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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Second meeting
Geneva, 13–17 February 2006
Item 5 (b) of the provisional agenda*

Inclusion of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: cyhexatin

Cyhexatin: additional information

Note by the secretariat

The annex to the present note contains the fact sheet issued following the removal of cyhexatin from the voluntary prior informed consent procedure, along with the amended decision guidance document containing the new information.

* UNEP/FAO/RC/CRC.2/1.

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Annex

List of documents annexed to UNEP/FAO/PIC/CRC.2/12/Add.3

- FACT Sheet on no longer inclusion of Cyhexatin in the PIC Procedure
- Revised Decision Guidance Document for Cyhexatin

CYHEXATIN IS NO LONGER INCLUDED IN THE PIC PROCEDURE

The FAO/UNEP Joint Group of Experts on PIC in March 1994 developed a policy for removing chemicals from the PIC procedure, based on reported actions of national authorities which had originally issued the bans or severe restrictions on which the decision to include the chemical had been taken. This policy is described on page 2 of this fact sheet.

Cyhexatin was originally included in the PIC procedure in 1991 because it was banned or severely restricted in 5 countries because of teratology concerns. Two manufacturers producing cyhexatin developed additional data on its teratogenic potential. This new/additional information was considered by the 1991 and 1994 FAO/WHO Joint Meeting on Pesticide Residues (JMPR). The 1994 JMPR stated that *"After taking into consideration the results of all the studies on teratogenicity in rabbits, the Meeting concluded that cyhexatin is not teratogenic to this species."*

The FAO/UNEP Joint Group of Experts at it's eighth meeting agreed that the developments relating to cyhexatin seemed to represent a situation where the information on which the regulatory actions were based was flawed. A more recent international review of all the available information on this particular aspect had changed the previous conclusion.

The procedure for removing a chemical from the PIC procedure was therefore brought to the attention of the Designated National Authorities in Cyprus, Hungary, Sweden, the United Kingdom and the USA in order to determine if, in the light of new or additional information which indicated that the scientific basis (teratogenic effects in rabbits) for their regulatory decision might have been flawed, they would reconsider their decision to ban the use of cyhexatin. They were also requested to indicate whether they were aware of this information in making their decision to ban cyhexatin and, if not, whether this information would have any impact on its present regulatory status. Responses were received from Cyprus, Hungary, Sweden and the United Kingdom.

The original DGD on cyhexatin was revised (toxicology section) to reflect the conclusions of the 1994 JMPR. The section on regulatory actions was amended to indicate that some countries were aware of the new data but in some instances had not been approached by the new manufacturers with a request to consider the new information to support a registration application. Other governments reported that they had reinstated its use based on the new information.

The revised DGD was circulated to all DNAs in September 1995, together with a covering letter highlighting the conclusions of the 1994 JMPR and drawing their attention to the present regulatory status in countries on which its entry into PIC was based. DNAs in importing countries were invited to reconsider their decision in the light of the new evidence and the removal of the chemical from the PIC procedure.

PIC Circular V, the Update of PIC Circular V and PIC Circular VI (July and December 1995 and July 1996) referenced the altered status of cyhexatin and the timeframe for its removal from the procedure.

As of 1 September 1996 import responses for cyhexatin were no longer circulated and cyhexatin would no longer be considered subject to the PIC procedure. A copy of the revised DGD can however be obtained upon request from the FAO/UNEP Joint Secretariat.

WHERE CAN FURTHER INFORMATION BE OBTAINED?

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POLICY FOR THE REMOVAL OF COMPOUNDS FROM THE PIC PROCEDURE - Taken from the report of the Seventh Meeting of the FAO/UNEP Joint Group of Experts on PIC, Section 8, p. 19

1. Companies can seek to have an inclusion or proposed inclusion in PIC reviewed in cases where:

(i) new scientific evidence is generated demonstrating that the health or environmental concerns that led to the ban or severe restriction which prompted inclusion in PIC are no longer substantiated; and

(ii) that evidence has been submitted for scientific review by national governments on whose actions the compound originally entered the PIC procedure.

2. The availability of an international peer review such as the JMPR, IPCS, etc., would be of interest in revising the DGD. The need would be considered on a case-by-case basis.

3. On the basis of the outcome of the scientific reviews by national governments, companies are invited to submit (in writing) a reasoned case for consideration by the Group when they believe removal from PIC or from consideration for inclusion is warranted.

