Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2003-01

Re-evaluation of Phorate

The organophosphate active ingredient phorate and associated end-use products were proposed for re-evaluation under Section 19 of the Pest Control Products Regulations in June 1999.

As a result of the re-evaluation, it is proposed that uses of phorate on corn, lettuce, beans and rutabaga for which alternatives exist, would be phased out by the end of 2003. For potatoes, where available pest management alternatives are limited (especially for wireworms), the Pest Management Regulatory Agency (PMRA) is proposing that use be phased out by the end of 2004.

This Proposed Acceptability for Continuing Registration document provides a summary of the data reviewed and the rationale for the proposed regulatory decision for phorate. The PMRA will accept written comments on the proposed regulatory decision up to 60 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address below.

(publié aussi en français)

January 24, 2003

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 0-662-32858-2
Catalogue number: H113-18/2003-1E-IN

Foreword

The re-evaluation of the active ingredient phorate and the associated end-use products for insecticidal use on corn, lettuce, beans, rutabagas and potatoes, has been completed by the Pest Management Regulatory Agency (PMRA).

The PMRA announced in June 1999 that organophosphate active ingredients, including phorate, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.[1]

The PMRA has carried out an assessment of available information and has concluded that the use of phorate and associated end-use products in accordance with the label does entail an unacceptable risk of harm to the environment pursuant to Section 20 of the PCP Regulations. Therefore, the use of phorate and associated end-use products on corn, lettuce, beans and rutabagas, for which alternatives exist, will be phased out by the end of 2003. For potatoes, where available pest management alternatives are limited (especially for wireworms), the PMRA is proposing that use be phased out by the end of 2004.

It is proposed that the Food and Drug Regulations be amended so that food with quantifiable residues of phorate cannot be sold in Canada once Canadian use has been phased out, unless additional data to support phorate residues in imported food are provided.

The PMRA will accept written comments up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

[1] See Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

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1.0 Purpose

The Pest Management Regulatory Agency (PMRA) announced in June 1999 that organophosphate active ingredients, including phorate, were subject to re-evaluation under authority of Section 19 of the Pest Control Product (PCP) Regulations.[2] The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the PMRA has completed a review of phorate. The document includes a human health assessment, an environmental assessment and information on the value of phorate to pest management in Canada. By way of this document, the Agency is soliciting comments from interested parties on the proposed regulatory decision for phorate.

2.0 General background on re-evaluation

The PMRA is re-evaluating, under Section 19 of the Regulations pursuant to the *Pest Control Products Act* (PCP Act), all pesticides, both active ingredients and formulated end-use products, that were registered prior to 1995 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, outlines the details of the re-evaluation activities. Phorate is under reassessment in the United States (U.S.) as a result of the *Food Quality Protection Act* and therefore is being re-evaluated by the PMRA under Program 3. The following components are addressed and considered in this re-evaluation:

Risk to human health: The initial focus of the re-evaluation of a pest control product in Program 3 is the risk to human health. As indicated in DIR2001-03, the reassessment in Program 3 pays particular attention to:

- pest control products with a common mechanism of toxicity,
- aggregate exposure to a pesticide arising from its residues in food and in drinking water, and from non-occupational exposure, such as from treatments in and around homes, and
- susceptibility and exposure of infants and children that may be different from that of adults during critical developmental stages.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Once the reassessments of all the individual organophosphates have been completed, a cumulative assessment of all the remaining uses of organophosphates will be conducted.

Risk to the environment: The environmental assessments will be tiered, with refined environmental risk assessments taking place only on those actives, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are

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[2] See Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

acceptable from a human health perspective. At the first tier, based on an identification of hazards to non-target organisms, measures to reduce environmental exposure will be implemented where warranted. These measures may include removing uses that are obsolete, reducing the number of applications, requiring buffer zones to protect sensitive habitats, and taking regulatory action against uses that have been determined to be extremely high risk to organisms in the environment. In general, uses that remain after the first tier assessment will be revisited when the results of refined environmental assessments are available.

Value: The PMRA seeks to understand, as early as possible in the process, the current uses of the products and their importance for pest management. The PMRA relies to a great extent on provincial and territorial government input. Registrants and users are also an important source of information. Environment Canada, the Department of Foreign Affairs and International Trade, Canadian Food Inspection Agency and Agriculture and Agri-Food Canada are also contacted in the process for information specific to their areas of expertise.

