Opinion regarding the evaluation of Flurtamone in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (opinion adopted by the Committee on 26 January 2001)

1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON THE EVALUATION OF FLURTAMONE IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

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2. TERMS OF REFERENCE

Following the opinion adopted by the Scientific Committee on Plants in 1998 [1] , the notifier has submitted new data to the Commission services.

The Scientific Committee on Plants (SCP) is now requested to respond to the following questions 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.

1. "Do the soil metabolites of flurtamone, particularly 3-trifluoromethylbenzoic acid (TFMBA), represent a risk for contamination of groundwater?"

2. "In the light of the new information submitted by the notifier, can the Committee confirm that Trifluoroacetic acid (TFAA) does not represent an unacceptable risk to groundwater?"

3. BACKGROUND

Flurtamone is a new active substance in the context of Directive 91/414/EEC [2]. In 1998, the Committee was consulted by the European Commission on the inclusion of flurtamone in Annex I to Directive 91/414/EEC. The opinion of the Committee was adopted on 18 December 1998. In its conclusions the SCP highlighted certain unresolved issues for the metabolites TFMBA and TFAA.

With respect to TFMBA, the SCP recommended the inclusion of soils with pH values between 7 and 8 in the sorption studies with this metabolite. The notifier (Rhône-Poulenc, now Aventis CropScience) agreed to perform these studies. The results have now been submitted to the Committee.

As regards the metabolite TFAA, in the 1998 opinion, the Committee concluded that the data made available did not enable to assess the risk of contamination of ground water by the said metabolite. The notifier has now submitted new data on the aquatic ecotoxicity of TFAA and a health risk assessment for this metabolite.

4. OPINION

4.1 Question 1:

"Do the soil metabolites of flurtamone, particularly 3-trifluoromethylbenzoic acid (TFMBA), represent a risk for contamination of groundwater?"

Opinion of the Committee:

The Committee concludes that concentrations of TFMBA leaching to groundwater are expected to be below 0.1 mg/l for soils with pH values that are not greater than 5. For most soils with pH values greater than 5, concentrations will remain below 0.1 mg/l. However, in a small percentage of cases/situations, concentrations exceeding 0.1 mg/l may occur. The Committee concludes that use scenarios exist for flurtamone which pose no unacceptable risk to groundwater with respect to leaching of the metabolite TFMBA.

Technical background on which the opinion is based:

Laboratory studies on the soil metabolism of flurtamone show that about 40% CO_2 and about 30% soil-bound residues are formed. In these studies two soil metabolites have been identified: 3-trifluoromethylbenzoic acid (TFMBA) and trifluoroacetic acid (TFAA). Both laboratory studies and field studies have shown that flurtamone can be transformed into TFMBA at levels above 10% of the applied amount in soils. In metabolism studies with flurtamone in three soils TFMBA reached maximum levels of 8.3 and 10.8% of the radioactivity dose in two soils whereas it was not detected in the third soil. In field studies TFMBA reached a maximum level of 11% of the dose. In its opinion of 1998, the Committee estimated the half-life of TFMBA at approximately 50 days for a sandy loam soil at 22 °C. At that time no sorption data were available for TFMBA. The Committee recommended to include soils with pH values between 7 and 8 in the sorption studies with TFMBA that the notifier had already agreed to perform. Since the 1998 opinion, the following new experimental information on behaviour of TFMBA was provided by the notifier:

1. The pK_A (dissociation constant) of the COOH-group in the TFMBA molecule is 4.2.

2. Adsorption of TFMBA was studied in four soils and the transformation rate was studied in three soils. The results are described in the following table.

Soil texture	organic carbon (%)	pH (0.01 M $CaCl_2$)	K_{OC} [3] (l/kg)	Half-life (days)
sandy loam	4.1	5.0	47	15
clay loam	3.8	7.2	16	12
loam	2.5	6.8	15	16
sandy loam	0.7	6.1	52	

Given the pK_A of 4.2, the adsorption of TFMBA is expected to vary strongly with pH in the range from pH 4 until about 6. Therefore the adsorption studies with the clay loam and loam soils give realistic worst-case K_{OC} values (15 and 16 l/kg).

The notifier provided additionally simulations for TFMBA leaching using the model PELMO 3.00 and using a soil and weather scenario as used in German pesticide registration. Using the

worst-case K_{OC} and half-life combination from the above table (15 l/kg and 16 days), concentrations of TFMBA were calculated to be lower than 0.001 mg/l. The Committee checked this by estimating TFMBA leaching with the PESTLA 1.1 model and the Dutch standard scenario (based on model output published in J. Environ. Qual. 20: 425-435). TFMBA was treated as if it was a parent compound. The Dutch standard scenario is based on a dose of 1 kg/ha. The assessment was based on a TFMBA application of 24 g/ha in spring assuming a linear relationship between dose and leaching (a conservative approach). An estimated groundwater concentration of 0.007 mg/l was found which is also far below the limit value of 0.1 mg/l.