4. In those situations where national governments are not interested in reviewing the new data or for commercial reasons, the manufacturer does not wish to resubmit the data for consideration, a letter from the responsible national authority or manufacturer stating these facts is required. A response must be received from all countries which indicated a ban or severe restriction that served as the basis for the compound's inclusion in PIC.

(i) The Secretariat will prepare a revised DGD which includes the new information and the updated regulatory status in countries.

(ii) DNAs of importing countries will be invited to reconsider decisions made in the light of the new evidence.

5. Compounds may be removed from the PIC procedure when all original bans are reviewed or when countries concur that the basis for the ban or severe restriction is no longer valid.

FAO/UNEP, 1 January 1997

The aim is to have a clear statement that the new scientific data relevant to the basis for the original ban or severe restriction have been evaluated by independent scientific authorities and the original decision reconsidered. It was recognized that it was difficult to develop a fixed procedure that would address every situation and that, while the proposed procedure was to serve as a guide to the process of removing a compound from the PIC, each proposal would have to be considered on a case-by-case basis.

The Meeting considered the following scenarios in attempting to provide guidance in the operation of the proposed procedure:

<u>A compound would be removed from the procedure where:</u>

- those countries which imposed the original ban or severe restriction, on the basis of which the compound entered the PIC procedure, have reviewed the new scientific data and reversed their decision;

- some countries have reviewed the scientific data and removed the ban or severe restriction but others were not interested in reviewing the new data.

On the basis of these actions the relevant DGD would be revised and reissued. It was suggested that there be a phased approach to removing the compound from the procedure and that the revised DGD remain in circulation for one year, after which the compound would be deleted from the list of compounds subject to the PIC procedure.

<u>A compound would remain in the procedure where:</u>

- those countries which imposed the original ban or severe restriction, on the basis of which the compound entered the PIC procedure, *have reviewed the new scientific data*, some have removed the ban or severe restriction but others have reaffirmed their previous decision.

OPERATION OF THE PRIOR INFORMED
CONSENT PROCEDURE FOR BANNED OR
SEVERELY RESTRICTED CHEMICALS
IN INTERNATIONAL TRADE

Revised
DECISION GUIDANCE DOCUMENT

Cyhexatin

JOINT FAO/UNEP PROGRAMME
FOR THE OPERATION OF PRIOR INFORMED CONSENT

United Nations Environment Programme

Food and Agriculture Organization
of the United Nations

OPERATION OF THE PRIOR INFORMED CONSENT PROCEDURE FOR BANNED OR SEVERELY RESTRICTED CHEMICALS IN INTERNATIONAL TRADE

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Cyhexatin

JOINT FAO/UNEP PROGRAMME FOR THE OPERATION OF
PRIOR INFORMED CONSENT

Food and Agriculture Organization of the United Nations

United Nations Environment Programme

Rome-Geneva 1995

DISCLAIMER

The inclusion of this

(ii)

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(N.B.: Chemical elements and pesticides are not included in this list)

ADI	acceptable daily intake
ai	active ingredient
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CCPR	Codex Committee on Pesticide Residues
DNA	Designated National Authority
EC	emulsion concentrate
EEC	European Economic Community
EPA	U.S. Environmental Agency
ERL	extraneous residue limit
FAO	Food and Agriculture Organization of the United Nations
g	gram
µg	microgram
GAP	good agricultural practice
GL	guideline level
ha	hectare
IARC	International Agency for Research on Cancer
i.m.	intramuscular
i.p.	intraperitoneal
IPCS	International Programme on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 103)
kg	kilogram
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, median
m	metre
mg	milligram

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ml	millilitre
m.p.	melting point
MRL	Maximum Residue Limit
MTD	Maximum tolerated dose
ng	nanogram
NOEL	no observed effect level
NOAEL	no observed adverse effect level
NS	Not Stated
OP	organophosphorus pesticide
PHI	pre-harvest interval
ppb	parts per billion
ppm	ppm (used only in reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used.)
ppt	parts per trillion
sp gr	specific gravity
STEL	Short Term Exposure Limit
TADI	Temporary Acceptable Daily Intake
TLV	Threshold Limit Value
TMDI	theoretical maximum daily intake
TMRL	Temporary Maximum Residue Limit
TWA	Time Weighted Average
UNEP	United Nations Environment Programme
WHO	World Health Organization
WP	wettable powder
wt	weight
<	less than
<<	much less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Revised July 1995