The outcome of the re-evaluation of a pesticide, including proposed risk mitigation measures, will be published in a consultation document at the end of the aggregate human health risk assessment and the first tier environmental assessment. In some cases, the PMRA will implement changes in regulatory status of products prior to public consultation, especially where the PMRA considers risk mitigation not effective or practical, or where registrants have opted for voluntary discontinuation of sale of products.

3.0 Re-evaluation of phorate

Phorate is one of the 27 organophosphate insecticides subject to re-evaluation in Canada. The re-evaluation of phorate was announced in REV99-01. Phorate is registered by BASF (formerly by Cyanamid Crop Protection) and is sold as a granular soil insecticide. There is one end-use product, Thimet 15-G Soil and Systemic Insecticide. This product uses clay granules as a carrier and is applied in-furrow at planting time to control a variety of insects feeding on potatoes, beans, corn, lettuce and rutabagas. Thimet 15-G is sold either in returnable Lock'n Load® containers, which are mounted on modified planter lids and are designed to minimize occupational exposure, or in 25 kg multiwall paper bags.

4.0 Effects having relevance to human health

4.1 Toxicology summary

The toxicology database supporting phorate is primarily based on studies available from the registrant. 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.

Reference doses have been set based on NOAELs for the most sensitive indicator of toxicity, namely acetylcholinesterase inhibition and cholinergic signs of toxicity. These reference doses incorporate various uncertainty factors to account for extrapolating between rats and humans and for variability within human populations as well as an additional safety factor to account for an extra level of protection that is warranted by the data (i.e., steepness and potency of the dose–response).

4.1.1 Acute reference dose (ARfD)

In animal studies, the adverse effects noticeable at the lowest dose (i.e., the toxicity end point) were clinical signs observed in an acute rat neurotoxicity study (NOAEL = 0.25 mg/kg body weight (bw)). The uncertainty factor was 100 (10× for interspecies extrapolation × 10× intraspecies variability). An additional safety factor of 10× was applied to account for the steepness of the dose–response and the high degree of potency (based on lethality at very low doses). The acute reference dose was calculated to be 0.00025 mg/kg bw (0.25 mg/kg bw ÷ 1000). This value was considered to be protective of infants and children.

4.1.2 Acceptable daily intake (ADI)

As the ARfD value was lower than any acceptable daily intake derived from any of the repeat-dose toxicity studies (reflecting the high acute toxicity and use of the additional safety factor), the ADI was established at the same value as the ARfD. Thus the ADI is 0.00025 mg/kg bw/d.

4.1.3 Occupational end points

The PMRA used a NOAEL of 0.41 mg/kg bw/d from a 28-day dermal toxicity study for short- and intermediate-term dermal risk assessment in which there was inhibition of

cholinesterase activity at the next dose level. A margin of exposure (MOE) of 1000 was selected to include 10× for interspecies extrapolation, 10× for intraspecies variability and an additional safety factor of 10×. This additional safety factor was selected to account for the steepness of the dose–response and potency of phorate via this route.

The PMRA used a NOAEL of 0.081 mg/kg bw/d from a 13-week dietary neurotoxicity study for short- and intermediate-term inhalation risk assessment, in which there was inhibition of cholinesterase activity at the next dose level. An MOE of 1000 was selected to include 10× for interspecies extrapolation, 10× for intraspecies variability and an additional safety factor of 10×. This additional safety factor was selected to account for the steepness of the dose–response and potency of phorate.

4.2 Occupational risk assessment

Workers can be exposed to a pesticide through loading or applying the pesticide, and re-entering a treated site. Worker risk is estimated by an MOE that determines how close the occupational exposure comes to the NOAEL taken from animal studies. For workers entering a treated site, re-entry intervals are calculated where required, to determine the minimum length of time required before workers or others are allowed to enter.

The risks from loading and applying the clay-based granular Thimet 15-G (15% active ingredient) using a Lock'n Load closed handling system and other mitigation measures, are below the PMRA's level of concern. Approximately 60% of Thimet 15-G is sold in Lock'n Load packaging, according to the registrant. The risk of loading Thimet 15-G in paper bags (open loading) exceeds the Agency's level of concern.

