Opinion on the evaluation of Pyraflufen-Ethyl (ET-751) 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 on 7 March 2001)

1. TITLE

Opinion of the Scientific Committee on Plants regarding the Evaluation of PYRAFLUFEN-ETHYL [ET-751] in the Context of Council Directive 91/414/EEC Concerningthe Placing of Plant Protection Products on the Market

(Opinion expressed by the Scientific Committee on Plants, 7 March 2001)

2. TERMS OF REFERENCE

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

In the context of the proposed uses, can the Committee comment on the risk of ground water contamination in particular in relation to metabolite E1?

3. BACKGROUND

Pyraflufen-ethyl [ET-751] is a new active substance (a.s.) in the context of Council Directive 91/414/EEC [1]. The draft Commission Directive for the inclusion of pyraflufen-ethyl 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 documentation comprising a draft evaluation report (monograph) prepared by the Rapporteur Member States (Belgium) based on a dossier submitted by the notifier (Nihon Nohayaku), a review report prepared by the Commission and the Recommendations of the ECCO [2] Peer Review Programme.

Pyraflufen-ethyl is a new herbicide of the peroxidizing herbicides. Pyraflufen is effective against broad-leaved weeds. It is intended for use in cereal crops at a rate ranging from 9 to 13.5 g a.s./ha in association with other herbicides.

4. OPINION

Question:

"In the context of the proposed uses, can the Committee comment on the risk of ground water contamination in particular in relation to metabolite E1?"

Opinion of the Committee:

The Committee concludes that groundwater concentrations of the metabolite E1 will usually be lower than 0.01 mg/l although values in the range from 0.01 to 0.1 mg/l cannot be excluded in exceptional cases (for two out of nine realistic worst-case scenarios values in range from 0.01 to 0.04 mg/l were found). It is unlikely that concentrations of E1 will exceed 0.1 mg/l. There is negligible risk of groundwater contamination for the parent compound and groundwater concentrations for other metabolites are expected to be considerably lower than those estimated for E1. The Committee concludes, that exposure to E1 through drinking water does not pose any significant health risk to humans.

Scientific background on which opinion is based:

4.1 Soil metabolism and degradation rates

In soil, the parent compound pyraflufen-ethyl is rapidly degraded showing half-lives that are usually shorter than 1 day. In an aerobic soil metabolism study, the following metabolites were detected:

- E1: 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazole-3yl)-4-fluorophenoxyacetic acid
- E2: 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazole-3yl)-4-fluorophenol
- E3: 4-chloro-3-(4-chloro-2-fluoro-5-methoxyphenyl)-5-difluoromethoxy-1-methylpyrazole
- E9: 2-chloro-5-(4-chloro-5-difluoromethoxylpyrazole-3yl)-4-fluorophenoxyacetic acid.

Pyraflufen-ethyl was practically completely degraded into E1 metabolite. E1 metabolite was to a large extent degraded into metabolite E2 and to a minor extent into metabolite E9. Metabolite E2 was almost completely degraded into metabolite E3. In the aerobic soil metabolism studies, soil bound residues were formed in percentages ranging from 15-17% and cumulative amounts of CO_2 ranged from 2 to 9%. The maximum levels and half-lives of E1, E2 and E3 in laboratory studies with aerobic soils are given in the following table.

	max. percentage (%)	half-life (days) at 20°C
E1	78	16 - 53
E2	39	6 - 11
E3	69	158 - 442

The half-lives of E2 and E3 given in this table were measured in studies in which either E2 or E3 was added to the soil. It was not attempted to derive half-lives of E2 and E3 from metabolism studies with the parent compound. However, the results of studies with the parent compound are not consistent with the half-lives of 6-11 days reported above for E2: in studies with the parent compound the percentage E2 after 100 days was 7, 12, 30 and 39% in four different soils.