CYHEXATIN

PRIOR INFORMED CONSENT

revised DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

1.1 **Common Name:** Cyhexatin

1.2 **Chemical Type:** Organotin compound

1.3 **Use:** Acaricide

1.4 **Chemical Name:** Tricyclohexylhydroxystannane or tricyclohexyltin hydroxide

1.5 **CAS No:** 13121-70-5

1.6 **Trade Names:** Pennstyl, Techn'acid, Dowco 213, Plictran, Acarstin

1.7 **Mode of Action as a Pesticide:** Photoplasmic poison

1.8 **Formulation Types:** Wettable powder 25%, 50%, flowable concentrate 600g/l, dust 1.5%, technical grade 95%

1.9 **Basic Producers:** Oxon Italia (Italy), Elf Atochem (France), Chemia SpA (Italy)

2. SUMMARY OF CONTROL ACTIONS

2.1 **General:** Cyhexatin entered the PIC procedure on the basis of control actions (bans) in Cyprus (1988), Hungary (1987), Sweden (1987) and the United Kingdom (1987). The USA found unacceptable margins of safety for female workers of child-bearing age who mix and load or apply cyhexatin or who harvest treated crops, which caused the registrant to voluntarily cancel all products containing cyhexatin.

As of March 1995 registration had been reinstated in Cyprus and Hungary. In the United Kingdom and Sweden bans are still in effect. If a request for registration is received from the manufacturer the new information will be evaluated and the regulatory status in these countries reconsidered (see Annex 1).

2.2 **Reasons for the Control Action:** All countries reported that evidence of teratogenic effects in mammalian species was the basis for their actions. 2.3 **Uses Banned:** All uses of cyhexatin have been banned in countries reporting control actions.

2.4 **Uses Reported to be Continued in Effect:** No previously registered uses were reported to have been retained by the countries identifying control actions.

2.5 **Alternatives:** Alternatives noted by countries reporting import decisions under the PIC procedure are listed in Annex 3.

2.6 **Contacts for Further Information:** Designated National Authorities (DNAs) in countries which took the decision to prohibit import of cyhexatin may be a further source of information (Annex 3). Further information may also be obtained through national or regional pest management centres.

3. SUMMARY OF FURTHER INFORMATION ON CYHEXATIN:

3.1 **Chemical Physical Properties:** The technical grade product is a white crystalline powder, nearly odourless, has no true melting point, degrades to bis-tricyclhexyltin oxide at 121-135°C, decomposes at 228°C and is soluble at various amounts in organic solvents such as carbon disulfide, carbon tetrachloride, chloroform, chlorobenzene, toluene, but is practically insoluble in water. The vapour pressure is negligible at 25°C for the pure active ingredient. Cyhexatin is stable in aqueous suspensions of neutral and alkaline pH. It reacts ionically in the presences of a strong acid to form salts, and is converted by exposure to UV radiation to dicyclohexyltin oxide, then to cyclohexylstannoic acid. Cyhexatin is non-corrosive.

3.2 **Toxicological Characteristics:**

The WHO Group of Experts on Pesticides of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) reviewed toxicological data relevant to the teratogenicity of cyhexatin in 1989, 1991 and 1994. The 1994 JMPR concluded that "after taking into consideration the results of all the studies on teratogenicity in rabbits, cyhexatin is not teratogenic to this species".

3.2.1 **Acute Toxicology**: Classified by WHO as a Class III "slightly hazardous" pesticide. This is based on an oral LD_{50} of 540 mg/kg. Further studies with technical grade cyhexatin showed a greater acute oral toxicity in females but not in males (LD_{50} 501 and 599 mg/kg/bw, respectively). Studies in female rats in another laboratory using technical grade cyhexatin from a different source demonstrated an oral LD_{50} of 274 mg/kg/bw (1994 JMPR).

The USEPA accepted a study done on rats which shows Plictran 50W has an Oral LD_{50} of 196 mg/kg; Dermal LD_{50}, no adequate study available. Acute inhalation in rat (Plictran 50W) LC_{50} - 6.35 mg/l.

Dermal sensitization (Plictran 47.5%) on humans, little or no skin irritation and no sensitization after repeated exposures to test group. However, there have been incidences of dermatitis reported, which indicates that some inert ingredients may be the cause or a sub-population may be sensitive.

3.2.2 **Short-term Toxicity:**

Developmental effects have been the major concern with this chemical.