Chemical-specific exposure information was used to assess the closed handling system scenario (Lock'n Load). The Pesticide Handlers Exposure Database (PHED) was used to assess the open mixing and loading scenario. For Thimet 15-G, adequate worker protection would be afforded under the following conditions: for loading activities: Lock'n Load packaging, and personal protective equipment including chemical resistant apron and gloves; and for application activities: closed cab. As an interim measure pending implementation of closed cabs, chemical resistant coveralls over long pants and long sleeves, chemical resistant gloves and a respirator are recommended for application activities.

Adequate MOEs were not obtained for open loading activities with Thimet 15-G packaged in paper.

The PMRA has concluded that exposure to persons entering treated sites after application is considered minimal due to the application method (soil incorporation at planting). A Re-entry interval of 48 h based on acute toxicity is sufficient to protect workers who may re-enter treated areas.

4.3 Dietary risk assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in fruits, vegetables, milk, meat, eggs and processed products, may be ingested with the daily diet. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, assessments take into account children's greater consumption of fruit, vegetables and juices for their body weight compared with adults.

4.3.1 Residue of concern

The residue of concern (ROC) has been redefined as phorate, phorate sulfoxide, phorate sulfoxone, phorate oxon, phorate oxon sulfoxide and phorate oxon sulfone. This ROC definition is consistent with that of other regulatory agencies including the U.S. Environmental Protection Agency (EPA), United Kingdom Ministry of Agriculture, Fisheries and Food (U.K. MAFF) and Codex.

4.3.2 Acute dietary (food) risk

Acute dietary risk is calculated using food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of food consumption and residue levels, to be combined to estimate a distribution of the amount of phorate residue that might be eaten in a day. An exposure value representing the high end (99.9th percentile) of this distribution is compared with the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the calculated intake, called the potential daily intake, from residues is less than the ARfD, the intake is not considered to be of concern.

The acute dietary risk from foods treated with phorate was not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ARfD is consumed). The assessment has been conducted using market basket survey, monitoring, and residue data, as well as maximum residue limits (MRLs) and U.S. tolerances for some imported crops. Percent crop treated data were used for domestic and imported crops, and processing factors were used where relevant. At the 99.9th percentile of exposure, the most highly exposed population subgroup, children (1–6 years old), consume 35% of the ARfD in their food. All other subpopulations had potential daily intakes less than 25% of the ARfD. Potatoes are the major contributor to the acute dietary risk.

4.3.3 Chronic dietary (food) risk

The chronic dietary risk was calculated by using the average consumption of different foods, and average residue values on those foods, over a 70-year lifetime. This expected intake of residues is compared with the ADI, which is the dose at which an individual

could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern. The risk assessment was conducted using MRLs, average residues, percent crop treated data and processing factors.

Chronic dietary exposure from foods treated with phorate is not a concern for the general Canadian population and all population subgroups including children and infants (i.e., less than 100% of the ADI is consumed).

The most highly exposed population subgroup, children (1–6 years old), consume 7% of the ADI in their food.

4.3.4 Aggregate risk

Aggregate risk assessment looks at the combined potential risk associated with exposures from food, drinking water, and residential uses of a pesticide. Generally, when the risks from these exposures are combined, and are still less than 100% of the ARfD and ADI, the aggregate risk is not considered of concern. As residential use of phorate is not permitted, the aggregate risk assessment for phorate considers food and water only.

The EPA assessment for phorate concluded based on conservative tier 1 (SCI-GROW) modelling that the maximum estimated concentrations of phorate and metabolites in groundwater are greater than the drinking water level of concern (DWLOC) for chronic drinking water exposure. As conservative modelling estimates exceed the DWLOC, drinking water monitoring data would be required to determine actual concentrations in drinking water if registration of these products is maintained.

5.0 Environmental assessment

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.

5.1 Environmental fate

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).

5.2 Environmental toxicology

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).

5.3 Terrestrial assessment

Extremely high risks to terrestrial organisms have been identified from currently registered uses of phorate. This assessment is supported by reports of incidents in Canada and the U.S. (see Appendix 1).

Estimated exposure concentrations for terrestrial organisms exceed acute effects levels for both birds and mammals. For in-furrow applications, the estimated surface exposure is 1% (see Appendix 2). For banded subsurface emplacement to corn and rutabagas, the

estimated surface exposure is 15%. The acute risk from direct consumption of granules is greatest for smaller species. The number of lethal doses (LD_{50}s) that are available within one square metre immediately after application ($LD_{50}s/m^2$) is used as the risk quotient (RQ) for granular products.

