Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-38

Re-evaluation of Phosmet

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of phosmet. This Proposed Acceptability for Continuing Registration (PACR) document provides a summary of the data and information reviewed, and the rationale for the proposed regulatory decision. This document outlines a proposed interim decision for phosmet pending refinement of the assessment of risks to postapplication workers.

By the way of this document the PMRA is soliciting comments from interested parties on the proposed regulatory decision of phosmet. The PMRA will accept written comments on this proposal and information up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision. All comments should be forwarded to the Publications Coordinator at the address below.

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Foreword

The re-evaluation of the available information on the active ingredient (a.i.) phosmet and the associated end-uses on food and non-food areas has been completed by the PMRA. The registrant of the technical grade active ingredient (TGAI) is the Gowan Company.

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

Subsequent to that announcement, the Gowan Company, the registrant of the TGAI and primary data provider in Canada, indicated that it intended to provide continued support for all uses included on the label of commercial class end-use products (EPs) except for high-pressure spray application on beef cattle and hogs. Furthermore, the Gowan Company indicated that it does not support domestic/homeowner use of phosmet and has discontinued sale of the only phosmet domestic class product registered for use in Canada.

The PMRA has carried out an assessment of available information and has concluded that the use of phosmet and its EPs on the sites supported by the technical registrant does not entail an unacceptable dietary or drinking water risk to human health, worker risk during mixing/loading and application, or risk to the environment, provided that the proposed mitigation measures described in the document are implemented and the required data are provided. The major residual concern is for postapplication workers: the estimated margins of exposure (MOEs) for workers re-entering treated areas are less than the estimated target MOEs. The estimated exposures are considered to represent conservative assessments; therefore, the PMRA is requesting, by 1 December 2006, information to refine the postapplication worker exposure assessment and demonstrate that MOEs for workers re-entering treated areas meet the targets. This will include data currently being generated by an industry led task force. The workers risk estimates will be revised using the submitted data and further measures will be considered at that time (e.g., longer restricted entry intervals [REIs], cancellation of uses), as necessary, to address any remaining concerns.

In the interim, the PMRA proposes the following measures to mitigate exposure and risk to the greatest extent possible:

1. maximum agronomically feasible REIs;
2. protective clothing for re-entry workers, including a long-sleeved shirt, long pants and chemical-resistant gloves; as well as
3. a product stewardship program to minimize re-entry worker exposure that includes double notification of REIs for postapplication activities.

It is important to note that while estimated MOEs are less than the target based on the current conservative assessment, the implementation of the proposed mitigation measures will

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

substantially reduce exposure and risk. This interim strategy is considered acceptable until the risk can be more accurately characterized.

By means of this document, the PMRA wishes to consult on the feasibility of these risk mitigation measures, including lengthening these interim REIs, prior to finalizing this interim decision.

The PMRA will accept written comments on this proposal 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.

Table of Contents

1.0 Purpose

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

2.0 General background of re-evaluation

The PMRA is re-evaluating, under Section 19 of the Regulations pursuant to the *Pest Control Products Act*, all pesticides, both active ingredients (a.i.) and formulated EPs, that were registered prior to 1995. As outlined in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, a modern scientific approach is used to determine the continuing acceptability of older active ingredients in relation to human health and the environment. Phosmet is under reassessment in the United States as a result of the *Food Quality Protection Act*. Therefore, the PMRA is re-evaluating phosmet 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 Regulatory Directive DIR2001-03, a reassessment in Program 3 pays particular attention to the following:

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

Once the non-occupational assessments of all the individual OPs have been completed, a cumulative assessment of all the remaining uses of OPs will be conducted.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Occupational risk assessments follow an internationally accepted tiered approach as described in the Organisation for Economic Co-operation and Development's *Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application*. The tiered approach involves increasing levels of refinement through consideration of

additional data such as dermal absorption, chemical-specific use-pattern information and biological monitoring data.

For OP compounds, there are often insufficient data available to the PMRA to refine occupational exposure assessments to higher tiers. Such refined assessments are now required for some of the OPs, due in part to the PMRA's policy of applying additional safety factors for workers as required to ensure their protection. It is important to note that the current re-evaluations of OPs were not preceded by a data call-in. As a result, in many cases, the PMRA does not have the types of information required to conduct refined, higher tiered occupational exposure assessments. Therefore, in these cases, the PMRA has conducted lower tier reviews based on conservative approaches.

However, the Agricultural Handlers Exposure Task Force and the Agricultural Re-entry Task Force (ARTF) are developing additional proprietary generic databases that will enhance our ability to conduct more refined assessments. Additional data that could be used to refine estimates include residue, dermal absorption and biomonitoring, as well as actual compound-specific use-pattern data (e.g., typical versus maximum rates, typical number of applications). These data could also be used in a probabilistic assessment to provide additional refinement. There is currently an international project of the International Life Sciences Institute (ILSI) to develop guidance on probabilistic techniques for worker assessment.

Based on an assessment of the data and information available to the PMRA, the following courses of action may be proposed for OPs where the margins of exposure (MOEs) are less than the target for workers:

1) Where estimated MOEs indicate significant concern, even with maximum feasible mitigation, a phase-out or cancellation would be proposed.

2) Where estimated MOEs are less than the target but where exposure estimates could be refined with additional data, continuing registration for a limited term will be granted conditional upon submission of those data. As an interim measure, maximum feasible personal protective equipment (PPE), engineering controls and restricted entry intervals (REIs) will be implemented pending finalization of the decision. Such measures will substantially reduce exposure and risk. The worker risk estimates will then be revisited before a final re-evaluation decision is made using the submitted data.

Risk to the environment

The environmental assessments will be tiered, with refined environmental risk assessments being conducted only for those active ingredients, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are 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 of 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 in agriculture, nursery trades, forestry and public health. 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, the 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 each 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 ineffective or impractical, or where registrants have opted for voluntary discontinuation of the sale of products.

3.0 Re-evaluation of phosmet

Phosmet is one of the 27 OP pesticides subject to re-evaluation in Canada. The re-evaluation of phosmet was announced in Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*. Phosmet is a broad spectrum organophosphate insecticide that inhibits the enzyme acetylcholinesterase, interrupting the transmission of nerve impulses. It works by contact and ingestion. Registered products containing phosmet are listed in Appendix I.