4.2 Sorption of pyraflufen-ethyl and its soil metabolites

The K_{OC} [3] of pyraflufen-ethyl was estimated to be larger than 1000 l/kg. Sorption studies with three soils were carried out for the E1, E2 and E3 metabolites and results are summarised in the following table.

	K_{OM} [4] (l/kg)
E1	47- 112
E2	823-1245
E3	1791-2488

The K_{OM} measurements of E1 indicated that the sorption is a decreasing function of pH as is shown by the following table:

pH-H_2O	K_{OM} (l/kg) of E1
5.2	112
6.7	58
7.6	47

This dependency between pH and K_{OM} was expected in view of the COOH-group in the molecular structure of E1.

4.3 Field persistence of pyraflufen-ethyl and its soil metabolites

Eight field persistence studies were carried out at four sites in Germany, France and UK. At each site pyraflufen-ethyl was applied both in spring and autumn at a rate of 200 g/ha to small plots of bare soil (5 x 7 m; three replicates). Soil was sampled up to 1 year after application (the number of samples and their surface area were not reported). The DT_{50} [5] values found for pyraflufen-ethyl ranged from 1-7 days and those found for E1 ranged from 11 to 44 days after spring application and from 35-71 days after autumn application. The DT_{90} [6] values found for E1 were 121-345 days after spring application and 115-236 days after autumn application. The metabolite E2 was not detected after spring application (detection limit 0.01 mg/kg) and its maximum content in soil was 0.02 mg/kg after autumn application. Maximum contents of the metabolite E3 were 0.05 mg/kg after spring application and 0.07 mg/kg after autumn application. These contents were measured in 5-cm thick layers. Assuming a dry bulk density of 1.4 kg/l, a content of 0.07 mg/kg in a 5-cm layer corresponds with about 50 g/ha of E3 which implies that E3 was formed in significant fractions of the applied amount in the field.

4.4 Leaching to groundwater

No lysimeter study was conducted because reported PEC [7] groundwater calculations for the German Hamburg scenario did not result in concentrations of E1, E2 and E3 exceeding 0.1 mg/l.

The Committee conducted PEC groundwater calculations for the FOCUS [8] scenarios (FOCUS 2000) with the PEARL model version 1.1.1 considering only the E1 metabolite because concentrations of the E2 and E3 metabolites can be expected to be lower. The calculations were based on the following model input:

- Pyraflufen-ethyl was applied to soil 15 days after emergence of winter wheat at a rate of 10.1 g/ha (based on a dose of 13.5 g/ha assuming 25% crop interception; see Table 2.14 of FOCUS, 2000).

- The K_{OM} of pyraflufen-ethyl was estimated to be 1150 l/kg and its half-life 1 day.

- The K_{OM} of E1 was estimated for each FOCUS scenario via considering the pH-H_2O of each FOCUS topsoil and selecting the K_{OM} value (47, 58 or 112 l/kg) whose pH value was closest to that of the FOCUS topsoil.

- The percentage formed of E1 out of the parent compound was estimated to be 100%.

- The half-life of E1 in top soil at 20°C and matric pressure of -10 kPa was estimated to be 39 days via averaging the half-lives of four soils (19, 20, 24 and 93 days) as derived from laboratory studies (the DT_{50} values found in the field persistence studies were not used because the Committee could not assess the acceptability of these data for this purpose; moreover, they were more or less consistent with the laboratory degradation rates). The moisture correction of all half-lives had to be based on Table 5.2 of FOCUS (2000) because the definition of maximum water holding capacity was not clear in the reported studies. The half-life of 93 days was based on a study with one soil at two temperatures (half-lives of 53 days at 20°C and of 328 days at 10°C) assuming the default value of 54 kJ/mol for the Arrhenius activation energy as recommended by FOCUS (2000). There was no need to include a pH-dependency of the half-lives in the calculations (the half-life/pH combinations were 20 days - 4.9, 19 days - 5.8, 93 days - 6.3, and 24 days - 7.8).

