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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Chemical Review Committee
Thirteenth meeting
Rome, 23–27 October 2017
Item 5 (b) (xi) of the provisional agenda*
Technical work: review of notifications of final regulatory action: phorate

Phorate: notification from Canada reviewed by the Chemical Review Committee and the rationale for its conclusion

Note by the Secretariat

As referred to in document UNEP/FAO/RC/CRC.13/13, the annex to the present note sets out notification of final regulatory action for phorate in the pesticide category from Canada reviewed by the Chemical Review Committee and the rationale for its conclusion. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.13/1.

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Annex

Phorate: notification from Canada reviewed by the Chemical Review Committee and the rationale for its conclusion

List of documents:

1. Notification of final regulatory action for phorate in the pesticide category submitted by Canada and reviewed by the Chemical Review Committee.

2. Rationale adopted by the Chemical Review Committee for its conclusion on the notification of final regulatory action for phorate in the pesticide category submitted by Canada.

Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

UNEP

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: CANADA

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	IDENTITY OF CHEMICAL	
1.1	**Common name**	Phorate
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: O,O-DIETHY S-ETHYLTHIOMETHYL PHOSPHORODITHIOATE CAS: O,O-DIETHYL S-[(ETHYLTHIO)METHYL] PHOSPHORODITHIOATE
1.3	**Trade names and names of preparations**	Thimet 15G Soil & Systemic Insecticide Granular
1.4	**Code numbers**	
1.4.1	**CAS number**	298-02-2
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	EEC No. 206-052-2, Caswell Number 660, CCOHS Record Number 502, RCRA Waste Number P094, RTECS Number TD9450000

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	X☐ This is a first time notification of final regulatory action on this chemical.
1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☐ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
UN/NA Number 2783	
WHO toxicity class (active ingredient)	1a
EPA (formulation)	1
EC risk	T+ (R27/28)
Other classification systems	**Hazard class**
Development codes EI 3911	
AC 3911 (Cyanamid)	
Official Codes ENT 24 042	
Source: The Pesticide Manual, Eleventh Edition, 1997.	

1.7 Use or uses of the chemical	
1.7.1	X☐ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Phorate is a systemic insecticide, which at the time of the regulatory action, was registered in Canada for use on potatoes, beans, corn, lettuce, and rutabagas. Source: - Proposed Acceptability for Continuing Registration (PACR 2003-01), Pest Management Regulatory Agency (PMRA) Re-evaluation of phorate, January 24, 2003.
1.7.2	☐ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8	**Properties**
1.8.1	**Description of physico-chemical properties of the chemical**

Molecular Weight:	260.4
Molecular Formula	$C_7H_{17}O_2PS_3$
Melting Point:	< -15°C
Boiling Point:	118-120°C /0.8mmHg
Specific Gravity/Density:	1.167 at 25°C
Water Solubility:	50 mg/L (25°C)
Solubility in Other Liquids:	Miscible with alcohols, ketones, ethers, esters, aromatic, aliphatic and chlorinated hydrocarbons, dioxane, vegetable oils, and other organic solvents.
Vapour Pressure	85 mPa (25°C)
Kow log P	3.92

Source:
- The Pesticide Manual, Eleventh Edition, 1997.

1.8.2	**Description of toxicological properties of the chemical**

In laboratory animals, phorate was found to be extremely acutely toxic following acute oral, dermal and inhalation exposures. Following both single and repeated dosing, the most sensitive indicator of toxicity was the inhibition of acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system or clinical signs of cholinergic toxicity. Female animals were more sensitive to the toxic effects of phorate. Phosphorylated phorate metabolites (phorate sulfoxide and phorate sulfoxone) are of comparable toxicity to phorate. Phorate did not cause any apparent delayed neurotoxicity and there was no evidence of histopathological effects on the central nervous system in any of the available studies. Phorate was not found to be genotoxic nor was it carcinogenic to either rats or mice. Phorate did not cause fetal malformations in either rats or rabbits, nor did it cause reproductive toxicity in rats other than reduced viability of the young at doses that were maternally toxic. The developmental and reproductive toxicity studies did not demonstrate any sensitivity of young animals relative to adult animals although lack of cholinesterase measurements in these studies precluded a definitive assessment of this issue. On the basis of the available toxicity studies, phorate is anticipated to have a high dermal absorption potential. One of the most remarkable features of phorate was the steepness and potency of the dose–response with acute and short-term dosing. No observed adverse effect levels (NOAELs) were very close to dose levels that elicited mortality in the test animals.

Two key factors are considered when assessing health risks: the dose levels where no health effects occur and the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Acute oral LD_{50} for male and female rats 3.7 and 1.6 mg/kg, respectively.
Acute oral LD_{50} for mice C. 6 mg/kg.
Skin and eye acute percutaneous LD_{50} for male rats 6.2, female rats 2.5 guinea Pigs 20-30, male rabbits 5.6, female rabbits 2.9, Guinea pigs 30.0 mg/kg.
Inhalation LC_{50} (1 h) for male rats 0.06 mg ai/L air; for females 0.011 mg/L air.