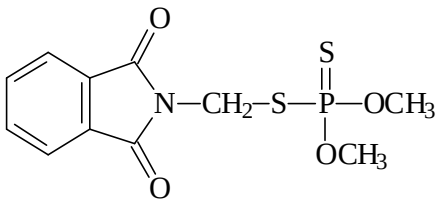
Much of the scientific information used by PMRA in its assessment of phosmet came from United States Environmental Protection Agency (USEPA) reviews. The USEPA Interim Reregistration Eligibility Decision (IRED) document for phosmet, dated 30 October 2001, can be referenced for further details regarding scientific studies used by the PMRA. This document, as well as other information on the regulatory status of phosmet in the United States, can be found on the USEPA's website at http://www.epa.gov/pesticides/op/status.htm.

3.1 Chemical identification

Chemical name: O,O-dimethyl S-phthalimidomethyl phosphorodithioate

Molecular formula: $C_{11}H_{12}NO_4PS_2$

Structural formula:



3.2 Description of current registered uses of phosmet

3.2.1 Type of pesticide

Insecticide (organophosphate)

3.2.2 Summary of use sites

In Canada, phosmet is registered for use on a wide variety of feed, food and nursery crops, as well as on livestock. The registered feed crop is alfalfa. Registered food crops are apples, blueberries, carrots, celery, cherries (sour), cranberries, grapes, peaches, pears, plums and potatoes. Registered nursery crops are ornamental shade trees, ornamental herbaceous plants and ornamental woody shrubs. The registered livestock are beef cattle and swine. The technical registrant is not supporting continuing registration of domestic class products. Sales of the last registered domestic class product were discontinued by this registrant, and the registration of this product expired in November 2002.

Use sites registered in the United States
In the United States, phosmet is registered for use on the same sites as in Canada with the exception of carrots and celery. Additional crops registered in the United States, but not in Canada, are apricots, Christmas trees, cotton, crabapples, dairy cattle (non-lactating), kiwi, nectarines, nut trees, peas, pine (seed orchards and seedlings) and sweet potatoes.

3.2.3 Target pests

Phosmet is registered in Canada for the control of a broad spectrum of insect and mite pests including:

Anoplura (sucking lice)	hog lice, cattle lice
Coleoptera (beetles)	alfalfa weevils, carrot weevils, Colorado potato beetles, Japanese beetles, plum curculio, potato flea beetles
Diptera (flies)	alfalfa blotch leafminers, apple maggots, blueberry maggots, cherry fruit flies, horn flies
Heteroptera and Homoptera (insects)	aphids on apple trees, pear psylla, potato aphids, potato leafhoppers, San José scale, tarnished plant bugs
Lepidoptera (butterflies, moths)	blackheaded fireworms, blueberry spanworms, codling moths, eastern tent caterpillars, elm spanworms, eyespotted budmoths, grape berry moths, green fruitworms, gypsy moths, obliquebanded leafrollers, oriental fruit moths, peach twig borers, redbanded leafrollers, spotted tentiform leafminers, spring cankerworms
Mallophaga (biting lice)	cattle biting lice
Acari (mites and ticks)	European red mites, twospotted spider mites, rust mites, sarcoptic mange mite of swine

3.2.4 Formulation types registered

Emulsifiable concentrate and wettable powder in water-soluble packaging.

3.2.5 Method and rates of application

In agriculture, phosmet can be applied by air blast, chemigation (cranberries only), boom, backpack sprayers and pour-on (see Table 3.2.5.1). The registrant of the TGAI and primary data provider does not support the use of high-pressure sprays on hogs and beef cattle; thus, this method of application was not assessed.

Table 3.2.5.1 Methods and rates of application for phosmet in Canada

Site	Method of application	Rate (a.i.)	Maximum applications/season	Preharvest interval (days)
cattle (beef), swine	pour-on	11.6 mg/kg bw	2**	7
alfalfa	boom	1125 g/ha	one per cutting (3 cuttings/season)*	7
apple	air blast	1875 g/ha	5**	1
sour cherry	air blast	1875 g/ha	4**	7
peach	air blast	1875 g/ha	4**	1
pear	air blast	1875 g/ha	2**	1
plum	air blast	1875 g/ha	3**	1
blueberry	boom, air blast	1120–1125 g/ha	2*	15
carrot, celery	boom	1125 g/ha	2*	40
cranberry	boom, chemigation	1100 g/ha	4*	30
grape	air blast	950–1550 g/ha	3*	7
potato	boom	1125 g/ha	5**	7
ornamentals (shade trees, shrubs and herbaceous plants)	backpack, air blast	625 g/ha	3**	not stated

* Maximum number of applications on the registered product labels

** Maximum number of applications not specified on the label. The number reported indicates the maximum number of applications/season proposed by the technical registrant.

4.0 Effects having relevance to human health

4.1 Toxicology summary

The toxicology database supporting phosmet is primarily based on studies available from the technical registrant. In laboratory animals, phosmet is highly toxic via the oral route of exposure in rats, mice and guinea pigs, and moderately toxic via the inhalation route in rats. Dermal exposure in rabbits shows phosmet to have a low dermal toxicity, but phosmet has

been found to be a moderate eye irritant. Signs of acute toxicity induced by phosmet are tremors, salivation, lacrimation, gasping, nasal discharge, exophthalmia and excessive urination. These signs are consistent with cholinesterase-inhibiting chemicals. With oral exposure, phosmet is rapidly absorbed from the gastrointestinal tract with peak blood levels occurring within 0.5 hours. Accumulation within tissues is minimal. Excretion is rapid and occurs mainly in the urine with lesser amounts recovered in feces and expired air. Two urinary metabolites have been observed, phthalamic acid and phthalic acid, with very little excreted as unchanged phosmet and the phosmet oxon.