1989 FAO/WHO Joint Meeting on Pesticide Residues (JMPR)

The Joint Meeting reviewed four oral teratogenicity studies in New Zealand white rabbits (IRDC Laboratories; Dow USA Laboratories and Hazelton, France). The results of the available studies were discrepant. In two cases (Hazelton Laboratories, Monnot 1989a, 1989b) the results were negative with respect to all parameters measured with no observable adverse effect levels (NOAELs) of 3 and 1 mg/kg bw/day.

In a third study, the NOAEL was 0.5 mg/kg bw/day based on increased post-implantation losses (IRDC Laboratories, Schardein *et al.*, 1986). However, this study is of uncertain validity. The concentrations of test material administered varied from 70-104 %, 91-125% and 55-137% of the nominal at 0.5, 1 and 3 mg/kg bw/day, respectively, suggesting non-homogeneity in the test material. Hydrocephalus was observed in 8 pups from 4 litters at 3 mg/kg bw/day. The distribution of these malformations raised the possibility that they may have been introduced by infection.

The second positive study (Dow Laboratories, Kirk *et al.*, 1987a) failed to show a NOAEL at the lowest dose tested (0.75 mg/kg bw/day). This dose level caused maternal toxicity and hydrocephalus. The abortion rate was high in both test groups (0.75 and 3 mg/kg bw/day) as was maternal toxicity in all groups. The possibility of infection could not be ruled out.

A further two teratology studies in which New Zealand white rabbits were treated dermally at 0, 0.5, 1.0 or 3.0 mg kg bw/day with (94.8-96% pure) cyhexatin were available to the Meeting. In the first the NOAEL for teratogenicity was 1.0 mg/kg bw/day. No systemic toxicity or embryotoxicity was noted at any of the dose levels tested (Kirk *et al.*, 1987b). In the second study the only treatment-related effect observed was local irritation at the site of application which was observed at all three dose levels. The apparent NOAEL for teratogenicity in this study was 3.0 mg/kg bw/day (Monnot, 1989c).

1991 JMPR

The Joint Meeting reviewed a new rabbit teratology study (Life Science Research, Bailey, 1990) using two different technical samples, one from the USA and the other from the Netherlands (the Netherlands material had a smaller particle size), and one pure sample of cyhexatin which indicated differences in the severity of cyhexatin maternal toxicity, which appeared to be related to the particle size, a smaller particle size resulting in increased toxicity. When the two technical samples were compared (high mortality with the pure material prevented valid interpretation of the comparative data), pre- and post-implantation losses, fetotoxicity and reduction in litter size followed a pattern similar to maternal toxicity. A high increase in folded retinas (exceeding the control range) was noted with both the technical samples at the lowest dose tested (0.75 mg/kg bw/day); the significance of this finding was uncertain. An increase in the occurrence of dilation of the third and/or lateral ventricle of the brain was noted with the US technical material and with the pure material at 3.0 mg/kg bw/day. There was no evidence of hydrocephaly at 0.75 mg/kg bw/day with technical cyhexatin. The NOEL (no observable effect level) in rabbit was determined to be $<$ 0.75 mg/kg bw/day.

1994 JMPR

In a teratogenicity study in rabbits given percutaneous doses of technical cyhexatin of 0, 0.5, 1 or 3 mg/kg bw per day, neither maternal toxicity nor teratogenic effects were observed (Jameson, 1991).

In reviewing additional data relevant to the (oral) teratology study considered by the 1991 JMPR (Ross, 1990; Tesh, 1994) it was concluded that a dose-response relationship could not be demonstrated for the increased incidence of folded retinas found in treated groups, and that fixation artifacts were considered likely. The NOAEL for this study was determined to be 0.75 mg/kg bw per day on the basis of possible maternal toxicity at higher doses.

After taking into consideration the results of all the studies on teratogenicity in rabbits, the Meeting concluded that cyhexatin is not teratogenic to this species.

The 1994 JMPR based the ADI on the NOAEL determined in the multi-generation study in rats (0.7 mg/kg/bw per day), applying a 100-fold safety factor. The acceptable daily intake for humans was estimated at 0-0.007 mg/kg bw.

3.2.3 **Chronic Toxicity:** The 1981 JMPR estimated a NOEL of 3 mg/kg bw/day for a two-year study in mice (JMPR 94).

3.2.4 **Epidemiological Studies:** No adequate epidemiological studies are available.

3.3 **Environmental Characteristics:**

3.3.1 **Fate:** Based on only limited data cyhexatin appears to be a slow-leaching compound that may present a ground water concern. However, additional studies are required before a proper assessment can be made for environmental fate characteristics of cyhexatin.