Acute Reference Dose: 0.00025 mg/kg bw
ADI : 0.00025 mg/kg bw/d

Source:
- Proposed Acceptability for Continuing Registration (PACR 2003-01), Pest Management Regulatory Agency (PMRA) Re-evaluation of phorate, January 24, 2003.
- The Pesticide Manual, Eleventh Edition, 1997.

1.8.3 Description of ecotoxicological properties of the chemical

The PMRA currently conducts a deterministic assessment of the environmental risk of pest control products. Environmental risk is characterized using the quotient method, which uses the ratio of the estimated environmental concentrations to the effects end point of concern. Quotient values less than one are considered indicative of a low hazard to non-target organisms, whereas values greater than one are considered to indicate that some degree of hazard exists for effects on non-target organisms.

Phorate is soluble in water at 50 mg/L and highly volatile with a vapour pressure of 85 mPa at 25°C. The *n*-octanol–water partition coefficient (log K_{ow}) is 3.92, which indicates potential for bioaccumulation. The Henry's law constant is 4.368×10^{-6}, which indicates there is potential to volatilize from water or moist soil.

Phorate in soil is transformed by chemical and microbial action. It is moderately persistent in soil (time required for 50% dissipation (DT_{50}) = 49–75 d) under field conditions, as seen in field studies in British Columbia. The major transformation products phorate sulfoxide and phorate sulfone, that are formed as a result of microbial action, are moderately persistent (DT_{50} = 65–137 d) in soil under laboratory conditions. These transformation products retain the phosphorylated structure and are expected to exhibit cholinesterase inhibition and therefore be as toxic as the parent compound phorate.

Phorate is strongly sorbed to soil and is classified as having slight (K_{oc} = 2000–3000) to moderate mobility (K_{oc} = 224–450) in a range of soil types. Phorate sulfoxide and phorate sulfone partition preferentially into water and are both classified as having moderate (K_{oc} = 172–210) to high mobility (K_{oc} = 71–91) in a range of soil types. Phorate and its major transformation products can enter aquatic systems through run-off, however, the latter are more mobile than the parent compound.

Although there may be contamination of surface water through run-off, phorate is not persistent in water owing to rapid hydrolysis. In sterile water at pH 5, 7 and 9, the half-lives are 2.6, 3.2 and 3.9 d, respectively. Photolysis is also an important route of transformation (dark control adjusted half-life of 1.9 d in pH 7 buffer solutions after 7 d of continuous irradiation). Formaldehyde, phorate sulfoxide and phorate sulfone are major transformation products formed during hydrolysis and aqueous photolysis. Aerobic aquatic biotransformation studies with nonsterile pond water showed that the parent compound and transformation products did not persist in the water (phorate DT_{50} of 0.5 d, phorate sulfoxide DT_{50} of 9 d, phorate sulfone DT_{50} of 21 d and formaldehyde reached 17% of applied by 14 d after treatment).

Studies have shown that phorate is very highly toxic to birds on an acute oral basis (mallard duck mean lethal dose (LD_{50}) = 0.62 mg a.i./kg), and is highly toxic to birds on a dietary basis (mallard duck LD_{50} = 248 mg a.i./kg). Phorate is very highly toxic to small mammals on an acute oral basis (rat LD_{50} = 1.1–3.7 mg a.i./kg), and on a dietary basis (rat LD_{50} = 28 mg a.i./kg). Phorate is very highly toxic on an acute basis to fish (rainbow trout mean lethal concentration (LC_{50}) = 13 µg a.i./L) and to aquatic invertebrates (*Gammarus fasciatus* LC_{50} = 4 µg a.i./L). Phorate is moderately to highly toxic to bees on an acute contact basis (0.32–10.1 µg a.i./bee).

Risk quotients and margins of safety calculated for applications of Thimet 15-G indicate risks for all groups of organisms (birds, mammals, fish and aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high risk for freshwater aquatic organisms and high to extremely high risk for birds. Similarly, risk to mammals is classified as high risk for large mammals to extremely high risk to small mammals.

The identified risks to birds and fish are supported by reported incidents arising from labelled use of the products.

Source:
- Proposed Acceptability for Continuing Registration (PACR 2003-01), Pest Management Regulatory Agency (PMRA) Re-evaluation of phorate, January 24, 2003.