- Risk quotients for acute effects in mammals were greater than 1 LD_{50}/m^2, the threshold of concern for tested species, for use on potatoes and beans. Risk quotients ranged from 198 to 13 112 LD_{50}/m^2 for surface broadcast applications to beans and 98 to 6 481 LD_{50}/m^2 for in-furrow applications to potatoes, depending upon the size of the mammal. For applications to lettuce, risk quotients ranged from 99 to 6556 LD_{50}/m^2, for corn from 101 to 6782 LD_{50}/m^2 and for rutabagas from 417 to 55 340 LD_{50}/m^2. These are classified as high to extremely high risk.

- Risk quotients for acute effects in birds were greater than 1 LD_{50}/m^2, the threshold of concern for tested species, for use on beans and potatoes. Risk quotients ranged from 170 to 21 623 LD_{50}/m^2 for surface broadcast applications to beans and 84 to 10 687 LD_{50}/m^2 for in-furrow applications to potatoes depending upon the size of the bird. For applications to lettuce risk quotients ranged from 85 to 10 811 LD_{50}/m^2, for corn from 88 to 11 184 LD_{50}/m^2 and for rutabagas from 358 to 91 263 LD_{50}/m^2. These risk quotients are classified as high risk to extremely high risk. Birds may also be exposed by other routes, such as by walking on exposed granules and bathing, drinking water contaminated by granules and by eating tainted prey.

5.4 Aquatic assessment

Extremely high risks to aquatic organisms have been identified from all currently registered uses of phorate. This assessment is supported by reports of incidents of adverse effects in the U.S. Similar effects may have occurred in Canada, but there is no equivalent reporting system in this country.

Estimated environmental concentrations exceed acute and chronic effects levels in both fish and aquatic invertebrates:

- Risk quotients for acute and chronic effects on the majority of freshwater aquatic invertebrates tested were greater than 1, the threshold of concern. Risk quotients exceeded 1000 for use on potatoes (RQ = 1476), beans (RQ = 1495), lettuce (RQ = 1917), corn (RQ = 2650) and rutabagas (RQ = 4500) and are classified as extremely high risk.

- Risk quotients for acute and chronic effects on freshwater fish were greater than 1, the threshold of concern. Values exceeded 100 for applications to beans (RQ = 165), corn (RQ = 122) and rutabagas (RQ = 415) and are classified as very high risk. For applications to lettuce (RQ = 89), the acute and chronic risks were classified as high risk, as the RQ was greater than 10.

- For estuarine and marine fish and invertebrates, the acute and chronic risk quotients exceeded 1000, which is classified as extremely high risk.

5.5 Environmental assessment conclusions

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.

5.6 Potential for environmental mitigation

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. In view of the extreme toxicity, reduction in application rates is unlikely to reduce risks appreciably. With granular applications to agricultural crops, the PMRA is aware of no mitigation options currently available for reducing terrestrial and aquatic exposure that have been confirmed by studies.

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.

6.0 Value

6.1 Major crop uses

Most phorate used in Canada is applied to potatoes. Phorate may also be used in beans, corn, lettuce and rutabaga. Clay granules containing phorate are distributed in the furrow or banded on each side of the row at planting time. Phorate is a systemic insecticide that controls foliage feeding insects in addition to soil insects.

Respondents to the 1998 Pest Management Regulatory Agency Pesticide Use Survey reported that phorate is used mainly for the control of potato pests including Colorado potato beetle (CPB), aphids, flea beetle and wireworm in Atlantic Canada and occasionally for control of wireworm in Western Canada. Other reported usage include cabbage maggot (CM) control in rutabagas and rootworm control in sweet corn.

6.1.1 Potatoes

Colorado potato beetle is very adaptable and readily develops resistance to chemical insecticides including phorate and other organophosphates. Although pesticides from several classes are registered for CPB (e.g., organophosphate, carbamate, synthetic pyrethroid, organochlorine, imidacloprid), their effectiveness varies among potato-growing regions due to the development of resistance. Some provinces (e.g., Manitoba) have reported that phorate is an important tool for controlling CPB to prevent development of resistance to other classes of insecticides (e.g., neonicotinoid). In addition, some provinces report that phorate is valuable for controlling wireworm in potatoes, being the only active ingredient currently registered for that use. Wireworms are long-lived beetle larvae that may cause severe damage in first year potatoes planted following grains or fallow.