3.3.2 **Effects:** Aquatic acute toxicity (tech.): *Daphnia magna* (1st instar) 44 mg/l at 21°C and 7.1 pH; Bluegill 44 mg/l at 18.°C and pH 7.1. Avian acute oral LD_{50} 250-400 mg technical cyhexatin/kg quail (moderately toxic); Avian dietary LC_{50} 195 ppm for bobwhite quail (highly toxic).

3.4 **Exposure:**

3.4.1 **Food:** Cyhexatin has been used on food crops worldwide for many years. Codex maximum residue limits have been established for a range of fruits and vegetables as well as meat, milk and milk products (see section 3.8).

3.4.2. **Occupational/Use:** On the basis of the teratological effects reported in rabbits a number of countries raised concern about the potential occupational exposure to cyhexatin of women of child-bearing age. The 1994 JMPR reported on two studies carried out on human occupational exposure to cyhexatin during mixing and spraying (Maroni, 1993; Scortichini *et al.*, 1986). The average exposure by inhalation was very low; cutaneous exposure ranged from 0.7 to 19 mg/day. Cutaneous exposure during picking fruit in cyhexatin-treated orchards ranged from 21 to 0.8 mg at 0 and 14 days after application respectively. No reliable measurements were reported of tin or cyhexatin in blood or urine.

3.4.3 **Environment:** There are no data available to assess the amount of environmental exposure that may occur from cyhexatin use.

3.4.4 **Accidental Poisoning:** The USA has reports between 1966 and 1981 of 14 human and one domestic animal incidents that involved cyhexatin alone. During that same period a single environmental incident together with 26 human accidental exposure were reported to involve cyhexatin in combination with other pesticides. Most occurred during agricultural applications and a few in industrial production plants. Most seemed to result from lack of or improper use of protective clothing, spray drift or spills.

Statement of practical treatment may include - **If swallowed**: call a physician or poison control centre. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. **If in eye**: flush with plenty of water for 15 minutes. Get medical attention. **If on skin**: wash with plenty of soap and water. Get medical attention if irritation persists. **If inhaled**: remove to fresh air if effects occur. Get medical attention.

3.5 **Measures to Reduce Exposure:** Exposure may be reduced by providing protective clothing: where dermal contact is likely (mixing, loading and applying the pesticide) wear chemical resistant gloves, goggles and a mask or pesticide respirator. In addition, refer to the FAO "Guidelines for Personal Protection when working with Pesticides in Tropical Climates" for other appropriate clothing for your local situation.

3.6 **Packaging and Labelling:** Follow FAO "Guidelines on Good Labelling Practices for Pesticides".

3.7 **Waste Disposal Methods:** Refer to "Technical Guidelines on Disposal of Bulk Quantities of Pesticides in Developing Countries".

3.8 **Maximum Residue Limits (MRLs), (mg/kg):** Codex Alimentarius definition of cyhexatin residue: cyhexatin; definition of azocyclotin residue: the sum of azocyclotin and cyhexatin.

Citrus fruits 2.0, cucumber 0.5, gherkin 1.0, meat 0.2, melon (except watermelon) 0.5, milks and milk products 0.05*, pear 2.0, pepper (sweet) 0.5, tomato 2.0, apple 5.0, common bean 0.2, strawberry 0.5, egg plant 0.1, grapes 0.2

(* at or about the limit of determination)

4. MAJOR REFERENCES:

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Food and Agriculture Organization. Guidelines on good labelling practices for pesticides. FAO, Rome (1995)

Food and Agriculture Organization. Guidelines on personal protection when working with pesticides in tropical climates. FAO, Rome (1990)

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Jameson, H. (1991). Cyhexatin percutaneous teratology study in rabbits. Unpublished report No. 737-088-161/T/122/91 from the Research Toxicology Centre S.p.A., Pomezia, Italy. Submitted to WHO by Chemia S.p.A, Ferrara, Italy

Maroni, M. (1993). Personal and biological monitoring of exposure to cyhexatin during agricultural use. Unpublished report from the International Centre for Pesticide Safety. Submitted to WHO by Oxon Italia, Milan, Italy

Ross,. F.W. (1990). Cyhexatin: Teratology study in rabbit. Unpublished report No. 89./0161 from Life Science Research Ltd., Eve, United Kingdom Submitted to WHO by Elf Atochem SA, Plaisir, France
(reported as Bailey et al., by the 1991 JMPR)

Scortichini, B.H, and Bohl, R.W. (1986). Evaluation of tractor/sprayer operator and orchard worker exposures to cyhexatin during orchard spraying with Plictran 50W miticide and reentry of treated orchards, Hartford, Michigan 28 July 1987. Unpublished report No,. HEH2-1-1-182 (72) from Dow Chemical Company Midland, Michigan, USA, Submitted to WHO by ELF Atochem Agri SA, Plaisir, France.