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION
2.1	**The chemical is:** ☐ **banned** **OR** X☐ **severely restricted**
2.2	**Information specific to the final regulatory action**
2.2.1	**Summary of the final regulatory action** The use of phorate and associated end-use products (EP) entails an unacceptable risk of harm to the environment pursuant to Section 20 of the Canadian Pest Control Product (PCP) Regulations. As a result, the Pest Management Regulatory Agency (PMRA) has determined that all uses for phorate are to be phased out as outlined below. Uses of phorate and associated end-use products on corn, lettuce, beans and rutabagas were phased-out as end of December 2004. Due to the lack of alternatives to phorate for control of wireworm on potatoes, the registration of phorate, for this use only, will be continued for the short term, with interim mitigation to protect workers (engineering controls, requirements regarding additional Personal Protective Equipment (PPE)) and the environment (environmental statements on the label). Please refer to the RRD 2004-11, Appendix II for proposed engineering controls, PPE and other proposed label statements.
2.2.2	**Reference to the regulatory document** - Proposed Acceptability for Continuing Registration (PACR 2003-01), Pest Management Regulatory Agency (PMRA) Re-evaluation of Phorate, January 24, 2003. - Re-evaluation Decision Document (RRD 2004-11), Phorate, 13 May 2004. - Re-Evaluation Note, REV2007-07, Update on the Use of Phorate on Potatoes, 5 June 2007. - PMRA Web Site, Re-evaluation Summary Table (http://www.pmra-arla.gc.ca/).
2.2.3	**Date of entry into force of the final regulatory action** No further use was allowed after December 2004, except on potatoes.

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	X☐ Yes ☐ No
	If yes, give information on such evaluation	
	The PMRA has concluded that the use of phorate and its associated end-use products entails an unacceptable risk of harm to the environment pursuant to Section 20 of the Pest Control Product (PCP) Regulations.	
	Reference to the relevant documentation	
	- Proposed Acceptability for Continuing Registration (PACR 2003-01), Pest Management Regulatory Agency (PMRA) Re-evaluation of Phorate, January 24, 2003. - Re-evaluation Decision Document (RRD 2004-11), Phorate, 13 May 2004. - Re-Evaluation Note, REV2007-07, Update on the Use of Phorate on Potatoes, 5 June 2007. - PMRA Web Site, Re-evaluation Summary Table (http://www.pmra-arla.gc.ca/).	

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☐ Yes X☐ No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	X☐ Yes ☐ No

If yes, give summary of the known hazards and risks to the environment

The PMRA currently conducts a deterministic assessment of the environmental risk of pest control products. Environmental risk is characterized using the quotient method, which uses the ratio of the estimated environmental concentrations to the effects end point of concern. Quotient values less than one are considered indicative of a low hazard to non-target organisms, whereas values greater than one are considered to indicate that some degree of hazard exists for effects on non-target organisms.

Phorate is highly toxic to all terrestrial and aquatic species tested. Incident reports of bird and mammal fatalities in Canada, the U.S. and the U.K. support the conclusion that phorate presents a significant risk to birds and wildlife. One granule is sufficient to kill a small bird or mammal.

Surface broadcast application presents the greatest risk owing to the large number of exposed granules. Although soil incorporation is expected to lower the risk of terrestrial and aquatic exposure, it still presents a very high risk owing to unincorporated granules remaining exposed on the surface. The risk to small and moderate sized birds and small or moderately sized mammals remains high to very high with either method of application. Owing to its extreme toxicity to all organisms tested, the very high risk to moderate and smaller sized birds and mammals, the incident reports of bird and mammal mortalities (including large raptors in Canada), plus the persistence and mobility of the toxic sulfoxide and sulfone transformation products, the PMRA has concluded that the use of phorate in Canada presents a high risk to the environment.

Reference to the relevant documentation

- Proposed Acceptability for Continuing Registration (PACR 2003-01), Pest Management Regulatory Agency (PMRA) Re-evaluation of Phorate, January 24, 2003.

Expected effect of the final regulatory action

- Reducing the risk of environmental exposure to phorate in a manner that is the least disruptive to the need to protect agricultural crops from pests.

2.5	**Category or categories where the final regulatory action has been taken**	
2.5.1	**Final regulatory action has been taken for the chemical category**	☐ **Industrial**

Use or uses prohibited by the final regulatory action

Use or uses that remain allowed

2.5.2	**Final regulatory action has been taken for the chemical category**	X☐ **Pesticide**

Formulation(s) and use or uses prohibited by the final regulatory action

All formulation of phorate and all uses were phased–out as 2004, with the exception of use on potatoes.

Formulation(s) and use or uses that remain allowed

	Registration of Thimet 15G Soil & Systemic Insecticide Granular on potatoes continues for the short term.

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	**Year**
Produced		
Imported		
Exported		
Used		

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions
	Phorate can cause harm to the environment. Preventing use of this chemical protects the environment and non-target organisms from the risk of exposure in other regions.

