Opinion regarding the evaluation of Lambda-Cyhalothrin 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 it be confirmed that the proposed risk mitigation measures for aquatic organisms would avoid unacceptable risk for the aquatic environment?

3. Can it be confirmed that the proposed risk mitigation measures are adequate to protect non-target arthropods and honey bees?

Background

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

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

Lambda-cyhalothrin is a synthetic pyrethroid insecticide and is effective against harmful organisms via contact and stomach action.

Plant protection products with lambda-cyhalothrin as an active substance are authorised for use in agriculture, horticulture, hops, viticulture, stored grain and forestry.

Question 1

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

Opinion

Lambda-cyhalothrin belongs to the group of pyrethroids containing an a -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, **lambda**-cyhalothrin should also undergo a short-term acute dietary risk assessment due to its potential neurotoxicity properties.

An Acute Reference Dose (ARfD) 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 it be confirmed that the proposed risk mitigation measures for aquatic organisms would avoid unacceptable risk for the aquatic environment?

Opinion

The Committee is of the opinion that the recommended buffer zones, based on a combination of laboratory and higher-tier mesocosm studies, are scientifically justifiable. It is recommended that the comprehensive set of buffer values recommended by the RMS be used for guidance purposes.

The Committee emphasises that whereas the recommended buffer zones provide a useful starting point for defining risk mitigation measures, they must be re-evaluated by each Member State with respect to local conditions and specific use scenarios of **lambda**-cyhalothrin. All of the recommended buffer zones are based on the German Spray Drift Model (Ganzelmeier et al. 1995), but local agronomic practices and aquatic ecosystems may vary considerably from the conditions under which this model has been derived, and therefore local variations should be taken into consideration when determining risk reduction measures at a Member State level. Given the very steep exposure-response curve for aquatic species, it is essential that the buffer zones, once adjusted for local conditions, be strictly enforced in practice.

Scientific Background on Which the Opinion is Based

The risk mitigation measures proposed to avoid unacceptable risk for the aquatic environment refer specifically to buffer zones. The conclusion of the evaluation group was that risk mitigation measures can be defined at the Member State level and that safe uses of **lambda**-cyhalothrin have been demonstrated. The RMS suggested that inclusion in Annex I should not require specific buffer zones but that risk reduction measures must be undertaken by individual Member States in order to protect aquatic life. It was concluded that no extra risk reduction measures were needed to protect sediment-dwellers.

Guidance on buffer zone distances was provided by both the RMS and the Notifier (Table 1). Exposure estimates for all of the buffer zone calculations were based on the German Spray Drift Model (Ganzelmeier et al. 1995). The RMSlab values shown in Table 1(from Table 12 in Appendix 3-Rev. 1 to **lambda**-cyhalothrin doc. 5684/VI/97-Rev. 8) were based on TWA [3] PEC [4] sw estimates, that assumed a DT [5] 50 value of 11 h, and acute toxicity for **Daphnia** (0.36 µg/l= 48 h EC [6] 50) and fish (0.21 µg/l =96 h LC [7] 50). The buffer zone was set at a distance at which TER [8] exceeded 100. The RMSmesocosm values (from Table 13 in Appendix 3-Rev. 1 to **lambda**-cyhalothrin doc. 5684/VI/97-Rev. 8) assumed a LOEC [9] of 0.17 g as/ha, estimated from Mesocosm Study I, and drift values calculated as in Ganzelmeier et al. (1995). The buffer zones were set so that the g as/ha from drift did not exceed the LOEC. The RMS recommended values take both the laboratory and mesocosm estimates into account and provide the final recommendation by RMS. For comparison, the Notifier's recommendations (from Table 15 in Appendix 3-Rev. 1 to **lambda**-cyhalothrin doc. 5684/VI/97-Rev. 8) are based on calculated TERs using laboratory toxicity data for **Daphnia** and fish, and TWA PECsw values that assumed a DT50 of 3 h.

Table 1. Summary of buffer zones for **lambda**-cyhalothrin proposed by the RMS and Notifier. The buffer zones are in units of meters. The RMS calculated buffer zones on the basis of both laboratory (column 3) and mesocosm (column 4) studies, and on the basis of these derived their recommended values (column 5). The Notifier's recommendations are shown in column 6.

