquatic environment with an estimated half-life of 10-60 days (Monograph Volume 3, p. 269-270). Three metabolites were identified in a sediment-water study. Metabolite Hoe[4] 126663 formed at concentrations up to 14% in the water phase and 27.4% in the sediment phase, metabolite Hoe 136086 formed at concentrations up to 4.2% in water and up to 17.3% in sediment, whereas metabolite Hoe 092944 was found only in sediment at concentrations up to 18%. In addition, photodegradation in surface water was significant (leading to 55% loss of parent compound during 30 days of sunlight irradiation) and led to the formation of several transformation products. According to the text, five metabolites/ transformation products were formed, but in the accompanying figure only Hoe 136087, Hoe 099095, and Hoe 092944 were identified (Monograph Volume 3, p. 267-268).

Aspects of the risk assessment that have been adequately addressed:

1. The toxicity of ethoxysulfuron to fish (3 species 96 hours; 1 species 28 days), *Daphnia magna* (48 hours and 21 days), algae (2 species; 72 hours and 96 hours) and *Lemna gibba* (14 days) was tested. Risk was assessed for some, but not all, scenarios of concern. Risk to aquatic organisms inhabiting adjacent waters exposed via spray drift (at 1 m distance and assuming a 1 m deep water body) and via outflow of paddy water (at 15 days after application; PECs[5] based on degradation curve from modelling studies) were estimated, and unacceptable risks to non-target plants were indicated.

2. The acute toxicity of metabolite Hoe F126663 to *Daphnia magna*, *Lemna gibba* and algae was tested. No test with fish was performed with this metabolite, but a sufficient reasoned argument was presented by the notifier to justify this. The acute toxicity of metabolite Hoe 136086 to Daphnia and algae was tested, but not at low enough concentrations to determine the algal NOEC[6].

Aspects of the risk assessment that have not been adequately addressed:

1. Despite partitioning of ethoxysulfuron and its metabolites, Hoe 126663, Hoe 136086, and Hoe 092944, to sediment, no test with sediment-dwelling species was performed. As the Committee has pointed out in several previous opinions (e.g., SCP 2000a), low toxicity of a pesticide or its metabolites to Daphnia is an inappropriate indicator of whether a test with sediment-dwellers should be performed. The TER[7] values for sediment-dwellers calculated on the basis of chronic toxicity to Daphnia (SCP/ETHOXY-BIS/004, p. 10-11) are invalid.

2. The toxicity of metabolite Hoe 136086 was neither tested on fish (though this is probably not an issue, no written justification was provided in the documentation available to the

[4] The Hoe coding for metabolites is used here, but it should be noted that in some of the documentation the metabolites have been recorded as AE.
[5] Predicted Environmental Concentrations.
[6] No Observed Effect Concentration.
[7] Toxicity Exposure Ratio.

Committee) nor *Lemna gibba* (which, given the high toxicity of the a.s. to this species, is considered a deficiency in the risk assessment).

3. The risk assessment carried out by the RMS did not consider aquatic organisms living within the paddy fields (and considered the channels surrounding the paddies as part of the paddy; SCP/ETHOXY-BIS/003, p. 32). However, for other substances to be used in rice paddies, risks to aquatic organisms both in the paddy as well as in adjacent water bodies have been included in the risk assessments by Member States. The Committee is not aware of a policy decision which would allow ignoring risk to organisms living in the treated crop, such as aquatic organisms in rice paddies in this case. In the absence of such decision, it is the SCP's view that such risks should be identified and assessed in order to allow for transparent and consistent decision making. In the case of rice paddies this means that risk scenarios for aquatic organisms within- as well as adjacent to paddies need to be considered in the risk assessment. Although the Committee recognises that there may be valid arguments for dealing with risk to organisms within the treated crop differently from those outside (e.g., SCP 2000b), it observes that current practice is inconsistent. The Committee recommends that a consistent approach to address risk to aquatic organisms associated with rice paddies be adopted for all Member States, and that the general significance of various in-crop organisms for pesticide risk assessment be clarified.