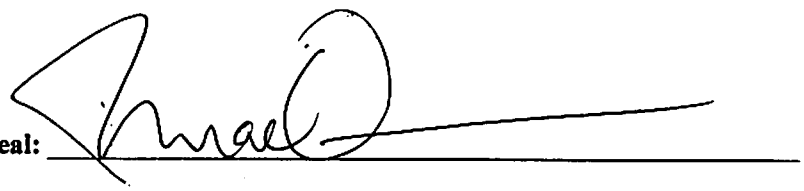
2.7	Other relevant information that may cover:

2.7.1	Assessment of socio-economic effects of the final regulatory action
	- Significant challenge for PMRA is a regulatory decision that moves towards the goal of eliminating phorate in a manner that is the least disruptive to the need to protect agricultural crops from pests. To meet its challenge, the PMRA has considered the availability of alternatives and the need for a transition period for those uses for which no or limited alternatives are available. - Significant challenge for industry is to develop alternatives in the relatively short time frame of proposed phase-outs. - Significant challenge for the agricultural sector is to reduce use during the transition period and be open to using alternatives.

2.7.2	Information on alternatives and their relative risks
	Phorate was registered on rutabaga for the control of cabbage maggot (CM). Other organophosphate insecticides, azinphos-methyl, chlorpyrifos, diazinon and terbufos, were also registered as a prophylactic treatment at planting to control CM. Phorate was registered for corn rootworm control. Alternative soil insecticides that were registered for control of this insect include carbaryl, chlorpyrifos, diazinon, terbufos and tefluthrin.
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Telephone	+ 1 613 736-3660
Telefax	+ 1 613 736-3659
E-mail address	Trish_MacQuarie@hc-sc.gc.ca
Designated National Authority	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Name of person in charge	Trish MacQuarrie
Position of person in charge	Director General, Policy, Communications and Regulatory Affairs Directorate
Telephone	+ 1 613 736-3660
Telefax	+ 1 613 736-3659
E-mail address	Trish_MacQuarie@hc-sc.gc.ca

Date, signature of DNA and official seal: 

Sept 3, 2008

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fifth meeting
Rome, 23–27 March 2009

Report of the Chemical Review Committee on the work of its fifth meeting

Annex III

Rationales for those chemicals for which only one notification met the criteria of Annex II

B. Phorate: rationale for the conclusion by the Committee that the notification for phorate (CAS No. 298-02-2) from Canada meets all the criteria of Annex II to the Rotterdam Convention

1. In reviewing the notification of final regulatory action by Canada, together with the supporting documentation provided by the Party, the Committee was able to confirm that the action had been taken to protect the environment.

2. The notification and supporting documentation identified phorate as a pesticide. It was used in Canada as an insecticide on corn, lettuces, beans, rutabagas and potatoes.

3. The Committee established that the final regulatory action had been taken on the basis of a risk evaluation and that the evaluation had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. It also showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada.

4. Phorate is highly toxic to all terrestrial and aquatic species tested. Incident reports of bird and mammal fatalities in Canada, the United States of America and the United Kingdom of Great Britain and Northern Ireland support the conclusion that phorate presents a significant risk to birds and wildlife. Surface broadcast application presents the greatest risk owing to the large number of exposed granules. Although soil incorporation is expected to lower the risk of terrestrial and aquatic exposure, it nevertheless presents a very high risk owing to unincorporated granules remaining exposed on the surface. The risk to small and moderate-sized birds and small or moderate-sized mammals remains high to very high with either method of application. Owing to its extreme toxicity to all organisms tested, the very high risk to moderate and smaller sized birds and mammals, the incident reports of bird and mammal mortalities (including large raptors in Canada), in addition to the persistence and mobility of the toxic sulfoxide and sulfone transformation products, Canada has concluded that the use of phorate in the country presents a high risk to the environment. Additional information on toxicity for aquatic organisms was also given in the supporting documentation provided by Canada. (UNEP/FAO/RC/CRC.5/9/Add.1.)

5. The Committee concluded that the final regulatory action taken by Canada on the basis of the available supporting documentation provided a sufficiently broad basis to merit including phorate in Annex III to the Rotterdam Convention in the pesticide category. It noted that the action had led to a decrease in the quantities of the chemicals used in the notifying Party. Use of phorate on four of five crops had been banned. The only remaining allowed use was to control wireworm on potato.

6. There was no indication that there were any industrial uses of phorate in Canada.

7. The Committee also took into account that the considerations underlying the final regulatory action were not of limited applicability since the uses on four of five crops had been banned. On the basis of information provided to the members at the fifth meeting of the Committee and other available information, the Committee concluded that there was evidence of ongoing international trade in phorate.

8. The Committee noted that the final regulatory action was not based on concerns about intentional misuse of phorate.

9. At its fifth meeting, the Committee concluded that the notification of final regulatory action on phorate by Canada had met the information requirements of Annex I and all the criteria set out in Annex II to the Convention.