Opinion of the Scientific Committee on Plants regarding the Evaluation of cyfluthrin in the context of Council Directive 91/414/EEC concerning the Placing of Plant Protection Products on the Market (Opinion expressed by the Scientific Committee on Plants, 28 January 2000)

TERMS OF REFERENCE

1. Can the Committee comment on the appropriate dietary risk assessment to be used?

2. Can the Scientific Committee on Plants confirm that the available ecotoxicological data supports uses only in glasshouses and for seed treatment?

BACKGROUND

Cyfluthrin is an existing substance in the context of Directive 91/414/EEC [1] concerning the placing of plant protection products on the market and covered by the first stage of the work programme provided under the Directive.

To answer the questions the Committee had access to documentation comprising a Monograph prepared by Germany acting as Rapporteur Member State (RMS) and further information from the ECCO [2] Peer Review programme.

Cyfluthrin is a synthetic pyrethroid insecticide which acts as contact and stomach poison with neurotoxic effects on insects. The opinion has been requested in connection with possible inclusion of the active substance in Annex I of Directive 91/414/EEC with a broad range of intended uses. They included spray applications against biting and/or sucking insects in arable crops, vegetables, ornamental plants and fruit crops and for use as seed dressing in cereals. Greenhouse uses are supported for tomatoes, sweet pepper and ornamental plants. Application rates for cyfluthrin range from 15 g a.s./ha to 50 g a.s./ha, with 1 - 2 applications per season depending on the crop. In most crops, applications are repeated after 14-21 days

(Monograph - list of intended uses supported by data).

The cyfluthrin molecule allows for 4 different stereoisomers (isomers I - IV). It consists of roughly equal amounts of all 4 isomer pairs (while β -cyfluthrin consists of the isomers II and IV, with traces of isomers I and III; (see separate opinion SCP/ β -CYFLU/002-Final). Isomers I and III contribute little to the efficacy which is reflected in the generally higher application rates of cyfluthrin as compared to β -cyfluthrin. The two active substances also have the same toxicological and ecotoxicological profiles, with a 2-5 times higher acute toxicity of β -cyfluthrin (for most organisms).

OPINION OF THE COMMITTEE

Question 1

Can the Committee comment on the appropriate dietary risk assessment to be used?

Opinion

Cyfluthrin belongs to the group of pyrethroids containing an α -cyano-group which are known to be potentially neurotoxic. In addition to a long-term dietary intake risk assessment, as routinely carried out for plant protection products, cyfluthrin should also undergo a short-term acute dietary risk assessment due to its potential neurotoxicity properties.

An ARfD [3] would be needed for this reason. For guidance on establishing an ARfD, the Committee refers the reader to the "Opinion of the Scientific Committee on Plants on the general criteria for setting acute reference doses for plant protection products", expressed on 28 January 2000. In addition, attention is drawn to the "Report of the International Conference on Pesticide Residues Variability and Acute Dietary Assessment", 1-3 December 1998, York, and the JMPR Report 1998 (FAO PLANT PRODUCTION AND PROTECTION PAPER 148).

Question 2:

Can the Scientific Committee on Plants confirm that the available ecotoxicological data support uses only in glasshouses and for seed treatment?

Opinion

The Committee confirms that uses as seed dressing and in greenhouses (except where beneficial arthropods are used) can be considered safe for non-target terrestrial and aquatic organisms, due to the specific circumstances of these applications and the immobility of cyfluthrin in soil.

As with other pyrethroid insecticides, the risk caused by cyfluthrin to non-target organisms is primarily influenced by its rapid, neurotoxic mode of action on arthropods ('knock-down effect') and a very steep dose-response-relationship.

For the aquatic environment, there is evidence that relevant taxa are more sensitive than the standard laboratory test species, with precise effects data lacking. Two higher-tier studies under conditions simulating field spray applications failed to show an NOEC [4] which could be considered safe to such systems.

For the terrestrial environment, high risk was also identified for a range of species of non-target arthropods. It was possible only for honeybees to demonstrate by field tests that spray uses of up to 75 g a.s./ha can be done safely when applying risk mitigation measures (restricting the application to periods when bees are not active). For other arthropods, no specific risk mitigation measures have been proposed to effectively mitigate the risk.

