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OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON A SPECIFIC QUESTION FROM THE COMMISSION CONCERNING THE EVALUATION OF FENARIMOL IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC

(Opinion adopted by the Scientific Committee on Plants on 8 November 2001)

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A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON A SPECIFIC QUESTION FROM THE COMMISSION CONCERNING THE EVALUATION OF FENARIMOL IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC
(Opinion adopted by the Scientific Committee on Plants on 8 November 2001)

B. TERMS OF REFERENCE

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

"Can the Committee comment on the approach taken to calculate Predicted Environmental Concentrations (PEC) in soil?"

C. OPINION OF THE COMMITTEE

The Committee is of the opinion that the transformation rate of fenarimol in field soil (once it has penetrated deep enough into the soil matrix to exclude loss processes at the soil surface such as photolysis) can be estimated on the basis of the soil incubation studies in the laboratory. This approach is consistent with the results from field persistence studies, when considering loss processes at the soil surface. The Committee disagrees with the approach taken to calculate PEC in soil because it is exclusively based on the overall results of the field persistence studies and as a consequence ignores the influence of the loss processes at the soil surface and the results of the soil incubation studies in the laboratory. The Committee proposes an alternative approach in which (a) the fraction of the applied amount which stays exposed at the soil or plant surfaces disappears so fast that it does not contribute to the long-term accumulation, and (b) the disappearance of the remaining fraction which penetrates into the soil is derived from the laboratory studies.

A. TITLE

REPORT OF THE SCIENTIFIC COMMITTEE ON PLANTS ON A SPECIFIC QUESTION FROM THE COMMISSION CONCERNING THE EVALUATION OF FENARIMOL IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC

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C. BACKGROUND

Fenarimol is an existing active substance (a.s.) in the context of Council Directive 91/414/EEC[1], which is covered by the first stage of the work programme established by Commission Regulation (EEC) 3600/92[2].

A draft assessment report (monograph) has been prepared by the Rapporteur Member State (RMS, UK) on the basis of a dossier presented by the notifier (Dow AgroSciences). In order to prepare its opinion the Scientific Committee on Plants had access to the documents listed below.

The SCP already issued an opinion on a question related to repro-toxicity (Opinion adopted 18 May 1999[3]). The remaining important issue identified by the evaluation group is that fenarimol is a very persistant compound which shows almost no degradation in laboratory tests and limited degradation in soil studies. A 5 years soil degradation study is currently carried out by the notifier and the results are expected in 2004. In the evaluation, the RMS concluded that fenarimol concentration in soil would reach a plateau after 4 years. Ecotoxicity data (earthworms studies, litter bag study, etc.) have been provided and end-points identified.

In order to confidently set TER[4] values for soil organisms, the Commission would like the SCP to comment on the approach taken to calculate PEC_{soil}[5].

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[1] OJ N° L 230 of 19. 8.1991, p. 1.
[2] OJ N° L 366 of 15.12.1992, p. 10.
[3] http://europa.eu.int/comm/food/fs/sc/scp/out42_en.html
[4] Toxicity Exposure Ratio.
[5] Predicted Environmental Concentration.

Source documents made available to the Committee:

1. Fenarimol: Terms of reference, submitted by DG Health and Consumer Protection, 26 June 2001 (SCP/FENARI-bis/001).

2. Fenarimol: Evaluation table - 6821/VI/97 - rev. 11 (02.04.2001), submitted by DG Health and Consumer Protection26 June 2001 (SCP/FENARI-bis/003).

3. Fenarimol: Danish comments on full report and evaluation table, submitted by DG Health and Consumer Protection, 26 June 2001 (SCP/FENARI-bis/004).

4. Fenarimol: Extract from Monograph (UK, RMS) Volume 3 Annex B, March 1996 PHYSICO-CHEMISTRY and FATE, prepared by DG Health and Consumer Protection, 26 June 2001 (SCP/FENARI-bis/005).