6.1.2 Rutabaga

In addition to phorate, other organophosphate insecticides, azinphos-methyl, chlorpyrifos, diazinon and terbufos, are registered as a prophylactic treatment at planting to control CM. Particular concern has been expressed regarding the ability to grow rutabagas, especially in Nova Scotia, without access to granular insecticides. Liquid formulations of organophosphate insecticides can be applied at planting or later as a drench. These later treatments fit into an integrated pest management approach for the control of CM in Newfoundland where drenches are timed to coincide with the start of the CM oviposition period. Rutabaga production in Newfoundland and in the rest of Canada remains dependent on the availability of chemical control.

6.1.3 Corn

Phorate is registered for corn rootworm control. Alternative soil insecticides that are registered for control of this insect include carbaryl, chlorpyrifos, diazinon, terbufos and tefluthrin. Growers in southern Ontario have rotated corn with soybean to prevent rootworm infestation. However, a rotation-resistant strain of western corn rootworm that has the ability to survive in soybean threatens to invade southern Ontario from the American Midwest where it is causing economically significant damage. Should this new strain of corn rootworm move into Canada, Ontario corn growers may need to revert to chemical control of corn rootworm. Phorate is potentially valuable for control of rotation-resistant corn rootworm, and may be valuable as an alternative to tefluthrin (synthetic pyrethroid) for resistance management. Rootworm resistant transgenic corn is being tested as an alternative to traditional chemical control.

6.2 Phorate and integrated pest management

Integrated pest management (IPM) measures are either not widely used or are not sufficiently effective to mitigate the need for chemical control, especially of CPB and wireworm.

The systemic activity of phorate may preserve populations of beneficial insects in some crops. However, the overall fit of this active in IPM programs is limited by the absence of tools to predict the summer populations of most pests, which would be needed to make treatment decisions based on the summer's economic thresholds at spring planting.

7.0 Other assessment considerations

Phorate (Thimet 15-G) was assessed in regard to the federal Toxic Substances Management Policy (TSMP) and PMRA DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Phorate does not meet the TSMP criteria for persistence. Its half-life in water (0.5 d) and soil (up to 75 d) are below the TSMP Track-1 cut-off criteria for water, sediment and soil. Phorate is not bioaccumulative by TSMP Track-1 cut-off criterion (log K_{ow} = 3.92). The major terrestrial transformation products (phorate sulfoxide, phorate sulfone), formed as a result of microbial action, are moderately persistent (DT_{50} = 65–137 d) in soil. The major transformation products in the aquatic environment (formaldehyde, phorate sulfoxide and sulfone) are not persistent. Therefore, the PMRA has concluded that phorate and its major transformation products do not meet the TSMP Track-1 classification criteria.

8.0 Proposed regulatory action

From an environmental perspective, granular pesticides with high acute toxicity to birds and mammals represent a high risk when ingested. The primary risk of granular pesticides to birds arises from the direct ingestion of granules following application in fields. Granules are intentionally selected and ingested by birds using them as grit or they may be mistaken as a food item. The risk is related to the degree of toxicity, with products for which only a few granules cause death being the most problematic. The overall risk is increased when such products are used on large acreage crops such as corn.

With this in mind, the PMRA is committed to reducing risk by moving towards the eventual elimination of such products. Unfortunately for some uses there are limited numbers of alternatives. Thus, elimination of such uses represents a significant challenge not only to the PMRA but to all stakeholders. For the PMRA, the challenge is a regulatory decision that moves towards the goal of eliminating such products 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. For industry, the challenge is to develop alternatives in the relatively short time frame of proposed phase outs. For the agricultural sector, the challenge is to reduce use during the

transition period and be open to using alternatives. This could include an evaluation of ways to move away from or reduce prophylactic uses of pesticides.