Accordingly the results of the new laboratory studies on adsorption and transformation rate in soil indicate that leaching to groundwater would always remain below 0.1 mg/l. However, using one of the soil metabolism studies (soil with pH=6.4) from the monograph, the Committee estimated the half-life of TFMBA of about 50 days at 22^{o}C (corresponding with a half-life of 43 days at 20^{o}C). Such a half-life would probably result in estimated groundwater concentrations of TFMBA exceeding 0.1 mg/l. A previously reported lysimeter study (soil with pH=6) resulted in an average concentration over a three year period of TFMBA of 0.09 mg/l after application in two successive years implying that annual average concentrations of TFMBA above 0.1 mg/l were measured.

With respect to the metabolite trifluoroacetic acid (TFAA) no new experimental information with respect to fate in soil was provided.

4.2 Question 2

"In the light of the new information submitted by the notifier, can the Committee confirm that trifluoroacetic acid (TFAA) does not represent an unacceptable risk to groundwater?"

Opinion of the Committee:

Based on the new data supplied, the Committee supports the assessment of the RMS that the observed leaching of TFAA does not represent an unacceptable risk to aquatic organisms via groundwater. This is due to the lack of effect on primary productivity in mesocosms, the evidence of very low toxicity on algae, Daphnia, fish and terrestrial plants, and the difference between concentrations in the leachate and lowest observed toxicity. The toxicological information made available to the Committee is insufficient for a full assessment of TFAA.

Scientific background on which the opinion is based:

Originally, the SCP had given the following opinion (excerpt of SCP/FLURT/004-Final, Opinion expressed by the SCP on 18 December 1998):

" In a duplicate lysimeter study the soil metabolite trifluoroacetic acid (TFAA) was shown to leach at average concentrations over a three-year period of 1.4 and 3.1 mg/l and accordingly represents a risk for contamination of groundwater. On the basis of aquatic toxicity data it was stated (1) that "TFAA is of low concern for the risk of aquatic organisms". However, these data were not included in the documentation submitted to the Committee. Furthermore, reference was made to data (1) on TFAA phytotoxicity and human toxicology that was also not submitted to the Committee. Therefore the Committee is unable to assess whether TFAA represents an unacceptable risk for contamination of groundwater . "

Subsequently, additional information was submitted to the SCP in September 1999 (SCP/FLURT/006 - 011), which was evaluated by the RMS in an addendum to the monograph of February 2000 (SCP/FLURT/013). The Committee, in order to be able to finalise the assessment, then requested the full report of a specific study (Bott & Standley; ref. 14-15) which was submitted in August 2000.

Ecotoxicological aspects:

The available data on aquatic toxicity of TFAA show rather low toxicity on a wide range of algal species. The NOEC [4] values are above 100 mg/l, with one exception (**Scenedesmus capricornutum**) at 0.12 mg/l. On terrestrial crop and weed plants, there was no phytotoxicity at rates up to 250 g/ha. Undiluted lysimeter leachates showed no effects.

For fish and **Daphnia**, toxicity of TFAA was very low (LC/EC_{50} [5] > 1200 mg/l).

Because of the occurrence of TFAA in the atmosphere as a metabolite of industrial chemicals (substances replacing ozone-depleting chlorofluorocarbons), a stream mesocosm study had been conducted (Bott & Stanley, 1995) to assess the effect of TFAA on biological processes in small streams. Following 5 months of exposure to 31-32 mg/l TFAA in the streams, samples of the microbial community were measured for activity. Primary productivity (measured as chlorophyll a) was unaffected by concentrations of up to 200 mg/l TFAA. However, the excretion of photosynthetate (measured as dissolved organic ^{14}C, thus reflecting the net balance of the microbial community of producers and consumers) by the microbial community differed significantly in one part of the study. The mechanism of this effect could not be entirely clarified but indications exist that the bacterial part of the community adapted to TFAA during the 5 months of preceding exposure to 31-32 mg/l, and was now more efficiently metabolising TFAA as compared to unacclimatised communities.

Macro-invertebrates were sampled twice (April and July) during the stream mesocosm studies. However, the exact method of sampling was not described, and there are unexplained inconsistencies (i.e., Coleoptera and Ephemeroptera being counted at one sampling date but merely recorded for presence at the other sampling date). Hence, the following results have to be qualified as indicative only.

Amphipods, oligochaetes and Ephemeroptera larvae were most abundant. Numbers of sampled animals or their recorded presence showed the variability typical for such studies, with no obvious effect of TFAA.

In summary, the database for TFAA is rather extensive in comparison to that for other metabolites. While stream mesocosm data suggest that continuous exposure (> 5 months) to TFAA at levels of 31-32 mg/l may cause adaptation in the physiology of stream bacterial communities, the Committee observed that this change should not be seen as a negative effect in this case, biological degradability being desired for substances introduced into the environment. Therefore, the Committee supports the assessment of the RMS that the observed leaching of TFAA does not represent an unacceptable risk to aquatic organisms via groundwater because of:

- the lack of effect on primary productivity in those mesocosms,
- the evidence of very low toxicity on algae, **Daphnia**, fish and terrestrial plants, and
- the difference between concentrations in the leachate and lowest observed toxicity.

