EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C3 - Management of scientific committees II; scientific co-operation and networks

SCIENTIFIC COMMITTEE ON PLANTS **SCP/THIABEN/002-Final**
22 September 2000

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF THIABENDAZOLE 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 22 September 2000)

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: B232 6/25.
Telephone: direct line (+32-2)295.77.05, switchboard 299.11.11. Fax: 295.73.32.

Internet: Michael.Walsh@cec.eu.int
F:\WebDev\4296.doc

1. TITLE

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

2. TERMS OF REFERENCE

The Scientific Committee on Plants (SCP) is requested to consider the following question:

"Can the Committee comment on the potential environmental risk associated with the post-harvest use of thiabendazole and can it confirm that the proposed risk mitigation measures (waste water treatment) are adequate to protect surface waters?"

3. BACKGROUND

The draft Commission Directive for inclusion of thiabendazole 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 an evaluation report (monograph) prepared by the Rapporteur Member State (Spain) of a dossier submitted by the notifier (Novartis), a review report prepared by the Commission and the Recommendations of the ECCO[1] Peer Review Programme.

Thiabendazole is a fungicide of the benzimidazole group. It is mainly used for post-harvest treatment (dipping or drenching) of fruits (bananas, citrus fruits, pome fruits) and potatoes (seed and ware potatoes).

4. OPINION

Question

"Can the Committee comment on the potential environmental risk associated with the post-harvest use of thiabendazole and can it confirm that the proposed risk mitigation measures (waste water treatment) are adequate to protect surface waters?"

[1] European Community Co-ordination.

Opinion

The SCP is of the opinion that a discharge of thiabendazole waste water (from dips and/or drenches) poses a potential risk for the functioning of the sewage treatment plant (STP) and for the receiving surface water.

Based on a risk assessment of untreated thiabendazole contaminated waste water the SCP is of the opinion that the waste water will not pose an unacceptable risk to the micro-organisms in the STP and the algae in the receiving surface water. A more refined risk assessment and/or mitigation measures are necessary for fish, daphnids and sediment dwelling organisms.

Based on the data provided, the SCP is of the opinion that the intended post-harvest uses (dipping and drenching) of thiabendazole for bananas, citrus, bulbs, pome fruits and potatoes in the EU will not pose an unacceptable risk to the aquatic organisms when adequate mitigation measures (depuration with diatom soil and activated carbon) have been carried out.

Scientific background on which the opinion is based

The risk of the use of a PPP[2] for aquatic organisms is normally based on a risk quotient, the TER[3]. The first step in the risk assessment is based on realistic worst case assumptions. When the TERs for the acute situation (based on EC_{50}[4] values) are above 100 for fish and daphnids and above 10 for algae the use of the PPP is considered to be safe. When the TERs are lower than 100 or 10 a refined risk assessment should be carried out or proposed mitigation measures must show that they are adequate to protect surface water.

4.1 Emission scenario

For the risk assessment of post-harvest uses of thiabendazole in dips and drenches an emission scenario depicted by Spain will be used. It is based on a representative citrus treatment (and covers also pome fruit applications[5]). Per day 50 tons of oranges are drenched in a total volume of 1000 litres containing 2.2 grams thiabendazole per litre (2.2 kg a.s.[6] per day). It is assumed that only 10% of this amount is adsorbed by the fruits. Therefore, the daily emission rate to the sewage treatment plant (STP) is 2 kg a.s.

4.2 Model calculations for STP according to USES 3.0

The computer model for the sewage treatment plant in USES 3.0 (RIVM, VROM, VWS 1999) is the same model as described in the Technical guidance document[7] in support of Commission Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance

[2] Plant Protection Product.
[3] The toxicity over exposure ratio.
[4] Median effective concentration.
[5] see document SCP/THIABEN/007.
[6] Active substance.
[7] Reference n° 3 in Section 5.

with Council Directive 67/548/EEC and Commission Regulation (EC) N° 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to human and the environment of existing substances in accordance with Council Regulation (EEC) N° 793/93.

The sewage treatment plant is modelled as an average-size treatment plant based on aerobic degradation by activated sludge, and consisting of 9 (or 6) compartments. This model is a multi-media box model of the 'Mackay-type, level III'. The model calculates steady-state concentrations in a STP consisting of a primary settler (optional), an aeration tank and a solid-liquid separator.

Input and configuration:

– Local emission to wastewater during episode	2 kg/day.
– Type of local STP	With primary settler (9-box)
– Calculate dilution from river flow rate	No
– Kom[8] (mean of 4 values)	4260

Local PECs[9] [based on Kom value (l/kg)]:

– PEC for micro-organisms in STP	0.539 mg/l
– Local PEC in surface water during emission period	0.0536 mg/l
– Local PEC in sediment during emission period	4.26 mg/kg wet weight

4.3 Available toxicity data

Organisms	Acute (EC_{50})	Chronic (NOEC[10])
Fish	0.55 mg/l	0.12 mg/l
Daphnids	0.81 mg/l	0.48 mg/l
Algae	8.99 mg/l	3.2 mg/l
Sediment dwelling organisms	--	3 mg/kg sediment
Micro-organisms (respiration)	>1000 mg/l [11]	--

4.4 TERs for the acute situation

Organisms	TER based on Kom (EC_{50} / PEC)
Fish	0.55/0.0536 = 10.2
Daphnids	0.81/0.0536 = 15.0
Algae	8.99/0.0536 = 168
Sediment dwelling organisms	3/4.26 = 0.7
Micro-organisms in STP	1000/0.539 = 1855

The TERs for acute exposure for algae and micro-organisms are above 10 and therefore no additional risk assessment is necessary.

