Opinion of the Scientific Committee on Plants regarding the inclusion of Fluroxypyr in annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/FLUROX/001-Final) - (Opinion adopted by the Scientific Committee on Plants on 18 May 1999)

TERMS OF REFERENCE

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

1. Is the environmental safety of the metabolites of fluroxypyr adequately addressed? Which metabolites are relevant?

2. Does the Committee confirm the conclusion of the peer review that the available data on the soil leaching behaviour of the parent and its metabolites are not sufficient to ensure the protection of ground water resources also for applications in autumn?

BACKGROUND

The draft Commission Directive for the inclusion of fluroxypyr 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 Dow AgroSciences, 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.

Fluroxypyr is a post-emergence herbicide against broad leaved weeds, acting similar to auxin-type herbicides in promoting cell elongation and interfering with RNA synthesis. Its current intended use is to control broad leaved weeds in cereals, maize, sorghum, pastures, amenity green, bulb onions, apple and olive orchards, and non-crop areas. The maximum rate of application per season is 0.4 kg active substance (as acid)/ ha (equivalent to 0.576 kg MHE / ha)

OPINION OF THE COMMITTEE

Question 1

Is the environmental safety of the metabolites of fluroxypyr adequately addressed? Which metabolites are relevant?

a) Metabolites occurring

Fluroxypyr is applied as methyl-heptylester (MHE) which is rapidly hydrolised to the corresponding acid (metabolite I). This is further degraded in relatively short time (few days)

under aerobic conditions and at temperatures above 20 ° C. Slower degradation occurs under anaerobic conditions or lower temperatures.

The following main metabolites have to be considered:

> Metabolite III (4-amino-3,5-dichloro-6-fluoro-2-methoxypyridine) is the main metabolite in soil where it occurs at levels of up to 38% of the applied radioactivity/dose. It does not occur in water/sediment systems. Metabolite II (4-amino-3,5-dichloro-6-fluoro-2-pyridinol) occurs in soil at levels of up to 18.7 %. Fate studies indicate that it may be stable in the top layer. Metabolite II is, however, clearly the main metabolite in water, with up to 62.4% under anaerobic and up to 44% under aerobic conditions. Metabolite II is (biologically) degraded further to metabolite IV: Metabolite IV (4-amino-3-chloro-6-fluoro-2-pyridinol), a minor metabolite in soil. In most water/sediment systems it occurs at levels less than 10%, but was detected under anaerobic conditions at up to 28.4%. Under aerobic conditions, it was detected at lower levels. Metabolite VI (4-amino-3,5-dichloro-6-fluoro-2- pyridinone) was only detected in two of 9 studies in water/sediment systems with 17 Â– 45%. The data provided suggest that it may occur in equilibrium with metabolite II. Further degradation is to metabolite IV.

Metabolites II and IV were microbially degraded further with DT $_{90}$Â's [2] of 60-120 days (i.e., within one season) under aerobic conditions. All metabolites in water/sediment-systems occurred at higher levels in the water phase, indicating low adsorption to the sediment. The potential for accumulation in the sediment is very low.

b) Ecotoxicological relevance of metabolites

Soil

Metabolite III has been tested for its effects on earthworms and soil micro-organisms. For earthworms, an NOEC [3] of 135 mg/kg was determined (LC $_{50}$ [4] = 313 mg/kg) in the standard 14 day test (nominal concentrations). Although this is more toxic than the active ingredient itself, the trigger value for a reproduction study was not reached. The NOEC is by a factor of 1400 and more above the worst-case estimate for the concentration of metabolite III in soil which is based on the highest application rate of 400 g acid/ha, and assuming 100% going into the soil in spite of vegetation cover. The time-weighted average PEC [5] values then range from 0.01 to 0.1 mg/kg, depending on soil type. For MHE, the initial PEC is 0.77 mg/kg.

With regard to possible effects on micro-organisms, concentrations of metabolite III equivalent to the highest intended application rate and to the five fold rate (0.132 and 0.66 mg metabolite III/kg, respectively) caused no significant effects on either microflora respiration or nitrogen turnover. Minor transient effects over the first 14 days of the test were observed on nitrogen turnover.

Metabolite II has not been tested on any soil organisms. It is structurally very similar to metabolite III and might therefore also be more toxic to soil organisms than the active substance. Since it may be stable under field conditions and remain in the biologically most important top soil layer, its environmental safety needs to be addressed by appropriate studies.

Water

Metabolite II as the main metabolite has been tested for its effects on algae, **Daphnia** and fish in the standard short-term tests. The resulting NOEC values of > 45 mg/L, > 49 mg/L and 29 mg/L, respectively, are approximately 100fold higher than the equivalent values for the active substance and the representative formulation, indicating that the metabolite II is far less toxic than the parent compound. The metabolite NOECÂ's are also by a factor of 300 Â– 450 above the worst-case (overspray situation) estimate for the initial environmental concentration of metabolite II in water. This is based on the highest application rate, assuming overspray of a pond of 30 cm depth. The highest TWA [6] PEC value then is 0.042 mg/L. For MHE, the initial PEC is 0.19 mg/L. All this refers to dark conditions; under light there is a faster breakdown.

The structural difference between metabolites II and VI is minimal (a hydrogen atom shifting between 2 neighbouring positions), and it can reasonably be concluded that they occur in an equilibrium. The toxicity tests done nominally with metabolite II can therefore regarded to cover metabolite VI as well.

No data are available on metabolite IV.

Question 2

Does the Committee confirm the conclusion of the peer review that the available data on the soil leaching behaviour of the parent and its metabolites are not sufficient to ensure the protection of ground water resources also for applications in autumn?

The Committee confirms this conclusion.

OVERALL CONCLUSION

The Committee can confirm the conclusion of the peer review that the use of fluroxypyr in autumn is not supported by the available data. The environmental safety of the relevant metabolites is not completely addressed: the safety of metabolite IV for aquatic organisms and of metabolite II for soil organisms needs to be addressed by further data.

ACKNOWLEDGEMENTS

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

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, H. Köepp and T. Sherratt.

---

[1] OJ No L 230, 19.8.1991, p.1.
[2] Disappearance time for 50/90% of compound
[3] No observed effect concentration
[4] Lethal concentration (50%)
[5] Predicted environmental concentration
[6] Time weighted average