Toxicological aspects:

A few mammalian toxicology data on TFAA were made available to the Committee. TFAA seems to be of moderate acute toxicity (oral rat LD_{50} [6] 200-400 mg/kg body weight) and is irritant to the skin. It induces peroxisome proliferation in rats repeatedly treated with very high doses (150-400 mg/kg body weight per day) and inhibits pyruvate kinase activity. Two bacterial mutagenicity studies gave negative results. Reproduction, developmental and long-term toxicity and carcinogenicity studies are missing. Summaries of inhalation and oral long-term/carcinogenicity studies with 1,1-dichloro-2,2,2-trifluoroethane and 1,1,1,2-tetrafluoroethane, which are partly metabolised to TFAA, were made available by the Notifier. However, the toxicological information made available to the Committee is insufficient for a full assessment of TFAA.

5. REFERENCES

1. Opinion of the Scientific Committee on Plants regarding the inclusion of flurtamone in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market adopted on 18 December 1998. click here

2. Boesten JJTI & van der Linden AMA (1991) Modeling the influence of sorption and transformation on pesticide leaching and persistence. J. Environ. Qual. 20: 425-435.

6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

- 1. Monograph prepared in the context of the inclusion of flurtamone in Annex I to Council Directive 91/414/EEC. Ministère de l'Agriculture, de la Pêche et de l'Alimentation, Direction générale de l'alimentation, France - March 1997.
- 2. Flurtamone: computer simulation of the potential for mobility of the metabolites TFMBA and TFAA in soil using the PELMO 3.00 model. G Reinken (1999). RPA Study 17862. Rhône-Poulenc Agriculture Limited, Ongar, UK.
- 3. [^{14}C]-3-Trifluoromethylbenzoic acid rate of degradation in three soils. CM Burr (1999). RPA Study 15616. Rhône-Poulenc Agriculture Limited, Ongar, UK.
- 4. [^{14}C]-3-Trifluoromethylbenzoic acid adsorption/desorption to and from four soils. MB Simmonds & CM Burr (1999). RPA Study 15618. Rhône-Poulenc Agriculture Limited, Ongar, UK.
- 5 Flurtamone: further assessment on the section fate and behaviour, submitted by France July, 9 1999. (Doc. SCP/FLURT/006).
- 6 Flurtamone: supplemental dossier # 3 for the evaluation of the active substance flurtamone according to Council Directive 91/414/EEC, P.E.Th. van der Kouwe, Rhône-Poulenc, July, 1 1999. (Doc. SCP/FLURT/007).
- 7 Flurtamone: response document to the French monograph and to the comments from Germany and the United Kingdom, July, 29 1999. (Doc. SCP/FLURT/009).
- 8 Addendum to the evaluation table for flurtamone doc. 7606/VI/97-Rev5, submitted by France, January 17 2000 (Doc. SCP/FLURT/012).
- 9 Addendum to the monograph of the active substance flurtamone; submitted by France, January, 17 2000. (Doc. SCP/FLURT/013).
- 10 Flurtamone: evaluation table doc. 7606/VI/97-Rev5, submitted by France, January 17 2000. (Doc. SCP/FLURT/014).

- 11 TFAA and TFMBA references as submitted by Rhône-Poulence Agro after the submission of the initial and reformatted EU registration dossier, submitted by France February 4 2000. (Doc. SCP/FLURT/015).
- 12 Flurtamone: Trifluoroacetic acid: health effect risk assessment - March 3, 1999, Giovanna Semino, Rhône-Poulenc Agro. (Doc. SCP/FLURT/016).
- 13 Letter from the Rapporteur Member State (France) enclosing data relating to the metabolite TFAA, March 9 1999. (Doc. SCP/FLURT/017).
- 14. Bott, T.L.; Standley, L.J. (1995): Potential Effects of Trifluoroacetate on Freshwater Algal Communities and Primary Productivity.
- 15. Bott, T.L.; Standley, L.J.: The Effect of TFAA on Biological Processes in Streams (undated).

7. ACKNOWLEDGEMENTS

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

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

Toxicology WG: Prof. Maroni (Chairman) and Committee members: Dr. Delcour-Firquet, Prof. Leszkowicz, Dr. Meyer, Dr. Moretto, Dr. Petzinger, Prof. Savolainen, Prof. Silva Fernandes, Dr. Speijers and invited experts: Dr. Fait, Dr McGregor.

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[1] Opinion of the Scientific Committee on Plants regarding the inclusion of Flurtamone in annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/FLURT/004-Final) - (Opinion expressed by the SCP on 18 December 1998).

[2] OJ N° L 230, 19.08.1991, P. 1.

[3] Organic carbon adsorption coefficient.

[4] No observed effect concentration.

[5] Median effective concentration.

[6] Lethal dose median.