5. Fenarimol: Addendum to the Monograph (Volume 3 Annex B), submitted by DG Health and Consumer Protection, 26 June 2001 (SCP/FENARI-bis/006).

6. Fenarimol: comments from the notifier, submitted 18 July 2001 (SCP/FENARI-bis/007).

7. Havens P.L. and Davis J.D., Soil Accumulation and Groundwater Predicted Environmental Concentrations of Fenarimol When Applied Under Worst-Case European Conditions-Revised Report, study, GH-C 4842R, submitted by Notifier, July 2001 (Property of Dow AgroSciences).

D. SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED

Question:

"Can the Committee comment on the approach taken to calculate Predicted Environmental Concentrations (PEC) in soil?"

Opinion of the Committee:

The Committee is of the opinion that the transformation rate of fenarimol in field soil (once it has penetrated deep enough into the soil matrix to exclude loss processes at the soil surface such as photolysis) can be estimated on the basis of the soil incubation studies in the laboratory. This approach is consistent with the results from field persistence studies, when considering loss processes at the soil surface. The Committee disagrees with the approach taken to calculate PEC in soil because it is exclusively based on the overall results of the field persistence studies and as a consequence ignores the influence of the loss processes at the soil surface and the results of the soil incubation studies in the laboratory. The Committee proposes an alternative approach in which (a) the fraction of the applied amount which stays exposed at the soil or plant surfaces disappears so fast that it does not contribute to the long-term accumulation, and (b) the disappearance of the remaining fraction which penetrates into the soil is derived from the laboratory studies.

Scientific background on which the opinion is based:

1. Soil degradation rates in laboratory studies

The transformation rate of fenarimol was studied in four soils (loamy sand, sandy loam, clay loam, clay) at 20^{o}C and at a moisture content corresponding with 40% of maximum water holding capacity (MWHC). The study lasted 180 days (0.5 years). After application of 0.05 mg/kg of fenarimol half-lives of 1.2 to 3.7 years were found and after application of 0.25 mg/kg of fenarimol half-lives of 2.4 to 5.0 years were found. For each soil the half-lives obtained with two application rates were averaged and these average half-lives were calculated back to the standard moisture content corresponding with a suction of -10 kPa as recommended by FOCUS (2000, p. 90). The results are as follows:

Soil	Average half-life (years) at 40% of MWHC	Half-life (years) at suction of -10 kPa
clay loam	1.8	1.1
sandy loam	1.8	1.2
clay	2.4	1.3
loamy sand	4.4	3.4

The half-life ranges from 1.1 to 3.4 years at a suction of -10 kPa and 20^{o}C which corresponds with a range from 2 to 7 years at 10^{o}C (assuming a Q_{10} factor for correction of soil temperature of 2.2 as recommended by FOCUS, 2000, p. 92).

Studies with five other soils showed similar results to those obtained with the four soils shown above.

2. Photolysis studies

Radioactive fenarimol was applied in chloroform at a rate of 8 kg/ha to a pan and the chloroform was evaporated. The pan was exposed to sunlight in Indiana (USA) at a maximum air temperature of 37^{o}C. After 8 days, 37% of applied radioactivity was recovered and 4% of applied radioactivity was fenarimol. In another study radioactive fenarimol was applied in dichloromethane at a rate of 2.3 kg/ha to a pan and the dichloromethane was evaporated. The pan was exposed to sunlight in Indiana (USA) for 100 days between December and February at a maximum air temperature of 18^{o}C. After 100 days, 72-85% of applied radioactivity was recovered and 33-38% of applied radioactivity was fenarimol.

Fenarimol was applied at a rate of approximately 0.1 kg/ha to a layer of 0.4 mm thick silt loam soil. The soil was exposed to sunlight in Indiana (no further details reported) and no decline in fenarimol was observed after 1.3 days.

Several studies on photolysis of fenarimol in water were conducted and half-lives ranging from 0.6 to 12 hours were found.