[8] Organic matter adsorption coefficient.
[9] Predicted environmental concentrations.
[10] No observed effect concentration.
[11] Reference is summarised in Attachment IX of Report 98-227-1047, J. van der Kolk (1998).

The TERs for fish and daphnids are below 100 and a therefore more refined risk assessment or immediate risk mitigation is necessary.

4.5 Percent reduction necessary to achieve acceptable TER values

TERs based on Kom:
- Fish (TER is below 100): necessary emission reduction of 90 % (2 kg to 0.2 kg/day).
- Daphnids (TER is below 100): necessary emission reduction of 85 % (2 kg to 0.3 kg/day).
- Algae (TER is above 10): no reduction is necessary.
- Sediment dwelling organisms (TER is below 10): necessary emission reduction of 93 % (2 kg to 0.14 kg/day).
- Micro-organisms (TER is above 10): no reduction is necessary.

An overall reduction factor of 20 by sewage treatment would be sufficient to reduce the risk to aquatic organisms to an acceptable level.

4.6 Waste water treatment information

Nine studies (two under GLP), carried out by Tecnidex S.A. from Spain, have been conducted to assess the efficacy of depuration of thiabendazole contaminated waste water. The depuration technique is based on adsorption on granular activated carbon and a pre-treatment filtration of the contaminated waste water through bags of mesh size 1 micrometer filled with a diatom soil for eliminating solids. Starting concentrations of thiabendazole in the waste water ranged between 74 and 3200 mg/l.

After the pre-treatment reductions of 50-70% of the thiabendazole concentrations were obtained. Combined with the adsorption on granular activated carbon a contamination reduction of at least a factor of 7000 could be achieved. The best performance in the test was obtained using three carbon bottles and a retention time of 2 hours (references 110, 113, 117, 118, 119, 120 and 121, numbers refer to the documentation that was send to the RMS[12]).

4.7 Conclusion

Discharging thiabendazole contaminated waste water from dips or drenches into the sewage system poses a potential risk for the sewage treatment plant and for the receiving surface water.

TERs greater than 10 have been calculated for micro-organisms in the STP and the algae in the receiving surface water. TERs smaller than 100 have been calculated for fish and daphnids and smaller than 10 for sediment dwelling organisms (based on Kom values).

The proposed risk mitigation measures (waste water treatment as described above) are adequate to protect surface waters; a reduction by a factor of at least 7000 can be

[12] Rapporteur Member State.

achieved (which is a factor 350 greater than that calculated to be necessary to reduce the risk to an acceptable level in the chosen scenario).

5. REFERENCES

1. Kolk, van der J. (1998) MK 360 B (Thiabendazole) Activated sludge, respiration test - OECD Guideline # 209. Springborn Laboratories Report # 98-227-1047.

2. RIVM, VROM, VWS (1999) Uniform System for the Evaluation of Substances 3.0 (USES 3.0). National Institute of Public Health and the Environment (RIVM, Ministry of Housing, Spatial Planning and the Environment (VROM), Ministry of Health, Welfare and Sport (VWS), The Netherlands. RIVM report 601450004.

3. Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances, EC Catalogue Numbers CR-48-96-001, 002, 003, 004-EN-C. Office for Official Publications of the European Community, 2 Rue Mercier, L-2965 Luxembourg.

6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

1. Terms of reference “Evaluation of thiabendazole in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market” (Doc. SCP/THIABEN/001).

2. Evaluation table, Doc. 7604/VI/97rev. 11 (Doc. SCP/THIABEN/003).

3. Draft review report, Doc. 7603/VI/97-rev 0 (Doc. SCP/THIABEN/004).

4. Appendices to the evaluation of thiabendazole in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Doc. SCP/THIABEN/005).

5. Document D2 List of authorised uses in the EU and actual uses sorted by crops. P. Dieterle /CP 6.62 / April 1999 version 3 (Doc. SCP/THIABEN/006).

6. Report (Monograph) and proposed decision of Spain made to the European Commission under Article 7(1) of Regulation 3600/92 – July 1996 (Volumes 1, 2, 3 and 4).

6. Addendum to the Monograph Environmental, Fate and Behaviour and Ecotoxicology, prepared by Instituto Nacional De investigation y Tecnologia Agraria y Alimentaria (I.N.I.A) Spain – December 1999 (Doc. SCP/THIABEN/007)

7. ACKNOWLEDGEMENTS

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

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