Crop	Appl. rate g as/ha	RMSlab	RMSmesocosm	RMS Recommended	Notifier Recommended
Field crops	7.5	10	> 3	3-5	3
	20		> 5	5-10	10
	15-30	20			5-10
	30		> 10	10-20	
Fruit crops	5-10		> 20	20-30	
	10-15	50			
	20-30	> 50			
	30		> 30	> 30	> 30
Grapes & cane fruit	5	20			
	5-10		> 10	10-20	
	17.5-26	> 50	> 20	20-30	20
	10-125			> 50	
Hops	20-125	> 50			
	Up to 44		> 50		> 50
	75-125		> 50		> 50
Hand-held sprayer (forestry)	10	20	> 10	20-30	
	25	> 50	> 20	20-30	20
Flowers & potatoes (high frequency)	7.5 and 15		20	20	

The Committee agrees that due to the rapid dissipation of **lambda**-cyhalothrin, chronic exposure of water column organisms is unlikely, and TERs based on 48 h and 96 h effects on **Daphnia** and fish, respectively, are the relevant effect endpoints to use in the risk assessment. TERs based on 48 h TWA PECsw and **Daphnia** toxicity versus 96 h TWA PECsw and fish toxicity gave very similar cut-off values (i.e. distances at which TER > 100 for different uses; Tables 9 & 10 of Appendix 3-Rev. 1). Although **lambda**-cyhalothrin adsorbs rapidly to sediment, risk assessment for chironomids indicated that buffer zones used to protect water column organisms would prevent unacceptable risk to sediment dwellers as well.

The RMS buffer zones assume up to 4 applications/season for all uses with the exception of flowers and potatoes for which more frequent applications are assumed. The buffer zones recommended by RMS are similar to those recommended by the notifier with the exception of the frequent uses (up to 18 applications with an interval of 7 days) on flowers and potatoes, for which the RMS recommends more stringent measures.

Despite disagreement between RMS and the notifier as to whether a DT50 of 3 (microcosm study) or 11 (water-sediment study) hours be used to calculate TWA PECsw values and as to whether the effects seen in Mesocosm Study I at the lower treatment level should be considered as ecologically relevant, the buffer distances recommended by the different approaches are very similar.

References

(1) Ganzelmeier H, Rautmann D, Spangenberg R, Streloke M, Herrmann M, Wenzelburger H-J, Walter H-F. 1995. Studies on the spray drift of plant protection products. Results of a test program carried out throughout the Federal Republic of Germany. Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem. Heft 305.

Question 3

Can it be confirmed that the proposed risk mitigation measures are adequate to protect honey bees and other non-target arthropods?

Opinion

No risk mitigation measures for honey bees or other non-target arthropods were proposed. In the absence of specific risk mitigation measures the data show that the intended uses of lambda-cyhalothrin pose an unacceptable risk to non-target arthropods under Annex VI criteria of Directive 91/414/EEC.

The SCP believes that if risk mitigation measures can be implemented, then there are indeed conditions under which the use of lambda-cyhalothrin will not pose an unacceptable risk to honey bees and other non-target arthropods. Specific risk mitigation measures that should be considered for honey bees include: (a) the control of the timing of application (time of day and season) with respect to (i) honey bee activity and (ii) flowering of the crop, and (b) restrictions on spraying close to hives. Specific risk mitigation measures that should be considered for other non-target arthropods include restrictions on the number of applications per season, restrictions on spraying close to field margins, selection of appropriate application techniques to minimise spray drift, and limits on the extent of application.

The SCP is generally satisfied that the use of **lambda**-cyhalothrin will not pose an unacceptable risk to honey bees if it is applied at application rates of 20g as /ha or less and the above risk mitigation measures can be implemented. However, since application rates are approximately 30g as /ha in fruit crops and vines and these crops are regularly visited by honey bees, the Committee recommends that a further risk assessment be conducted to determine the likely effects of **lambda**-cyhalothrin in these systems.

Beneficial arthropods were monitored in European arable crops during field trials involving application rates of 5.0-10 g as/ha. Some species showed no effect after applications of the active substance, but populations of other species were significantly reduced, taking approximately 3-5 weeks to recover. In these trials, recovery over this time period must have arisen largely through immigration. The SCP suggests that in principle, it is entirely appropriate to take natural recolonisation from off-crop habitats into account in the risk assessment process. However, initial population effects were observed. Furthermore, given the nature of the recovery, the permanent viability of source populations will depend on the usage pattern of the compound. Thus, there remains a need for specific risk reduction measures (see above).