The photolysis studies demonstrate that fenarimol can be transformed photochemically and that the exposure conditions have a strong effect on the photolysis rate.

3. Sorption and mobility

Adsorption studies with three topsoils resulted in values of the organic-carbon/water distribution coefficient (K_{OC}) of 634 to 992 L/kg. An adsorption study with a sand containing only 0.3% organic carbon and 5% clay resulted in a K_{OC} value of 500 L/kg.

4. Field persistence studies

Fenarimol was sprayed onto bare soil (0.27 kg/ha) at four German field sites in May 1990. Plot sizes varied from 50 to 84 m^2. The monograph presents the results as a graph of the concentration (mg/kg) in the 0-20 cm layer over a period of 610 days. The poor graphical resolution of the graph enables only superficial assessment by the Committee. The results for two of the four sites (Alsfeld and Grebin) are unreliable because immediately after application concentrations were found corresponding with three to four times that predicted from the application rate (as noted by the RMS). The other two sites (Ismaning and Rohr) showed DT_{50}[6] values of 95-123 days and DT_{90} values greater than 610 days.

Fenarimol was sprayed onto bare soil (0.27 kg/ha) at two German field sites in May 1992 (Herford and Gornitz). The plot size was 75 m^2. Soil samples were taken up to 609 days after application. The monograph reports only the resulting DT_{50} and DT_{90} values which were 60 and 489 days for Herford and 130 and >609 days for Gornitz.

Two field studies were conducted in Greenfield (Indiana, USA). In the first one, radioactive fenarimol (1.2 kg/ha) was added to the surface of silt loam soil (in steel cylinders with 10 cm diameter). In the second field, radioactive fenarimol (1 or 6 kg/ha) was incorporated in the top 8 cm of the same soil of a small plot (0.65 m^2). Weather conditions were normal (no further details available). In the first experiment a DT_{50} of 112 days was found and after 511 days still 35% of the applied fenarimol was recovered. In the second experiment, 65% of the applied fenarimol was recovered after 903 days so the DT_{50} was longer than 2.5 years (65% after 903 days corresponds with a DT_{50} of about 4 years assuming first-order kinetics).

In conclusion, seven field experiments on soil persistence are available in which fenarimol was applied to the soil surface. The Committee excludes the Alsfeld and Grebin experiments from further discussion because these are considered not reliable. The remaining five experiments showed DT_{50} values ranging from 60 to 130 days. The only field experiment in which fenarimol was incorporated into soil showed a DT_{50} of more than 2.5 years. The Committee attributes the more rapid decline of surface-applied fenarimol to loss processes at the soil surface such as photolysis and runoff. The photolysis studies have demonstrated that photolytic transformation of fenarimol is possible. Runoff cannot be excluded because fenarimol is strongly sorbed and because the German plot sizes were small (50-84 m^2). Runoff losses are especially relevant for the Ismaning and Rohr sites which received 140-240 mm rainfall in the first month after application. For the USA field study with surface-applied fenarimol losses resulting from raindrop splash are not unlikely in view of the 10-cm diameter of the columns. The only field study in which fenarimol was incorporated into soil showed a DT_{50} that is consistent with the half-lives obtained in the soil incubation studies in the laboratory. The Committee concludes that the field persistence studies do not demonstrate that the transformation of fenarimol in field soil (once it has penetrated deeper than, say, the top

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[6] DT_{50} and DT_{90} are time periods necessary for disappearance of 50 and 90% of the applied amount.

centimetre) proceeds faster than expected on the basis of the nine incubation studies in the laboratory.