In subchronic oral toxicity studies in rats and dogs, the most sensitive endpoint is the inhibition of cholinesterase activity (plasma, brain and erythrocyte). Inhibition of cholinesterase activity is seen via the oral and dermal routes of entry. Repeat-dose inhalation studies were not available. The inhibition of cholinesterase activity occurred in all studies regardless of duration and appeared to be dose related. There do not appear to be any sensitivities related to gender, and duration of exposure did not affect this endpoint. Assessment of relative species' sensitivity to cholinesterase inhibition reveals no appreciable differences between rats, mice and dogs. Additional endpoints noted in the chronic studies include the following: effects on the liver (increased weight in mice), hepatic degenerative changes (fatty liver, centrilobular vacuolation), hyperkeratosis of the stomach, mineralization of the thyroid, and a decrease in absolute kidney weight in rats. A decrease in spleen, adrenal, ovarian and testicular weights were also seen in rats in the reproduction study.

There is evidence of neurotoxicity, exhibited as tremors, subdued behaviour and unsteady gait in the developmental toxicity studies in rats and rabbits. In the acute neurotoxicity studies, clinical signs include decreased motor activity in rats and unsteadiness, subdued behaviour, recumbency and salivation in hens. Brain cholinesterase inhibition was observed in every species tested in all studies in which it was measured. In the delayed neurotoxicity study in hens, no evidence of delayed neurotoxicity was evident.

There is evidence of carcinogenicity in mice receiving phosmet via their diet. An increased incidence of liver tumours was observed in male B6C3F1 mice at the high dose, which was statistically significant by pair-wise comparison, with a statistically significant trend. These hepatic tumours had an apparent early onset. Female mice also had a significant dose-related trend for liver tumours. There is no evidence of carcinogenicity in rats. Studies have shown phosmet as being a potent direct-acting mutagen. An assessment of mutagenic potential in a variety of bacterial and mammalian in vitro and/or in vivo studies was performed for phosmet. These studies included gene mutation, chromosomal aberrations, DNA repair, sister chromatid exchange and micronucleus formation. Evidence from these studies indicate that phosmet is positive in the following in vitro assays: reverse mutation using the Ames test with activation, forward-mutation and sister chromatid exchange using mouse lymphoma cells.

In the rat two-generation study, reproductive toxicity is seen, with a decrease in testes weight in F_0 and F_1 as well as in ovarian weight in F_0. There is a decrease in the fertility index, and offspring toxicity is expressed as fewer pups per litter, decreased pup body

weight, decreased pup survival and decreased erythrocyte cholinesterase activity at this level. Parental systemic toxicity is indicated by decreased weight gain, inhibition of erythrocyte cholinesterase and clinical signs. There is no evidence of sensitivity of the young in the reproductive toxicity study. Developmental toxicity in rats and rabbits is expressed as delayed ossification or decreased fetal weights. However, these effects are only noted at maternally toxic dose levels indicating an absence of sensitivity of the young.

Reference doses have been set based on no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) for the most sensitive indicator of toxicity, namely acetylcholinesterase inhibition. These reference doses incorporate various uncertainty factors to account for extrapolating between laboratory animals and humans, for variability within the human population and for the use of a LOAEL instead of a NOAEL where necessary.

The toxicology endpoints used in the risk assessment of phosmet are summarized in Appendix II.

4.2 Occupational and residential risk assessment

4.2.1 Occupational and residential toxicology endpoints

For short- and intermediate-term dermal risk assessments (< 30 days), the NOAEL of 15.0 mg/kg bw/day is selected from the 21-day dermal toxicity study, based on brain cholinesterase inhibition in female rats at the LOAEL of 22.5 mg/kg bw/day. The target margin of exposure (MOE) selected when using this study is 100; this accounts for standard uncertainty factors of 10× for interspecies extrapolation and 10× for intraspecies variability.

The effect on fertility indices in the multigeneration study is only observed in the second mating of the F_0 generation, indicating that continuous, prolonged exposure is required to produce this effect. Thus, it is unnecessary to account for this in the short/intermediate (< 30 days) term scenario.

For a short- and intermediate-term inhalation exposure (< 30 days), the rat subchronic neurotoxicity study is used with an oral NOAEL of 1.5 mg/kg bw/day (based on inhibition of brain cholinesterase in females). The target MOE selected when using this study is 100; this accounts for standard uncertainty factors of 10× for interspecies extrapolation and 10× for intraspecies variability.

For assessment of short-term non-dietary oral ingestion, the oral NOAEL of 1.5 mg/kg bw/day from the subchronic neurotoxicity rat study is selected for risk assessment. The target MOE selected when using this study is 100; this accounts for standard uncertainty factors of 10× for interspecies extrapolation and 10× for intraspecies variability.

A quantitative risk assessment was conducted based on statistically significant increased hepatocellular adenomas/carcinomas in male mice that had an apparent early onset. Female

mice also had a significant dose-related trend for liver tumours, but no evidence of carcinogenicity was noted in rats. Phosmet also demonstrated mutagenic potential in a number of assays. A cancer potency factor (Q_1*) of 1.06×10^{-2} $(mg/kg\ bw/day)^{-1}$ was generated based on the "poly-k" method (Portier and Bailer 1989[2]).

4.2.2 Mixer/loader/applicator exposure

There are potential exposures to mixers, loaders, applicators or other handlers. Based on typical use patterns, the major scenarios identified were as follows:

- mixing/loading wettable powder for application to terrestrial field crops, fruit trees and ornamentals;
- applying wettable powder as sprays to field crops or ornamentals by groundboom;
- applying wettable powder as sprays to field crops, fruit trees and ornamentals by airblast sprayer;
- mixing/loading wettable powder for chemigation application;
- mixing/loading liquid for application as a pour-on to livestock;
- mixing/loading/applying wettable powder to ornamentals by high-pressure handwand;
- mixing/loading/applying wettable powder to ornamentals by low-pressure handwand; and
- mixing/loading/applying wettable powder to ornamentals by backpack sprayer.

The PMRA estimated handler exposure based on different levels of personal protection, as follows:

- Baseline PPE: Single layer clothing, i.e., long-sleeved shirt and long pants, shoes and socks
- Minimum PPE: Baseline + chemical-resistant gloves
- Maximum PPE: Baseline + coveralls (cotton or chemical-resistant, as specified) + chemical-resistant gloves
- Engineering Controls: Represents the use of an appropriate engineering control, such as closed tractor cab or closed loading system. Engineering controls do not apply to handheld application methods, which have no known devices that can be used to routinely lower the exposures for these methods. For groundboom and airblast applicators, the engineering controls comprised closed cab and baseline PPE.