There are two main patterns of use in which it was particularly difficult to assess risk to non-target arthropods: (a) applications to cereals at concentrations of approximately 20g/ha (well above field rates employed in European field trials) and, (b) applications to citrus, pome fruits and vines. The SCP recommends that further risk assessments for these intended uses should be conducted.

1. Scientific background on which the opinion is based

1.1 Honey bees

1.1.1 Review of available ecotoxicity data

Laboratory assays

- The estimated mean 24 hr LD50 [10] for worker bees after contact exposure was between 51 and 95 ng as/bee, depending on formulation. The estimated mean 24 hr LD50 for oral administration was somewhat higher (between 965 and 570 ng as/bee).

Greenhouse tunnel trials

- A greenhouse study was conducted, in which individual colonies of honeybees were enclosed and observed in tunnels containing treated winter wheat. Treatment levels (7.5g as /ha and 15 g as /ha **lambda**-cyhalothrin) were somewhat less than the critical Good Agricultural Practice (GAP) proposed for cereals in some regions (20 g as/ha), but the close confinement can often result in longer periods of exposure than equivalent field trials. Overall, mortality rates did not differ significantly between treatments. There was some evidence of foraging inhibition lasting up to 3 days in treatments, and abnormal locomotive behaviour was also observed.

Field trials

- A field study was conducted in plots of flowering winter rape. The application rate (10 g as / ha) was again less than the critical GAP for this crop in some regions (20-30 g as / ha). The mortality rate did not differ significantly between **lambda**-cyhalothrin treated and controls (2 replicate plots of each, 5 bee colonies plot), while foraging was significantly depressed for a short while after application. There were also no observed effects on egg-laying or brood development.

- Given this data, ECCO 3 considered application rates up to and including 15 g **lambda**-cyhalothrin /ha to be safe and acceptable with respect to honey bees. To support application rates > 15g as/ha, higher tier bee data (e.g. semi field/field data) would be required. The notifier has since responded by providing provisional details (subject to audit by Quality Assurance) of a trial conducted in a number of fields of oil seed rape using application rates that included 20 and 25 g as / ha (another trial was also commissioned, but there was insufficient bee activity). Although more than twice the number of bee deaths were recorded in high dose treatments compared to controls on the day of application and the following day, in the medium-term (³ approximately 2 days following application) the daily numbers of bee deaths recorded fell to levels that were comparable to pre-treatment levels.

1.1.2 Importance and adequacy of risk mitigation measures

Given the high sensitivity of bees reported under laboratory conditions, risk mitigation measures should be implemented before safe use can be confirmed. No specific risk mitigation measures for honey bees have so far been proposed that the notifier wishes to support in the context of Annex 1. However, appropriate measures that should be considered include : (a) the control of the timing of application (time of day and season) with respect to (i) honey bee activity and (ii) flowering of the crop, and (b) restrictions on spraying close to hives.

The SCP supports the RMS opinion that, if the above risk mitigation measures are implemented, then applications up to 20-25 g as/ha would not pose an unacceptable risk to honey bees. However, this preliminary interpretation needs to be reviewed when the final report on the field trial in oil seed rape is made available.

The SCP notes that a reliable risk assessment for honey bees is difficult under some of the application scenarios listed by the notifier. These cases merit more detailed consideration. In particular, the SCP notes that no study has been conducted to evaluate the effects of application rates of **lambda**-cyhalothrin of the order of 30 g as / ha or higher. Yet the critical good agricultural practice application rate of **lambda**-cyhalothrin is 30 g as / ha for citrus, pome fruit and stone fruit in several southern European countries. Since these crops are likely to be regularly visited by bees, the Committee is of the opinion that a further risk assessment of on-crop effects in fruit crops and vines should be required (see also section 2.2.2).