5. Approach of the RMS to calculate Predicted Environmental Concentrations (PEC) in soil

The RMS selected the German field site with the longest DT_{50} (Gornitz) and used a model assuming √1st order kinetics. Linear regression of the Gornitz data resulted in a √1st order DT_{50} of 120 days. The RMS assumed that fenarimol was equally distributed over the top 5 cm and used a dry bulk density of 1.5 kg/L. Two application scenarios were considered (apples and turf). For both scenarios 50% crop interception was assumed. For apples the RMS assumed that fenarimol was applied 6 times at a rate of 80 g/ha with a 7 day application interval. This resulted in a plateau concentration of 0.28 mg/kg after 3 years with the peak concentration in soil after the last application in the third years being 0.34 mg/kg. For turf the RMS assumed that fenarimol was applied 4 times at a rate of 1500 g/ha with a 21 day application interval. This resulted in a plateau concentration of 0.74 mg/kg after 3 years with the peak concentration in soil after the last application in the third year being 2.76 mg/kg. The RMS used a non-conventional model to calculate plateau levels in soil but did not provide a detailed description of the calculation procedure.

6. Committee's assessment of approach of the RMS to calculate Predicted Environmental Concentrations (PEC) in soil

The transformation rate of fenarimol was slow in all incubation studies with soil (half-lives ranging from 1.2 to 5 years) and it was persistent in all field studies (DT_{90} values of >1.7, >1.7, 1.3, >1.7, >>1.4 and >>2.5 years). Therefore any approach to calculate the long-term PEC in soil implies extrapolation in time far beyond the duration of any of the laboratory and field experiments. This implies that the conceptual assumptions in the approach have probably a large effect on the outcome.

Based on the assessment of the field persistence studies (see Section 4, p. 6) the Committee concludes that the results of the laboratory studies should be taken into account in the calculations of the PEC for soil. Consequently the approach of the RMS is unacceptable because it ignores these results.

Additionally the Committee considers the conceptual basis of the model used by the RMS too weak for the estimation of fenarimol persistence based on the following argumentation. The Committee assumes that the √1st-order-kinetic model is represented by $y = y0 \exp(-a \sqrt{t})$ in which y is the remaining amount of pesticide, $y0$ is the applied amount of pesticide, a is the parameter describing the transformation rate and t is time. The Committee considers this model inappropriate for predictive calculations because it is not based on a rate equation (e.g. the first-order kinetic model assumes that the rate is proportional to the remaining amount and no equivalent assumption can be formulated for the √1st-order-kinetic model). If no explicit expression for the rate is available, the conceptual basis of the model is not clear which is undesirable for extrapolative calculations such as those carried out by the RMS.

Instead the Committee proposes to calculate PEC in soil based on the following assumptions:

1. Both the fraction of the applied amount that is intercepted by the crop and the fraction that reaches the soil but does not penetrate into soil, disappear so fast via loss processes at the plant and soil surfaces that they can be ignored in the calculation of the PEC in soil.

2. The fraction of the applied amount that penetrates into soil (so the remaining part of the applied amount) is transformed in soil at rates corresponding with a half-life that ranges from 2 to 7 years at 10^{o}C and a suction of –10 kPa.

3. Because the interception depends on the treated crop, the fraction of the applied amount that penetrates into soil will also depend on the treated crop; this fraction is expected to range from 10 to 50% and has therefore been considered.

If these assumptions are correct, it will take 6-20 years to reach a steady-state situation in North West Europe. It is likely that leaching contributes significantly to loss from the top 5 cm over such a time period (assuming no tillage for the scenario crops apples and turf). Therefore the Committee recommends to using one of the FOCUS simulation models to calculate the PEC in the top 5 cm of soil.

7. Committee's assessment of approach of RMS to calculate Predicted Environmental Concentrations (PEC) in groundwater

The Committee noted that PEC in groundwater was calculated using PELMO and a field DT_{50} of 100 days. PELMO uses this DT_{50} value to calculate transformation rates within the soil matrix over periods of many years. In view of the above considerations, the Committee considers the PEC in groundwater reported by the RMS to be unreliable. It can be expected that a DT_{50} of 2 to 7 years for part of the applied amount will lead to much higher values for the PEC in groundwater.

E. References

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

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