The Committee therefore supports the conclusions reached during the evaluation by member states that field spray applications of cyfluthrin have not been shown to be sufficiently safe under the criteria required by Annex VI to Directive 91/414/EEC. The Committee agrees that uses as seed dressing and in greenhouses (except where beneficial arthropods are used) can be considered safe to non-target terrestrial and aquatic organisms, due to the specific circumstances of these applications and the immobility of cyfluthrin in soil.

Scientific Background on Which the Opinion is based

I. Risk to the aquatic environment

In common with other pyrethroid insecticides, the risk caused by cyfluthrin to the aquatic environment is primarily influenced by the fast, neurotoxic mode of action of these substances, a steep dose-response-relationship and their rapid dissipation from the water column due to strong adsorption. Field situations can be expected to be one or several distinct contamination events rather than a continuous input. Hence, constant chronic exposure is expected to be unlikely for water-column organisms. The most relevant endpoints in the assessment are therefore those from short-term tests (acute toxicity) or from longer tests if they were performed under a predominantly static design (i.e., the 28-day benthic *Chironomus* test; spiked-water design). Long-term, semistatic tests (*Daphnia* reproduction test) are considered relevant for uses with repeated applications. Long-term flow-through tests are likely to exaggerate bioavailability and therefore overestimate toxicity.

In standard laboratory tests, very high toxicity was determined:

Species	Test design	Endpoint	Value [µg/l]	Substance
Rainbow trout	96 h flow-through	LC [5] 50	0.47	Cyfluthrin
Rainbow trout	96 h static	LC50	0.68	Cyfluthrin
Rainbow trout	58 d flow-through	NOEC	0.01	Cyfluthrin
Daphnia magna	48 h static	LC50	0.14	Cyfluthrin
Daphnia magna	48 h static	LC50	2.7	Cyfluthrin
Daphnia magna	21 d semistatic	NOEC	0.02	Cyfluthrin
Chironomus riparius	28 d static	EC [6] 15	0.36	β -cyfluthrin *

- It should be noted that, apart from normal intra- and inter-laboratory variation, the difference of test results with cyfluthrin as compared to β -cyfluthrin largely depends on the test design. As mentioned above, in aqueous solution there is a rapid, partial conversion of the isomers II and IV (i.e., β -cyfluthrin) into isomers III, and I resulting in mixtures of identical composition for both active substances (see evaluation tables, p.3-4). Since field situations can be expected to be one or several distinct contamination events rather than a continuous input, it is considered appropriate to use static ecotoxicological studies with β -cyfluthrin (like the existing *Chironomus* test) also in the assessment of cyfluthrin.

The RMS also evaluated two higher-tier studies, one microcosm and one field pond study. Both were performed with a formulated product of cyfluthrin. Applications were the equivalents of 12.5 and 62.5 g a.s/ha in the natural ponds while the microcosms received 2.5 and 12.5 g a.s. /ha. Initial nominal concentrations of the active substance ranged from 0.2 to 7.8 μ g/L; measured initial peak concentrations in the water phase reached 0.034 and 0.1 μ g/L in the microcosms and, respectively, 0.22 and 1.8 μ g/L in ponds. Although this is partly below the toxic thresholds reported for the acute *Daphnia* tests (NOECs 0.01 - 0.1 μ g/L in 48h static tests; LOEC [7] s 0.02 - 0.3 μ g/L), crustacean populations were severely depressed (not reported to what extent in the monograph). Chironomids in the sediment also suffered mortality. All treatment levels caused effects, i.e.an NOEC for the ecological systems could not be determined. The observed field effects at concentrations below or in the range of the laboratory NOEC levels indicate a higher sensitivity of zooplancton species other than *Daphnia magna*. This conclusion is supported by both field and laboratory data on cyfluthrin and other pyrethroids where generally decapod crustaceans and insect larvae (e.g., *Ephemeroptera* and *Trichoptera*) were more sensitive than *Daphnia* (Hill et al., 1994; Hill, 1989). Risk assessments must also take into account that some of the more sensitive taxa have different life cycles, e.g., only one generation per year. Therefore, the 'recovery study' with *Daphnia* which is mentioned in the evaluation tables for β -cyfluthrin is unlikely to contribute sufficient information in this context.

The Committee therefore concludes that *Daphnia*-based TER [8] s and risk mitigation measures are unlikely to be sufficiently protective for other zooplancton species/populations.