Calculated 80th percentile groundwater concentrations of E1 for the nine FOCUS groundwater scenarios were 0.000, 0.000, 0.001, 0.001, 0.002, 0.003, 0.007, 0.010 and 0.038 mg/l. These scenarios should be viewed collectively as representing realistic worst-cases for major agricultural areas in the EU (FOCUS, 2000).

4.5 Toxicological assessment

E1 is a major metabolite of pyraflufen-ethyl in rats, therefore its toxicity is covered by the toxicological testing of the parent compound.

When considering the human risk, the Committee has compared the worst-case exposure scenario of humans to E1 through drinking water with the provisional acceptable daily intake (ADI) value of pyraflufen-ethyl, 0.2 mg/kg bw/day. The calculated concentration of E1 in ground water due to leaching through the soil will usually be below 0.01 mg/l although values in the range of 0.01 mg/l and 0.04 mg/l cannot be excluded in exceptional cases (for two out of worst case scenarios, values from 0.01 mg/l and 0.04 mg/l [10-40 ng/l] were found). Assuming an average intake of water of 2 l/day, a maximum intake of 80 ng of E1 /day can be expected. This would result, assuming a 70 kg average man, in a maximum daily intake of 1.1 ng/kg bw, indicating a safety margin of 1.8×10^5 with respect to the provisional ADI [9]. The Committee, therefore, concludes that exposure to E1 through drinking water does not pose any significant health risk to humans.

5. REFERENCES

FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. EC Document Sanco/321/2000 rev.2, 197 pp.

6. DOCUMENTS MADE AVAILABLE TO THE COMMITTEE

- 1. Pyraflufen-ethyl: Terms of reference (SCP/PYRAF/001 submitted by DG SANCO, 8 August 2000).
- 2. Pyraflufen-ethyl: Evaluation table -Doc. SANCO/3038/99 rev. 0 - 03.07.00 (SCP/PYRAF/003 submitted by DG SANCO, 18 December 2000).
- 3. Pyraflufen-ethyl: List of end points (SCP/PYRAF/004 submitted by DG SANCO, 18 December 2000).
- 4. Pyraflufen-ethyl: Effects on non target species (SCP/PYRAF/005 submitted by DG SANCO, 18 December 2000).
- 5. Pyraflufen-ethyl: Residues (SCP/PYRAF/006 submitted by DG SANCO, 18 December 2000).
- 6. Pyraflufen-ethyl: Draft Review report for the active substance pyraflufen-ethyl 23 June 2000 (SCP/PYRAF/007 submitted by DG SANCO, 18 December 2000).
- 7. Pyraflufen-ethyl: Impacts on human and animal health (SCP/PYRAF/008 submitted by DG SANCO, 18 December 2000).
- 8. Pyraflufen-ethyl: Danish comments - 14-07-2000 (SCP/PYRAF/009 submitted by DG SANCO, 18 December 2000).
- 9. Pyraflufen-ethyl: Fate and behaviour (SCP/PYRAF/010 submitted by DG SANCO, 18 December 2000).
- 10. Pyraflufen-ethyl: draft evaluation report (monograph) prepared by Belgium as Rapporteur Member State (Volumes 1 to 4) - June 1999.

7. ACKNOWLEDGEMENTS

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Environmental assessment WG: Prof. Hardy (Chairman) and Committee members: Mr. Koepp, Prof. Leszkowicz, Prof. Papadoupoulou Mourkidou, Dr. Sherratt, Prof. Silva Fernandes, invited experts: Dr. Boesten, Dr. Carter, Dr. Forbes, Dr. Hart and Dr. Luttik.

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[1] OJ N° L 230, 19. 8.1991, p. 1.
[2] European Commission Co-ordination.
[3] Organic carbon adsorption coefficient.
[4] Organic matter adsorption coefficient.
[5] Period required for 50% dissipation.
[6] Period required for 90% dissipation.
[7] Predicted Environmental Concentration.
[8] Forum for the Co-ordination of pesticide fate models and their use.
[9] Acceptable daily intake.