No chemical-specific handler exposure data were submitted for phosmet; therefore, daily dermal and inhalation handler doses were calculated using data from the Pesticide Handlers' Exposure Database (PHED), Version 1.1. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates

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[2] Bailer, A.J., and C.J. Portier, 1989. Testing for increased carcinogenicity using a survival-adjusted quantal response test. *Fundam. Appl. Toxicol.* 12:731–737

the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE.

Occupational non-cancer risk is estimated by comparing a calculated MOE to a target MOE incorporating safety factors protective of the most sensitive subpopulation. Calculated MOEs greater than or equal to 100 do not require risk mitigation. Occupational cancer risk is calculated assuming 35 years of exposure over a 70 year lifetime. The product of expected exposure and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk in the range of 1 in 10^{-5} to 1 in 10^{-6} in worker populations is generally considered acceptable.

Occupational cancer and non-cancer risk estimates associated with applying, mixing and loading for current label uses are acceptable, provided engineering controls or PPE are used as summarised in Table 1 of Appendix III.

4.2.3 Postapplication exposure

The postapplication occupational risk assessment considered exposures to workers entering treated sites in agriculture. Based on the phosmet use pattern, there is potential for short- and intermediate-term (< 30 days) postapplication exposure to phosmet residues for workers.

Workers who re-enter treated sites to conduct activities involving foliar contact, e.g, pruning, thinning, harvesting and scouting, may be exposed to phosmet. Potential exposure to re-entry workers was estimated using activity-specific transfer coefficients and dislodgeable foliar residue (DFR) data. Transfer coefficients measure the relationship between exposure and DFRs for individuals engaged in a specific activity (e.g., scouting or harvesting) for a specific crop or crop group. The technical registrant is a member of the Agricultural Re-entry Task Force (ARTF), which is finalizing a substantial database of transfer coefficients. Conservative default transfer coefficients based on the data being developed by the ARTF were used for this assessment pending full review of the ARTF database by the PMRA.

REIs were calculated for specific tasks under Canadian conditions of use (e.g., application rates). An REI is the duration of time that must elapse before dislodgeable residues decline to such a level that entry into a treated area to perform a specific activity does not result in unacceptable exposures.

The postapplication non-cancer risks to re-entry workers performing high-exposure activities, such as thinning, pruning and harvesting of most crops, and low-exposure activities, such as scouting of fruit trees, do not meet the target MOEs (i.e., MOE < 100), based on current REIs and label use patterns. To achieve the target MOEs for postapplication workers based on available data, most REIs would need to be significantly increased in length. Calculated REIs for selected re-entry activities based on currently available exposure data and the target MOE of 100 are shown in Table 2 of Appendix III. Many of these REIs are not practical for growers.

Table 3 of Appendix III shows cancer and non-cancer risk estimates based on REIs considered agronomically feasible by the USEPA, or current Canadian preharvest intervals (PHIs) where established. With these REIs, which range from three to seven days for most crops, target MOEs are not met for many scenarios. Postapplication cancer risks for re-entry workers performing low-exposure activities, such as irrigating or scouting, range from 10^{-6} to 10^{-5}. High-exposure activities, such as thinning, pruning or harvesting, have cancer risk estimates in the range from 10^{-6} to 10^{-4}.

These postapplication risk estimates include a number of conservative inputs, such as the assumptions that workers:

- are exposed to residues following the maximum number of applications at the maximum rate; and
- are performing activities that involve foliar contact during the phosmet postapplication residue window for up to 30 days a year.

The assessments could be refined with the following data:

- enhanced information on the phosmet use pattern, including typical rates and number of applications per season;
- survey information on critical worker activities that typically take place for each crop during the use season, and the timing of these activities with respect to crop growth and applications of phosmet;
- data being developed by the ARTF or other exposure data such as passive dosimetry, biological monitoring and additional DFR data; and
- a probabilistic assessment using the full distribution of all available data.

With these additional data and information, it is expected that estimated exposure and risk would decrease.

To further reduce exposure in the interim, the following measures are proposed in addition to the maximum agronomically feasible REIs:

- protective clothing for workers (long-sleeved shirt, long pants and chemical-resistant gloves); and
- a product stewardship program to minimize re-entry worker exposure, that include double notification of REIs for postapplication activities.

The PMRA will work with the registrant of the TGAI to ensure development and implementation of an effective stewardship program.

4.2.4 Residential exposure

The postapplication risk assessment considered exposures to homeowners maintaining plants treated by commercial applicators, i.e., thinning or pruning ornamentals such as roses. Youth assisting with the gardening activities were included in the assessment.

Homeowner risks from postapplication contact with commercially treated ornamentals do not pose a health concern. Cancer risk estimates for homeowners performing high-exposure re-entry activities exceed one in a million. However, these estimates are highly conservative, and the cancer risk is not considered a health concern.

4.3 Dietary risk assessment

In a dietary exposure assessment, the PMRA determines how much pesticide residue, including residues in milk and meat, may be ingested as part of the daily diet. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, assessments take into account differences in children's eating patterns, such as food preference and greater consumption of food relative to their body weight compared with adults.

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

Chronic dietary risk is 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 to the acceptable daily intake (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 a health concern.

Cancer risk from dietary exposure is calculated on the same 70-year lifetime exposure as for the chronic dietary risk. The product of expected intake of residues and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk of less than 1×10^{-6} in the most exposed subpopulation is not considered a health concern.