The RMS and other member states concluded in their evaluation that uses in greenhouses and as seed dressing can be considered safe. For field spray uses, safety could not be demonstrated. The respective TER values for field spray applications were below the trigger values required by Annex VI. The two higher-tier studies were not considered sufficiently conclusive to dismiss the concern raised by the previous risk assessment (i.e., not sufficient in the sense of the *unless-clause* of Annex VI).

The notifier, with respect to the field spray applications, claimed that refined exposure estimates (i.e., time-weighted average concentrations considering adsorption, such as calculated by EXAMS) would be sufficient to demonstrate their safety. The Committee disagrees with this view for two main reasons:

a. because of the rapid mode of action, only peak (initial) or TWA [9] -concentrations of up to one day should be used. Such TERs are still below the ones required by Annex VI

b. as described above, there are serious concerns derived from the effects assessment, mainly the demonstrated higher sensitivity of taxa other than *Daphnia* and the lack of a system-NOEC in higher-tier studies. These have not been addressed by the notifier.

Conclusion on aquatic environment:

The Committee, in view of the evidence of higher sensitivity of other taxa, and of the lack of an NOEC from the two higher-tier studies, supports the conclusions reached by member states that field spray uses of cyfluthrin have not been shown to be safe under the criteria of Annex VI. The Committee agrees with member states that uses as seed dressing and in greenhouses can be considered safe to the aquatic environment, due to the specific circumstances of these applications and the immobility of cyfluthrin in soil.

The Committee is of the opinion that where available, such as in the case of pyrethroid insecticides, risk assessments should make full use of the weight of evidence from the available scientific literature; e.g., on species susceptibility, rather than concentrate on the standard species alone (in this case *Daphnia*). In addition, reviews of higher-tier studies in the monograph need to be far more detailed for meaningful subsequent use of such documents.

II. Risk to the terrestrial environment

The evaluation by member states identified serious concerns with regard to terrestrial non-target arthropods:

Honeybees: The RMS identified a high risk (100% mortality) of cyfluthrin for honeybees in laboratory tests both with the active substance and a formulated product when exposed by contact, overspray or orally to doses equivalent to those in arable crops. However, mortality in semi-field and field tests with the same product sprayed in the evening after bee flight was very low even at high application rates (up to 75 g a.s./ha), and brood status or colony size were not affected.

Those higher-tier studies reflect standard risk management for honeybees (i.e., restricting the application to seasons or times of day when bees are not active in the crop). The Committee expects this type of risk mitigation to be effective, and that field spray uses of cyfluthrin may be conducted safely with respect to honeybees.

Other non-target arthropods: A number of different taxa (parasitoid wasps, predatory mites, ground-dwelling carabid beetles) were tested in the laboratory with a formulated product of cyfluthrin at concentrations equivalent to exposure from application rates between 2 and 250 g a.s. /ha. A field test was performed with plant-dwelling predatory coccinellid beetles at 62.5 g a.s. /ha. Endpoints varied according to test guidelines.

Effects ranged from 27% mortality (adults of *Poecilus cupreus* at 15 g a.s. /ha while 100% showed sublethal effects) to 100% (all other species tested; exposure at 2, 15, 17.5, 56 and 62.5 g a.s./ha respectively, covering arable and fruit crops, different endpoints; e.g., mortality and feeding rate).

Importance and adequacy of risk mitigation measures

The SCP agrees with the rapporteur that the data show an unacceptable risk to non-target arthropods from the intended field spray uses cyfluthrin. So far, no specific risk mitigation measures for arthropods have been proposed. The SCP is aware that for other substances, recovery of arthropods is under discussion as a means of risk mitigation. In the following paragraphs, the SCP wishes to discuss a number of key features of recovery and their possible implications for risk mitigation.