4. Risk assessments for the metabolites/ transformation products of ethoxysulfuron were either entirely lacking (i.e., for Hoe 095404, Hoe 136087, Hoe 099095, and Hoe 092944 occurring from photodegradation in surface water; for Hoe 092944 formed in the sediment-water study) or incomplete (i.e., Hoe 126663 and Hoe 136086 formed in the sediment-water study). Although toxicity tests were performed with Hoe 126663 and Hoe 136086, no TER values were calculated for aquatic organisms either within or adjacent to paddy fields. This should have been done especially given that 1) both of these metabolites were more toxic to *Daphnia magna* than the a.s. and 2) different algal species were tested with the parent compound and metabolites.

5. For assessing risks to non-target species within the paddy, water depth at the time of application can have an important influence on PEC_{sw}[8]. The proposed GAP[9] involves application to a water-free paddy field after germination (ca. May), followed by flooding of the paddy (Monograph Volume 1, p. 11) during 14 days before out-flooding. This does not represent a worst case scenario under European conditions, where the water within paddies is changed every 2 to 4 days because of problems of salt, lack of oxygen and algae formation. Given the early application time, water depth within the paddy following application is expected to be relatively low (i.e., $\leq$ 10 cm; SCP 2001) and therefore to result in a higher PEC_{sw} than that obtained from the standard 30 cm scenario.

6. For assessing risks to non-target species in adjacent water bodies, the typical assumptions for PEC_{sw} calculations include a 30 cm static water body. Most of the TER calculations in the monograph assumed a 1 m deep water body (and either 1 or 2 m buffer; see Monograph Volume 1, p. 24 and Volume 3, p. 272). The 30 cm scenario results in an initial PEC_{sw} from outflow of 0.15 µg/L, whereas the 1 m scenario yields an initial PEC_{sw} of 0.044 µg/L (this is the time-weighted mean starting with 15 days after application;

[8] Predicted Environmental Concentration in Surface Water.
[9] Good Agricultural Practice.

Monograph Volume 3, p. 308). Though this difference will not affect whether TER values for fish, Daphnia or algae drop below Annex VI trigger values, they decrease the TER for Lemna in adjacent water bodies from 5.5 to 1.6. This can have important implications for risk mitigation requirements. Insufficient justification was provided in the documentation available to the Committee to support the less conservative assumption.

7. The documentation available to the Committee did not state whether aerial application of ethoxysulfuron to rice paddies may be used. If so, then the risk assessment for aquatic organisms occupying adjacent water bodies will need to be adjusted to include direct overspray.

E. CONCLUSION -RECOMMENDATIONS

The Committee concludes that assessment of the risk of ethoxysulfuron to aquatic organisms is lacking in several respects, in particular with respect to sediment-dwelling organisms. Only risks to aquatic organisms occupying adjacent water bodies have been assessed, whereas risk to aquatic organisms within the paddies have not been considered. Assessment of the risks to aquatic organisms from the metabolites of ethoxysulfuron is incomplete. Assumptions used for calculating predicted environmental concentrations deviate in some respects from previous rice paddy scenarios dealt with by the Committee, and this may have important implications for risk mitigation requirements to prevent unacceptable effects on non-target aquatic plants. The Committee recommends that a consistent approach, based on realistic worst-case assumptions, be used to address risk to aquatic organisms associated with rice paddies. Further, the general significance of various in-crop organisms for pesticide risk assessment should be clarified for rice paddies.

F. REFERENCES

SCP (2000a). Opinion of the Scientific Committee on Plants regarding the Draft guidance document on relevant metabolites (Document SANCO/221/2000-Rev.2 of October 1999) (Opinion adopted by the Scientific Committee on Plants on 30 November 2000).
http://europa.eu.int/comm/food/fs/sc/scp/out82_ppp_en.html

SCP (2000b) Opinion on the evaluation of cyfluthrin in the context of Council Directive 91/414/EEC for placing plant protection products on the market (Opinion adopted by the Scientific Committee on Plants on 28 January 2000)
http://europa.eu.int/comm/food/fs/sc/scp/out59_ppp_en.html

SCP (2001) Opinion on the evaluation of cyhalofop-butyl [DE-537] in the context of Council Directive 91/414/EEC for placing plant protection products on the market (Opinion adopted by the Scientific Committee on Plants on 7 March 2001)
http://europa.eu.int/comm/food/fs/sc/scp/out96_ppp_en.pdf

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