Tesh, J.M. (1994). Tricyclohexyltinhydroxide teratology study in the rabbit. Expert review. Unpublished report No. 89/MTC010/0161 from Pharmaco LSR, Ltd. Submitted to WHO by ELF Atochem Agri SA, Plaisir, France (expert review of the Ross study)

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The Pesticide Manual: A World compendium. (Worthing, C.R. and R.J. Hance, Eds.) 9th ed. Surrey, U.K. : British Crop Protection Council (1991)

ANNEX 1

CURRENT STATUS OF CONTROL ACTIONS REPORTED BY COUNTRIES LISTED IN THE ORIGINAL DGD (NOVEMBER 1991)

ORIGINAL BANS REVOKED:

Cyprus

Initially banned in February 1988 on the basis of toxicological concerns (teratology). The Pest Control Products Board re-evaluated the new scientific data including toxicological studies submitted by the Italian manufacturer and having in mind that most European countries including Italy gave a new registration for cyhexatin, decided in September 1992 to give a new registration for cyhexatin.

Hungary

Two formulations of cyhexatin (Flowable and WP) are presently registered (March 1995) in Hungary as an acaricide in fruits, grapes and soybean.

BANS STILL IN EFFECT

Sweden

The use of cyhexatin has been forbidden in Sweden since 1987. This decision was based on studies in rabbits, in which cyhexatin gave severe teratogenic and embryotoxic effects after exposure to low doses (3 mg/kg) both after oral and dermal applications. Sweden does not intend to re-evaluate the ban of cyhexatin at present. If the manufacturer applies for a new approval of the pesticide in Sweden the application will be handled as usual and the new studies evaluated.

United Kingdom

Approval for use of cyhexatin as a pesticide was withdrawn in 1988 because of evidence of teratogenicity. There has not been any subsequent request for this decision to be reviewed and no new data have been submitted to the UK regulatory authorities - the position therefore remains unchanged. If a request for re-approval is received, new data will be considered as part of the normal approval procedure.

WITHDRAWN:

USA (1987) Voluntary cancellation by the registrant

ANNEX 2

SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR CYHEXATIN AS REPORTED BY COUNTRIES SINCE NOVEMBER 1991

BANNED:

Belize	(1988) Banned for use
China	(1990) Banned as agricultural chemical
Indonesia	(1988) All uses banned
Kuwait	(1980) Banned for use
Philippines	(1983) Banned for use

WITHDRAWN:

Australia	(1987) Withdrawn by industry
Austria	(1989) Withdrawn by manufacturer
Malaysia	(1987) Voluntarily withdrawn
New Zealand	(1987) Withdrawn
Thailand	(1988) Withdrawn

Suspended from use in Italy and Argentina in 1987 and 1991 respectively; however, it was reinstated in 1992 in both countries.

ANNEX 3

The following alternatives were noted by countries reporting import decisions under the PIC procedure:

Indonesia:	alternative miticides: dicofol, propargite, amitraz;
Thailand:	dicofol, tetradifon;
United States:	propargite, sulphur, fenbutatin-oxide, dicofol, bifenthrin, avermectin.

It is essential that before a country considers substituting any of these reported alternatives, it ensures that the use is relevant to their national needs. A first step may be to contact the DNA in the country where the alternative has been reported. It will then be necessary to determine the compatibility with national crop protection practices.

Addresses of the Designated National Authorities:

Indonesia:

Chairman Pesticides Committee
Departemen Pertanian
Direktorat Bina Perlindungan Tanaman
Pasar Minggu
Jakarta 12520

Thailand:

The Director-General
Dept. of Agriculture
Ministry of Agriculture & Co-operatives
Rajadamnern Avenue
Bangkok 10200

United States:

Ms. Cathleen M. Barnes
Section Head, Int. Activities
Office of Pesticide Prog. (7501)
Environmental Protection Agency
401 M St. S.W.
Washington DC 20460
USA

Address and contact point of the known manufacturers:

Countries interested in obtaining copies of the individual toxicology studies referenced in the Evaluations of the FAO/WHO Joint Meeting on Pesticide Residues, or additional data, should contact the manufacturers at the addresses below.

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