4.3.1 Acute reference dose

The acute (1 day) reference dose (ARfD) was derived from an acute neurotoxicity study in rats that had a NOAEL of 4.5 mg/kg bw based on decreased brain and erythrocyte cholinesterase activity as well as decreased motor activity in the animals. An overall uncertainty factor of 100 was required to account for interspecies extrapolation (10×) and intraspecies variability (10×), resulting in an ARfD of 0.045 mg/kg bw (4.5 mg/kg bw ÷ 100). This value was considered to be protective of all populations including infants and children

4.3.2 Acceptable daily intake

The chronic (lifetime) dietary reference dose, the acceptable daily intake (ADI), selected was based on a LOAEL of 1.0 mg/kg bw/day from a two-year chronic toxicity/carcinogenicity study in mice. The LOAEL was based on decreased brain cholinesterase in both sexes at interim sacrifice. An overall uncertainty factor of 300 was required to account for interspecies extrapolation (10×), intraspecies variability (10×) and the use of a LOAEL (3×), resulting in an ADI of 0.0033 mg/kg bw/day (1.0 mg/kg bw/day ÷ 300). This value was considered to be protective of all populations including infants and children.

4.3.3 Carcinogenicity

A quantitative risk assessment was conducted based on statistically significant, increased hepatocellular adenomas/carcinomas in male mice that had an apparent early onset. Female mice also had a significant dose-related trend for liver tumours but no evidence of carcinogenicity was noted in rats. Phosmet also demonstrated mutagenic potential in a number of assays. A cancer potency factor (Q_1*) of 1.06×10^{-2} $(mg/kg\ bw/day)^{-1}$ was generated based on the "poly-k" method (Portier and Bailer 1989[3]).

4.4 Dietary exposure

Acute, chronic and cancer dietary exposure and risk estimates were generated using Dietary Exposure Evaluation Model (DEEM®) software and updated consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (1994–1998). Drinking water levels of comparison (DWLOCs) were also calculated and compared to the expected environmental concentration (EEC) of phosmet in drinking water. To calculate a DWLOC, all relevant exposures are considered in comparison to the relevant reference dose to calculate the maximum concentration in drinking water that would not result in unacceptable risk.

4.4.1 Acute dietary risk

The acute dietary exposure was calculated using a refined probabilistic assessment. Refinements for commodities on which use of phosmet is registered in Canada or the United States include generating residue distribution files that incorporated the following, where appropriate:

- empirical data from magnitude of residue (MOR) studies,
- processing studies,
- Pesticide Data Program (PDP) and United States Food and Drug Administration's (USFDA) monitoring data, and
- estimates of the percentage of a commodity that is treated.

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[3] Bailer, A.J., and C.J. Portier, 1989. Testing for increased carcinogenicity using a survival-adjusted quantal response test. *Fundam. Appl. Toxicol.* 12:731–737

The acute potential daily intake (PDI) accounted for < 10% (99.9th percentile) of the ARfD for all subpopulations, with children 1–6 years old being the most highly exposed subpopulation.

4.4.2 Chronic (cancer and non-cancer) dietary risk

The chronic dietary exposure was calculated using a refined deterministic assessment. Refinements for commodities on which phosmet is registered in Canada or imported from the United States included incorporating the following, where appropriate:

- mean residues from MOR studies, processing studies,
- PDP and USFDA monitoring data, and
- estimates of the percentage of a commodity that is treated.

The chronic PDI accounted for < 2% of the ADI for all subpopulations, with children 1–6 years old being the most highly exposed subpopulation. In addition, the lifetime cancer risk was less than one in a million (1.0×10^{-6}).

These chronic and acute dietary risk assessments demonstrated that there were no dietary concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. Further, there are no dietary concerns for nursing or pregnant females or based on gender in general.

4.4.3 Exposure from drinking water

DWLOCs were calculated for acute, chronic non-cancer and chronic cancer exposure to phosmet in drinking water, and compared to the maximum and average EEC of phosmet in surface water. The maximum EEC (60.2 µg a.i./L) was less than the acute DWLOCs for all subpopulations. The average EEC (0.49 µg a.i./L) was less than both the chronic non-cancer and cancer DWLOC for all subpopulations. Therefore, the PMRA concludes that residues of phosmet in drinking water, when considered along with dietary exposure, would not result in aggregate risk estimates that exceed the level of concern.

4.5 Aggregate risk assessment

Aggregate risk assessment looks at the combined potential risk associated with food, drinking water and residential exposures. Acute aggregate risk assessments do not combine residential and dietary exposures, as it is improbable that an individual would be exposed to high-end dietary and residential exposure on the same day. A probabilistic model with supporting data would be required to aggregate acute dietary and residential exposures. For phosmet, acute aggregate exposure is, therefore, from dietary and drinking water exposures (see Section 4.3). Residential exposures are discussed in Section 4.2.4.

Short-term aggregate exposure to phosmet is comprised of contributions from food, drinking water and residential exposure (dermal, inhalation). The relevant duration of exposure to assess toxicological endpoints for this assessment would be a period of up to one month. As inhibition of brain cholinesterase is a common toxic endpoint observed or anticipated among all routes of exposure, relevant studies have been selected.

To assess the dermal component, the 21-day dermal rat toxicity study is chosen with a NOAEL of 15 mg/kg bw/day based on a decrease in brain cholinesterase in females at the next highest dose. The database did not include a study for the inhalation route of exposure; hence, the oral subchronic neurotoxicity study was used for the inhalation route with a NOAEL of 1.5 mg/kg bw/day based on inhibition of brain cholinesterase at the next higher dose. The target MOE selected for the aggregate assessment is 100, comprised of the standard uncertainty factors of 10× for interspecies extrapolation and of 10× for intraspecies variability.

The chronic dietary exposure is considered representative of a typical exposure since it represents the average daily exposure over an individual's lifetime. This exposure was combined with short-term residential exposure estimated for youth and adults. Resulting DWLOCs were less than the estimated maximum EEC (60.2 µg/L). Therefore, short-term aggregate exposure from all relevant sources is not considered a health concern.

5.0 Environmental assessment

This assessment was based partly on the USEPA environmental risk assessment presented in the IRED document for phosmet.

In characterizing the environmental risk of phosmet, the PMRA utilized a deterministic approach that characterizes the risk by the quotient method. In this method, a risk quotient (RQ) is calculated as the ratio of the EEC to the toxicity endpoint of concern. RQs less than one are considered as a low risk to non-target organisms whereas, RQs greater than one indicate some degree of risk.

