

Opinion of the Scientific Committee on Plants regarding the inclusion of Spiroxamine in annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/SPIROX/004-Final) - (Opinion adopted by the Scientific Committee on Plants on December 18, 1998)

TERMS OF REFERENCE

The draft Commission Directive proposing the inclusion of spiroxamine in Annex 1 to Directive 91/414/EEC had been referred to the Scientific Committee on Plants for consultation with the following questions:

1. Does the data submitted allow an appropriate risk assessment for operators?
2. Having regard to the intrinsic aquatic ecotoxicological effects of spiroxamine and the proposed uses, the Committee is requested to evaluate the risk to the environment which could occur from its uses.

BACKGROUND

The draft Commission Directive for the inclusion of spiroxamine in Annex 1 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 documentation comprising a dossier provided by Bayer AG, a monograph prepared by the German authorities, a review report prepared by the Commission services of the Directorate General for Agriculture and the Recommendations of the ECCO Peer Review Programme.

Spiroxamine is a systemic fungicide with apoplastic translocation in plants. It inhibits the biosynthesis of fungal sterols. Its current intended use is on cereals, to control powdery mildew, leaf blotch brown and yellow rusts. The maximum rate of application per season is 1.5 kg active substance / ha.

OPINION OF THE COMMITTEE

Question 1

Does the data submitted allow an appropriate risk assessment for operators?

When addressing questions related to operator exposure, the SCP notes that uniform and scientifically agreed set of criteria and procedures for the risk assessment of operators, bystanders and agricultural workers is not yet available in the European Union. Therefore, the SCP has decided to make case-by-case evaluations of each plant protection product accepting the various procedures adopted by the different evaluation groups as long as they do not show major conflicts with the generally agreed scientific criteria for health risk assessment.

For spiroxamine, the following Acceptable Operator Exposure Level (AOEL) values have been proposed:

AOEL (oral) 0.034 mg/Kg bw (UF¹ = 100)

AOEL (inhalation) 0.05 mg/Kg bw (UF = 100)

AOEL (dermal) 0.05 mg/Kg bw (UF = 100)

AOEL (systemic) 0.024 mg/Kg bw (UF = 100, based on the oral value with an absorption of 70%)

Although these values have been derived from short-term animal studies, this choice has no major implications with respect to the use of other types of studies, due to the rather similar NOEL values observed in the long-term studies. Therefore the proposed AOELs are acceptable, at least until uniform criteria for setting AOELs are agreed at the European Community level.

For the intended uses, estimated operator exposure accounts for 73% of AOEL with the use of gloves, protective garment and sturdy footwear, thereby providing a sufficient margin of safety.

Question 2

Having regard to the intrinsic aquatic ecotoxicological effects of spiroxamine and the proposed uses, the Committee is requested to evaluate the risk to the environment which could occur from its uses.

The Committee notes that spiroxamine is highly toxic to algae () with a 72 h EC₅₀² for **Scenedesmus subspicatus** of 3 mg as/l. Although the rapid partitioning of spiroxamine to sediment will reduce exposure to algae in the water column, TER³ values estimated according to the German drift model by the Rapporteur Member State (RMS) indicate that the use of spiroxamine directly adjacent to surface waters may result in an unacceptable risk to algae.

Although spiroxamine is not an herbicide, it appears to be three orders of magnitude more toxic to algae than to fish or **Daphnia**. The Committee considers that evaluation of the ecotoxicological risk associated with this substance should include information on its toxicity to plants. However, the Committee notes that no information on toxicity to aquatic plants was provided in the monograph. A higher-tier test, as requested () to remove restrictions, should therefore also address the issue of higher, rooted aquatic plants.

The rapid partitioning of spiroxamine to sediment and its persistence in sediment (DT₅₀⁴ of 106 days ()) indicate a potential risk to sediment-dwelling organisms. One study with **Chironomus riparius** was performed in which no effect on emergence or development was detected at the highest exposure treatment of 2.5 mg as/l. The RMS estimated an initial surface water PEC⁵ for overspray associated with an application rate of 0.75 kg as/ha as 250 mg as/l (). PECs estimated from spray drift ranged from 0.25-1.6 mg as/l () to

12.5 mg as/l (). Given that the estimated PECs are close to or substantially higher than the highest exposure concentration employed in the **Chironomus** test it could not be assumed that no effects on sediment-dwelling organisms would occur from proposed use. In addition, the above calculations assume one application of 0.75 kg as/ha. Given that two applications per

season are possible and that spiroxamine is persistent in sediment, a maximum exposure deriving from 1.5 kg as/ha should be employed in the risk calculations.

The Committee notes reference to a new study, HBF/Ch 21 submitted by the applicant on 9 April 1998() that reports a 28-d NOEC⁶ for **Chironomus riparius** of 3.2 mg/l, giving a TER for overspray of approximately 12 (assuming one application of 0.75 kg as/ha). Although no specific trigger values for sediment-dwelling organisms are stated in Annex II of Directive 91/414/EEC, the estimated TER of 12 for one application per season (above) is close to the trigger value of 10 used for other long-term tests (i.e., fish and **Daphnia**). For two applications per year the TER would be below a value of 10. The Committee considers therefore that the use of spiroxamine directly adjacent to surface waters at proposed application rates may result in unacceptable risk to sediment-dwelling invertebrates.

CONCLUSION

It is the Committee's opinion that the use of spiroxamine directly adjacent to surface waters at proposed application rates may result in unacceptable risks to algae, sediment-dwelling organisms, and possibly plants.

ACKNOWLEDGEMENTS

The Committee wishes to acknowledge the contribution of the following working groups and rapporteur that prepared the initial draft opinions:

Operator Exposure: Professor M. Maroni

Environmental: Professor A Hardy (Chairperson), and Committee Members Dr H.G. Nolting and Professor A. Silva Fernandes and invited experts Professor V. Forbes and Drs J. Boesten, A. Carter and T. Sherratt.

¹ Uncertainty factor

² Effective concentration 50%

³ Toxicity: exposure ratio

⁴ Disappearance time 50%

⁵ Predicted Environmental Concentrations

⁶ No observed effect concentration