1.2. Other arthropods

1.2.1 Review of available ecotoxicity data

Laboratory assays

- The notifier has provided details of a large number of laboratory tests to evaluate the toxicity of **lambda- cyhalothrin** to both beneficial non-target arthropods and pests. These tests cover ground beetles (**Trechus quadristriatus**, **Pterosticus melanarius**, **Poecilus cupreus**), a predatory hoverfly (**Episyrphus baleatus**), a parasitic wasp (**Aphidius urzbeckistanicus**), lycosid spiders (**Pardosa** sp.), 4 species of linyphiid spider and a predatory mite (**Typhlodromus**), as well as several pest species (the aphids **Rhopalosiphum padi** and **Sitobion avenae** and the herbivorous mite **Panonychus ulmi**).

- In several tests, nominal concentrations fell in the range of 6.25-9.0 g as / ha which is less than the critical GAP application rate for a number of crops. Overall, while aphids appeared highly sensitive to **lambda**-cyhalothrin, it was also highly toxic to both linyphiid and lycosid spiders, as well as mites. Significant mortality and reductions in mobility were also recorded in the other tests (e.g. beetles), although in these tests the rate of mortality did not exceed 30%.

Field trials

- The notifier also provided details of three intensive field studies conducted in winter wheat crops in Berkshire, UK. Additional details were also sent to the RMS at a later date (along with details of a soyabean study in Brazil, a rice study in the Phillipines and a cotton study in the USA). In one of the Berkshire trials **lambda**-cyhalothrin was applied at 5 g as /ha to replicated plots (> 4ha in size) in November on consecutive years, while in the other Berkshire trials the chemical was applied to plots (> 1ha) at a rate of 7.1 g as/ha (trial 1) and 5, 7.5 or 10 g as/ha (trial 2) in June. A number of other chemicals were also applied to the experimental fields both before and during the surveys. In these experiments, some species of polyphagous predators (Carabidae, Staphylinidae and Araneae) showed significant reductions in population size compared to controls, which persisted on average for 4-5 weeks in the November trials and 3-4 weeks in the June trials.

- In these trials the observed recovery over this time period can only have arisen through immigration of predators from untreated fields and field margins, rather than through reproduction.

1.2.2 Importance and adequacy of risk mitigation measures

The RMS suggests that, while beneficials appear to be maintained in arable crops, a mean recovery rate of 4-5 weeks as observed in the European field highlights the need for risk reduction measures. The SCP agrees with this interpretation: the data show that the intended uses of **lambda**-cyhalothrin pose an unacceptable risk to non-target arthropods under Annex VI criteria, unless specific risk mitigation measures can be implemented. So far, no specific risk mitigation measures for arthropods have been proposed that the notifier wishes to support through Annex 1. In the following paragraphs the SCP expands on why it considers risk mitigation to be important even in the light of the observed recovery, and the same reasoning is used to identify some appropriate mitigation measures.

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 feels that it is necessary to 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, the SCP recommends 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.

As far as we can assess, the majority of critical GAP scenarios provide a considerable interval outside a short period of spraying activity to enable recovery, if it occurs at approximately the observed rates. The likely effects of **lambda**-cyhalothrin and the subsequent recovery of beneficial arthropods under certain GAPs are however difficult to gauge. In particular, the SCP notes that the critical GAP for cereals in Italy and France involves 2 applications 15 days apart at twice the maximum application rate (20 g as / ha) used in the European field studies. While beneficial arthropod populations will probably show the same pattern and begin to recover several weeks after the second spray (as indicated by several of the notifiers' trials outside the EU), it is clearly more difficult to assess the risk to beneficial arthropods under these particular conditions, and further work to assess risk under these conditions is recommended. As with the honey bees, high application rates of **lambda-**cyhalothrin to citrus, pome fruits and vines pose risks to terrestrial non-target arthropods which are difficult to ascertain. The Committee therefore feels that it is appropriate to : (a) restrict the general use of **lambda**-cyhalothrin in these crops and/or (b) initiate reliable monitoring programmes, until further assessments are conducted.

2. References

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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.

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[1] OJ No L230, 19.8.91, p. 1

[2] European Community Co-ordination

[3] Time weighted average

[4] Predicted environmental concentration in surface water

[5] Period required for 50% dissipation

[6] Median effective concentration

[7] Lethal concentration , median

[8] Toxicity exposure ratio

[9] Lowest observable effect concentration

[10] Lethal dose 50%