Initial and cumulative EECs were calculated for soil, water and wildlife food sources for the spray formulations of phosmet. A range of application rates were used to calculate the EECs along with the maximum number of applications and minimum interval between applications. The cumulative EECs were estimated by adjusting the sum of the applications for dissipation between applications using the time for 50% decline (DT_{50}) for the appropriate environmental media. Effect endpoints included both acute and chronic, chosen from the range of toxicity tests on species available. Effect endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with phosmet.

5.1 Environmental fate

Phosmet is soluble in water (25 mg/L), not likely to volatilize (vapour pressure is 6.0×10^{-5} Pa [4.5×10^{-7} mm Hg]; Henry's Law constant is 7.5×10^{-9} atm m^3/mole) and has a potential to bioaccumulate (K_{ow} = 3.04). Phosmet is not persistent in the aquatic environment (hydrolysis half-lives = 179 hours at pH 5, 9.4 hours at pH 7 and 5.5 minutes at pH 9). In addition, the experimental aquatic phototransformation half-life at pH 5 was 2.4 days and, thus, may be a contributing factor to the dissipation of phosmet in acidic water. Under aerobic conditions, phosmet is classified as non-persistent on soil (DT_{50} = 3 days). The biotransformation DT_{50} under anaerobic conditions indicates that phosmet is

slightly persistent (DT_{50} = 15 days). Adsorption–desorption studies indicate that phosmet is immobile. There was evidence in the leaching study that the transformation products are more mobile than the parent phosmet. No data were available to assess the field dissipation of phosmet and phosmet oxon in Canada. Phosmet oxon, the transformation product of toxicological concern, was identified as a major transformation product in the hydrolysis study; therefore, additional fate data are required for this transformation product.

5.2 Environmental toxicology

Available toxicity studies for wildlife indicate that phosmet is highly toxic to honey bees (LD_{50} = 1.06 µg a.i./bee). On an acute basis, phosmet is highly toxic to red-winged blackbirds (LD_{50} = 18 mg a.i./kg bw) and practically non-toxic to mallard ducks (LD_{50} = 2000 mg a.i./kg bw). On a dietary basis, phosmet is moderately toxic (northern bobwhite quail LC_{50} = 501 mg a.i./kg diet) to practically non-toxic to birds (mallard duck $LC_{50} \geq$ 5000 mg a.i./kg diet). Adverse effects on reproduction in birds are expected to occur at dietary concentrations greater than 60 mg a.i./kg diet. Laboratory studies indicate that phosmet is moderately toxic to mammals (rat LD_{50} = 113 mg a.i./bw diet) on an acute basis. Adverse effects on reproduction of mammals are expected to occur at dietary concentrations greater than 20 mg a.i./kg diet. Laboratory toxicity studies with freshwater aquatic invertebrates indicate that phosmet is very highly toxic to invertebrates (*Gammarus* LC_{50} = 2.0 µg a.i./L) on an acute basis, and chronic effects are expected to occur at concentrations greater than 0.75 µg a.i./L. Phosmet was classified as being slightly toxic (channel catfish LC_{50} = 11000 µg a.i./L) to very highly toxic (bluegill sunfish LC_{50} = 70 µg a.i./L) on an acute basis to freshwater fish. Adverse effects on reproduction in freshwater fish are expected to occur at concentration greater than 3.2 µg a.i./L. Phosmet is classified as moderately toxic (eastern oyster $LC_{50} \geq$ 1000 mg a.i./L) to very highly toxic (mysids LC_{50} = 1.6 µg a.i./L) to estuarine and marine invertebrates. Adverse chronic effects in estuarine and marine invertebrates are expected to occur at concentrations greater than 0.37 µg a.i./L. Phosmet is classified as highly toxic to estuarine and marine fish (sheepshead minnow LC50 = 170 µg a.i./L).

5.3 Concentrations in drinking water

Residues of phosmet in drinking water sources in Canada were estimated using Level 1 LEACHM and PRZM/EXAMS models. LEACHM was used to estimate the residues in groundwater whereas, the residues in reservoirs and dugouts were estimated using PRZM/EXAMS. Monitoring data from groundwater revealed that the drinking water concentration should be considered as 0.08 µg a.i./L for both acute and chronic exposure. This value represents the concentration of a single detection in well water in the apple growing region of Quebec. LEACHM predicted that no residues will reach groundwater. This model does not take into consideration preferential flow; therefore, use of the monitoring value is recommended. For residues in reservoirs, the acute and chronic exposure concentrations predicted by PRZM/EXAMS were estimated to be 60.2 and 0.49 µg a.i./L, respectively. For residues in dugouts, the acute and chronic exposure concentrations predicted by PRZM/EXAMS were estimated to be 19.1 and 0.08 µg a.i./L.

These values are considered the upper bound values for both acute and chronic exposures. Lower bound concentrations for phosmet exposure on an acute and chronic basis were determined from the available monitoring data as 0.36 and 0.18 µg a.i./L for both reservoirs and dugouts.

5.4 Terrestrial assessment

Phosmet is highly toxic to honey bees on an acute basis. In addition, 3-hour residues of phosmet were very highly toxic to honey bees; therefore, mitigation measures are necessary. The toxicity of phosmet to bees was supported by two bee mortality reports identified in the USEPA IRED for phosmet. The two incidents occurred as a result of phosmet use in orchards (one apple and one apricot). The risk to beneficial arthropods and predators was not assessed given the lack of data. Based on the acute oral toxicity data, a risk of adverse effects was identified for smaller birds (i.e., red-winged blackbird) as the number of days to reach the LD_{50} was determined to be lower than one day. In addition, a risk of adverse effects was identified for larger birds following the final application at the highest application rate. Based on the dietary toxicity data, the risk to wild birds was determined to be moderate for both acute (RQ = 2.2–8.2) and chronic (RQ = 1.8–6.8) exposure.

Mammals must consume contaminated food for 0.6 to 2 days to reach the LD_{50}, indicating that at the higher application rates there is a high chance that acute effects may occur from exposure to phosmet. Taking into consideration feeding preferences, the calculated quotients range from 1.7 to 6.2, indicating a moderate risk from acute exposure. For chronic exposure the calculated quotients ranged from 5.5 to 20.2, indicating moderate to high risk. Toxicity data were not available for terrestrial vascular plant species.