8.1 Thimet 15-G Soil & Systemic Insecticide Granular

In light of the identified high risk to the environment, the PMRA has determined that all uses of phorate should be phased out. The proposed schedule for phase-out of all uses of Thimet 15-G Soil & Systemic Insecticide Granular (registration number 24648, PCP Act) is as follows:

- Uses on corn, lettuce, beans and rutabagas would be phased out according to the following schedule:
  (1) Last date of sale of Thimet 15-G for these uses by the registrant: December 31, 2002
  (2) Last date for sale of Thimet 15-G for these uses by distributors or retailers: May 1, 2003
  (3) Last date for use of product for these uses by users and growers: December 31, 2003
- Uses on potatoes would be phased out according to the following schedule:
  (1) Last date of sale of Thimet 15-G by the registrant: December 31, 2003
  (2) Last date for sale of Thimet 15-G by distributors or retailers: May 1, 2004
  (3) Last date for use of product by users and growers: December 31, 2004

Information available to the PMRA indicates that there are effective alternatives to phorate for management of insect pests on corn, lettuce, beans and rutabaga. The PMRA, therefore, has proposed to phase out these uses of phorate along a shorter time frame than that for the use in potatoes, where available pest management alternatives to phorate are limited (especially for wireworm). The longer phase-out period for potatoes would allow time for the development and registration of alternatives.

Under the above time frame, the registration for all uses of Thimet 15-G would be cancelled on December 31, 2004. Disposal of any product that still remains following cancellation of the registration would be at the expense of the owner.

In the interim, until uses are cancelled on December 31, 2003 or 2004, the PMRA recommends that users observe the following measures to increase the safety margins of exposure for workers involved with loading and application activities:

- for loading activities: closed systems (Lock’n Load packaging) and chemical resistant apron and gloves; and
- for application activities: closed cab. Where closed cabs are not available, applicators should wear additional personal protective equipment and clothing (chemical resistant coveralls over long pants and long sleeves, chemical resistant gloves and a respirator).

With regards to the environment, users should take note of the following environmental concerns:

- This product is highly toxic to birds, small mammals, fish and aquatic invertebrates. Its use poses a high risk to these species as has been documented by incident reports of adverse effects. One granule is sufficient to kill a small bird or small mammal.

8.2 Maximum residue limits (MRLs) for phorate

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to prevent unauthorized use of the pesticide by recommending new residue limits at the limit of quantification for any agricultural commodities not approved for continued treatment in Canada. Additional MRLs for import purposes will be considered if sufficient data are provided by interested parties to allow a reassessment of those residues. The implementation date of lowered MRLs will take into consideration the last date of legal use of treatment products in Canada and the expected time for treated commodities to clear the channels of trade, usually one year. The U.S. EPA undertakes similar action in such circumstances. Proposed amendments to the Food and Drug Regulations reflecting these MRLs will be published in the Canada Gazette.

In the case of phorate, there are currently no specific maximum residue limits (MRLs). Consequently, any residues on imported or domestic commodities must not exceed 0.1 ppm, a default value specified by the Food and Drug Regulations subsection B.15.002(1). As use of phorate will be discontinued in Canada, it is proposed that potatoes with residues less than 0.1 ppm may be sold until December 31, 2005; all other agricultural commodities, including corn, lettuce, beans and rutabagas with residues less than 0.1 ppm may be sold until December 31, 2004. After these dates, produce with residues above the limit of quantification may not be sold in Canada unless sufficient additional data are provided to support imports.

Parties interested in supporting an MRL to allow imports of specific commodities treated with phorate should contact the PMRA during the consultation period to discuss the submission of appropriate data.

8.3 Proposed re-evaluation decision

The Pest Management Regulatory Agency has carried out an assessment of available information and has concluded that the use of phorate and associated use-products in accordance with the label does entail an unacceptable risk of harm to the environment pursuant to Section 20. Therefore, based on the considerations outlined above, the use of phorate and associated end-use products on corn, lettuce, beans and rutabagas, for which alternatives exist, will be phased out by the end of 2003. For potatoes, where available pest management alternatives are limited (especially for wireworms), the PMRA is proposing that use be phased out by the end of 2004.

It is proposed that the Food and Drug Regulations be amended so that food with quantifiable residues of phorate cannot be sold in Canada once Canadian use has been phased out, unless additional data to support phorate residues in imported food are provided.