The observation of population recovery through immigration from unsprayed sources raises a fundamental issue: should it be incorporated into the risk assessment process, and if so how? Furthermore, if recovery is considered, what risk mitigation measures should be implemented to ensure that recovery can take place via this process? Immigration is a natural ecological process, and as such, the SCP feels that it is appropriate to consider it in the context of a risk assessment. Indeed, it would often be impractical to attempt to rule it out as a factor in field trials. However, it is important to recognise that the actual rates of immigration of arthropods into treated areas are likely to be highly dependent on the sizes and proximities of suitable source populations. Thus, repeated applications of the chemical may eventually deplete the sizes of the source populations through continued attrition (Sherratt & Jepson 1993). Similarly, the rates of recovery of arthropod populations within the treated crop will depend on the actual sizes of populations that were lost after treatment. Thus, if sprays are applied extensively, then large populations are likely to be affected and the subsequent rate of recovery is likely to be low. This reasoning is supported by experimental data which show that the rate of recovery will depend on the area of crop sprayed (e.g. Jepson & Thacker 1990; Thomas *et al.* 1990). Another important caveat is that the rate of recovery of arthropods in the treated area will depend not just on the frequency and extent of application of the pesticide in question, but on the suitability of the surrounding habitats for arthropods, and the toxicities and patterns of use of other pesticides.

Whenever initial population reductions are observed in the field, then this should raise cause for concern. Furthermore, whenever immigration is seen as an important factor in the recovery process, then it is likely that the usage pattern of the compound will have a correspondingly high influence on long-term viability of affected populations in the treated area. Therefore, in such cases, the SCP feel that it is necessary implement risk mitigation measures. One appropriate measure is to restrict spraying close to any off-crop areas that are likely to support significant populations of beneficial arthropods. Such a restriction might also involve selection of appropriate application techniques to minimise spray drift. While it is also recognised that repeated or extensive applications of the compound may affect the ability of beneficial arthropod populations to recover, there are currently no agreed guidelines with which to set quantitative limits on these parameters. Given the uncertainty, we recommend that selection of appropriate upper levels of frequency and extent of application should be based on a consideration of the conditions under which field trials were conducted.

Conclusion on terrestrial environment *:*

For honeybees, field tests demonstrated safety of field uses of up to 75 g a.s. /ha by effective mitigation of otherwise high risk. Uses as seed dressing and in greenhouses (except where beneficial arthropods are used) can also considered to be safe to non-target terrestrial arthropods due to the specific circumstances of the applications and the immobility of cyfluthrin in soil.

With regard to non-target arthropods, the evaluation by member states showed that the Annex VI trigger of 30% mortality/effect was exceeded for most species tested. No specific risk mitigation measures have been proposed to effectively mitigate the risk to non-target/beneficial arthropods other than bees. In addition, many species of the above are vital in IPM programmes. Field spray applications of cyfluthrin must therefore be considered incompatible with IPM in the absence of suitable risk mitigation.

REFERENCES

Hill, I.R., Shaw, J.L., Maund, S.J. (1994): Review of Aquatic Field Tests with Pyrethroid Insecticides. In: Freshwater Field Tests for Hazard Assessment of Chemicals. Eds.:Hill, I.R., Heimbach, F., Leeuwangh, P., Matthiessen, P., 249-271

Hill, I.R. (1989): Aquatic Organisms and Pyrethroids. Pestic. Sci. 27, 429-465

Jepson, P.C. & Thacker, J.R.M. (1990). Analysis of the spatial component of pesticide side-effects on non-target invertebrate populations and its relevance to hazard analysis. *Functional Ecology*, **4**, 349-355.

Sherratt T.N. & Jepson, P.C. (1993). A metapopulation approach to modelling the long-term effects of pesticides on invertebrates. *Journal of Applied Ecology*, **30,** 696-705.

Thomas, C.F.G., Hol, E.H.A., Everts, J.W. (1990). Modelling the diffusion component of dispersal during recovery of a population of linyphiid spiders from exposure to an insecticide. *Functional Ecology*, **4**, 357-368.

ACKNOWLEDGEMENTS

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

Toxicology: Professor M. Maroni (Chairman), and Committee Members Dr. M.-P. Delcour-Firquet, Dr. R. Hans, Dr. O. Meyer, Prof. A. Silva Fernandes, Dr. G. Speijers

Environmental Assessment: Professor A Hardy (Chairman), and Committee Members Mr H. Koepp, Dr. H. G. Nolting, Professor A. Silva Fernandes and Dr. T. Sherratt and invited experts Dr. V. Forbes, Dr. J. Boesten, Dr. A. Carter, Dr. R. Luttik.

----

[1] OJ No L230, 19.8.1991, p.1

[2] European Community Co-ordination

[3] Acute Reference Dose

[4] No Observed Effect Concentration

[5] Lethal Concentration, median

[6] Effective Concentration

[7] Lowest Observable Effect Concentration

[8] Toxicity Exposure Ration

[9] Time Weighted Average