5.5 Aquatic assessment

For the aquatic risk assessment, potential exposures were estimated using the standard PMRA approach, which is based on maximum deposit when label rates are applied to a 1-ha pond of 30-cm depth. Currently, the PMRA does not have an acceptable model to estimate the potential environmental concentrations that may occur from the pesticide runoff.

Aquatic invertebrates are at extremely high risk of acute exposure to concentrations of phosmet that would result from 100% deposit into a body of water (risk quotients range from 1040 to 6300 for freshwater invertebrates and 1302 to 7880 for marine and estuarine invertebrates). The calculated acute risk quotients for freshwater fish range from 29.8 to 180, indicating that freshwater fish are at high risk of acute effects from exposure to concentrations of phosmet resulting from over spray into a body of water. Similar results were obtained for estuarine and marine fish. It is unlikely that repeated exposure would occur in neutral or alkaline waters because of the very rapid hydrolysis; although, repeated exposure may occur under acidic conditions, resulting in adverse chronic effects. Therefore, the estimated chronic risks stated are for acidic locations. The calculated chronic risk quotients for aquatic invertebrates range from 375 to 1680 for freshwater

invertebrates and from 760 to 3410 for estuarine and marine invertebrates. These RQs indicate that aquatic invertebrates are at very high to extremely high risk of chronic effects. Chronic risk quotients calculated for acidic bodies of water indicate that freshwater fish are at high to very high risk (RQ = 87.9–394) of chronic effects.

5.6 Livestock uses

Livestock applications pose a different but lower exposure level for wildlife. Currently, the PMRA does not have an acceptable method to assess the risk from exposure to phosmet applied to livestock. It is possible that birds may be exposed to phosmet while perching on freshly treated cattle through dermal adsorption and ingestion of insects that may be on the surface of the cattle. However, as toxicity is moderate and exposure is limited, the risk to birds is minimal. In addition, aquatic organisms can be exposed to phosmet from freshly treated cattle wading into a body of water. However, this scenario is not common. The risk to birds and aquatic organisms is expected to be minor compared to the other uses of phosmet. The registrant of the EP for use on cattle has agreed to discontinue the use of applying phosmet to beef cattle and hogs by high-pressure spray to the point of runoff.

5.7 Environmental assessment conclusions

Phosmet will not persist in the environment and is not likely to significantly affect groundwater sources. This active ingredient is highly toxic to honey bees and, thus, poses a high risk to honey bees and other pollinating insects that are present or in the vicinity during and following the application of phosmet. This conclusion is supported by mortality reports involving honey bees. The risk of phosmet to beneficial insects and arthropods was not determined given the lack of toxicity data. Acute risk to birds was identified as high to small, song bird sized birds. The dietary risk to wild birds is moderate, whereas the risk to wild mammals is high at the highest application rate. Aquatic organisms are at particular risk to phosmet that enters bodies of water during application of phosmet. The PMRA believes that the high risk associated with applying phosmet can be effectively mitigated through the addition of appropriate label statements regarding the toxicity of phosmet to honey bees and through the addition of buffer zones to protect aquatic environments. A label statement indicating that any water used within the cranberry bog must remain impounded until the residue levels are below that of the most sensitive aquatic organism is required to protect the aquatic environment surrounding cranberry bogs. Currently, most cranberry bog operators undertake toxicity testing using aquatic organisms before releasing the water from the bog.

5.8 Environmental risk mitigation

Effects in a terrestrial ecosystem are often difficult to mitigate due to the presence of non-target species in treated areas. For bees, it may be possible to prevent non-target effects by increasing applicator awareness and improving communication between applicators and beekeepers. In addition, limiting sprays to times when bees are not actively foraging will decrease effects to this non-target species. For other terrestrial organisms

such as birds and mammals, options are limited and include decreased rates, numbers and/or frequencies of application.

For aquatic systems, inputs from both runoff and drift are potential sources of contamination. Runoff is difficult to effectively mitigate. Available information suggests that vegetative filter strips may partially mitigate contamination of aquatic systems from runoff.

Spray drift can be effectively mitigated in some cases through the use of spray buffer zones, or through a combination of buffer zones and use of low-drift application technologies. Buffer zones are useful for preventing drift into non-target habitat. Currently, a single spray buffer zone is set based on a standard set of assumptions for spray configuration and weather conditions. The proposed buffer zones are presented in Table 8.1.4.1.

To protect the aquatic environments surrounding cranberry bogs the water used for irrigation and harvesting must be impounded until the phosmet levels are below the no observed effect level (NOEL) of the most sensitive aquatic environment (0.2 µg/L). This will ensure that no adverse effects in aquatic environments will result from the release of water from cranberry bogs.

6.0 Value

6.1 Evaluation method

6.1.1 Agricultural uses of phosmet

The importance of phosmet EPs for managing specific pests on specific agricultural use sites in Canada was evaluated based on the availability of registered alternative pesticides that are potential substitutes. The field use of phosmet in agriculture in Canada was assessed by a survey of OP use conducted in 1998 (the "1998 OP Survey") with the cooperation of provincial governments. This use was also assessed after 1998 from consultations with crop production specialists as well as expert opinion of provincial agricultural officials, grower groups and other stakeholders.

Uses of phosmet were classified into two value classes as follows.

Key uses
Some uses of phosmet were considered "key uses" because they matched one or more of the following criteria:

- there was reported use on at least 10% of the use site and there are no registered alternatives; or
- there was reported use on at least 10% of the use site and alternative active ingredients are registered; however, phosmet is the primary active ingredient (for reasons that are discussed on a case by case basis) for that use; or
- maintaining registration was considered key for resistance management and/or plays an important role in integrated pest management programs; or

- the use site is of high importance to the economy of Canada.

Non-key uses
Uses of phosmet were considered to be "non-key uses" either because they did not match the "key use" criteria or because the information available to the PMRA indicated little or no use in Canada.

6.1.2 Non-agricultural uses of phosmet

Information regarding the extent of non-agricultural use of phosmet was obtained from consultation with provincial governments and crop protection specialists. These uses were also categorized into "key uses" and "non-key uses" based on the above criteria.