The PMRA will accept written comments up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

List of abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CM	cabbage maggot
CPB	Colorado potato beetle
d	day(s)
DT_{50}	time required for 50% dissipation
DWLOC	drinking water level of concern
EPA	Environmental Protection Agency
h	hour(s)
IPM	integrated pest management
kg	kilogram
K_{oc}	absorption quotient normalized for organic carbon
K_{ow}	*n*-octanol–water partition coefficient
LC_{50}	mean lethal concentration
LD_{50}	mean lethal dose
MAFF	Ministry of Agriculture, Fisheries and Food (United Kingdom), renamed Department for Environment, Food and Rural Affairs (DEFRA) in 2001
m	metre
mg	milligram
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
Pa	Pascal
PCP	Pest Control Products
PHED	Pesticide Handlers' Exposure Database
PMRA	Pest Management Regulatory Agency
RED	Reregistration Eligibility Document
ROC	residue of concern
RQ	risk quotient
TSMP	Toxic Substances Management Policy
U.S.	United States
U.K.	United Kingdom

Appendix I Evidence for bird kills with granular phorate applications

There are ample data available in the literature that indicate that granular phorate causes significant bird mortalities. In Canada, all of the incidents reported are associated with a special study of granular insecticide effects on raptors in Western Canada (Elliot et al., 1997; Mineau et al., 1999; Mineau, 1999; Wilson, 1996). In the Canadian Wildlife Service database, eight incidents of bird kills that involved bald eagles and other raptors have been reported (Mineau, 1999). A total of 27 birds (Northern harriers) were involved in one incident in Alberta near Beaverhill Lake. Wilson et al. (1996) also reported 36 waterfowl related incidents over the period 1960–1994 in the lower Fraser Valley, B.C., involving 2100 birds associated with granular insecticides (phorate, fonofos, terbufos and carbofuran). An unspecified proportion of these incidents are associated with phorate.

No additional data are available for Canada specifically on phorate. However, to date there is no incident monitoring system. Available data are from special studies rather than routine monitoring or reporting. There are data available on the effects of other granular insecticides on birds in other parts of Canada.

Incidents of bird mortalities have also been reported from the U.S. and the U.K. from use of granular phorate. In the U.S., as reported in U.S. EPA RED (1999), one of these incidents of bird mortalities involved 2008 birds (blackbirds, pheasants, pigeons). There were other incidents that demonstrated effects on a wide variety of birds and weight ranges. The species included birds such as raptors, waterfowl, shorebirds, gulls, egrets, quail, grouse, curlews and songbirds. In six of the incidents, bird mortalities varied from 60 to 200 per incident. In one instance, seven bald eagles and one golden eagle were found dead due to secondary poisoning from phorate.

Avian bird mortalities in the U.K. (MAFF, 1994) have included waterfowl, lapwings, gulls, pheasants and partridge. The numbers of dead birds varied from 2 to 32 per incident, and in one instance the numbers dead were not counted but were estimated as “numerous”.

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Appendix II Information used to estimate the surface exposure of granular phorate

There are several references in the literature that indicate that a fraction of granules remain exposed at the surface even with subsurface emplacement techniques such as in-furrow emplacement. In addition, there is a recent study conducted by the Canadian Wildlife Service (Clark, 1997). For in-furrow emplacement, the U.S. EPA uses 1% surface exposure (i.e., 1% unincorporated) as the standard in all of their risk assessments with granular insecticides (U.S. EPA RED, 1999). The same value was used in the PMRA risk assessment and is a non-conservative estimate. Most of the literature indicates that subsurface emplacement results in much higher rates of surface exposure. Erbach and Tollefson (1983) found that press wheel incorporation resulted in 15% exposure. Hummel (1983) found 4–31% remained on the surface with banded subsurface applications and generally 1% remained exposed with in-furrow applications. The U.S. EPA bases their estimate on Hummel's (1983) estimates. Additional exposure occurs in turn rows. Maze et al. (1991) found exposures of 0.1–7% of applied granules for double disk press drill, hoe drill and pneumatic air seeder applicators. Segstro (1998) found 1–5% surface exposure with in-furrow applications.

Most of the literature available on in-furrow emplacement of granular insecticides describes efficacy data for corn, cereals or other crops. There is no literature available on the efficacy of emplacement for potato planting. However, regardless of the methods used for in-furrow emplacement or the efficacy, the evidence from Western Canada (Mineau, 1999) indicates that phorate use (which was mainly on potatoes) does result in bird mortalities. Given its extreme toxicity (0.6 granules/LD_{50} for a small bird, 10 g body weight, 42 granules/LD_{50} for a large bird, 1.2 kg body weight), relatively few granules are required to kill a bird and even less to have sublethal cholinesterase inhibition.

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