6.2 Evaluation results

6.2.1 Sites with key uses of phosmet

The following use sites were identified as having "key uses" of phosmet.

Carrots
There are no registered alternatives to phosmet for the control of carrot weevil on carrot.

Celery
There are no registered alternatives to phosmet for the control of carrot weevil on celery.

Blueberries
The only registered alternative to phosmet in Canada for control of spanworms on blueberries is trichlorfon. Trichlorfon is under re-evaluation. If the use of trichlorfon to control spanworms on blueberries is removed, use of phosmet to control spanworms on blueberries will be considered a "key use".

There are registered alternatives to phosmet to control blueberry maggots, and only one of these alternatives (the OP dimethoate) is preferred over phosmet for control of this pest. Dimethoate is under re-evaluation. If the use of dimethoate to control blueberry maggots on blueberries is removed, use of phosmet to control blueberry maggots will be considered a "key use".

Apples
While alternative chemistries are registered to control apple maggots, it was reported in the 1998 OP Survey that OPs were the only effective controls since long residual action is required to kill female flies before they lay eggs in apples. Phosmet is the primary active ingredient for controlling this pest.

For codling moth control in British Columbia, azinphos-methyl was important in reducing codling moth populations in areas before the initiation of the sterile insect release program. In eastern Canada, sterile insect releases and mating disruption with pheromones are not

considered to be feasible for controlling codling moths due to the abundance of wild alternative hosts for codling moths and the number of other pests that need to be controlled using other methods. Azinphos-methyl was also the primary active ingredient used for the first seasonal codling moth spray in eastern Canada due to its long residual activity. However, the use of phosmet is considered key: it is used for subsequent summer sprays as it is considered less toxic to beneficial arthropods than azinphos-methyl. Azinphos-methyl is being phased-out (RRD2004-05).

There are effective alternatives to phosmet for other pests on apples for which this active ingredient is registered.

Pears
The considerations pertaining to the control of codling moths on pears are very similar to those for apples.

There are effective alternatives to phosmet for other pests on pears for which this active ingredient is registered.

6.2.2 Sites with non-key uses of phosmet

The following sites were identified as having no "key uses" of phosmet: alfalfa, beef cattle, swine, cherries (sour), cranberries, grapes, peaches, plums and potatoes as well as ornamental shade trees, ornamental shrubs and ornamental herbaceous plants in nurseries.

7.0 Other assessment considerations

7.1 Toxic Substances Management Policy

During the review of phosmet, the PMRA has taken into account the federal Toxic Substances Management Policy[4] and has followed its Regulatory Directive DIR99-03[5]. It has been determined that this active ingredient and two of its major transformation products do not meet TSMP Track 1 criteria for the following reasons.

- The log octanol–water partition coefficient (log K_{ow}) is 3.04, which is below the TSMP Track 1 cut-off criterion of log $K_{ow} \geq 5.0$.

4 The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics

5 Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca; or through our website at www.pmra-arla/.gc.ca

- Phosmet does not meet the criteria for persistence as its half-life values in water (< 1 day) and soil (3.5 days) are below the TSMP Track 1 cut-off criteria for water (≥ 182 days), sediment (≥182 days) and soil (≥ 182 days). No data were provided for persistence of phosmet in air.

- The major transformation products, phosmet oxon and phthalamic acid, do not meet the TSMP Track 1 cut-off criterion for bioaccumulation (log K_{ow} > 5.0). The calculated log K_{ow}'s for these two transformation products are 2.01 and 0.15, respectively. Little information regarding the persistence of the major transformation products is available.

7.2 Formulant issues

Formulant issues are being addressed through implementation of the PMRA's formulants program (Regulatory Directive DIR2004-01, *Formulants Program*).

- List 1 formulants are subject to removal from products as communicated to registrants of affected products in September 2001.

- Registrants of products containing nonylphenol ethoxylates have been requested to replace nonylphenol ethoxylates with less harmful alternatives.

- Other formulants, including List 2 formulants, formulation preservatives and allergens, will be subject to future regulatory action as indicated in the PMRA's Formulants Program.

Petroleum distillates (USEPA Inerts List 2) were identified as a formulant in one or more of the phosmet products. In addition, nonlyphenolethoxylates were identified as a formulant in one or more of the phosmet products.

8.0 Proposed regulatory actions

The PMRA has determined that the dietary and drinking water risks, worker risks during mixing, loading and application as well as risks to the environment are acceptable, provided that the mitigation measures listed in Section 8.1 are implemented and the required supporting data presented in Section 9.0 are provided. The one remaining residual concern is for postapplication workers: some estimated non-cancer MOEs for workers re-entering treated areas do not meet the target MOEs, but it is expected that exposure and risk estimates could be refined with the provision of additional data. At this stage of the re-evaluation process, the PMRA requests, by 1 December 2006, data needed to refine the postapplication worker exposure assessment and demonstrate acceptable MOEs for workers re-entering the treated areas (as outlined in Section 9.1). Registrants of other OP pesticides may wish to cooperate in the development of further generic data (e.g. use-pattern data).

The uses of phosmet products proposed for continuing registration, together with proposed interim mitigation measures and use limitations, are presented in Appendix IV.

8.1 Proposed mitigation measures and label changes

8.1.1 Toxicological information

A. Labels of pesticide products carry statements regarding symptoms of poisoning and treatment, which are especially important for those who may be overexposed when working with the product in a commercial or industrial setting, e.g., mixers/loaders who handle more concentrated forms. Based on the toxicological assessments, the label text of the phosmet-containing products should be expanded and/or standardized, as follows:

Toxicological Information

Phosmet is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician

B. For those products that contain greater than 10% petroleum distillates, the following text should also be added to the Toxicological Information section (placed at the end of the paragraph presented above), as an additional aid to the attending physician:

NOTE: Product contains a petroleum distillate solvent.

8.1.2 Proposed measures to protect mixer/loader/applicator

A. Liquid pour-on formulations

Mixers/loaders/applicators must wear:
- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves

B. Wettable powder formulations (must be in water-soluble packaging)

Mixers/loaders must wear:
- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves

Custom mixers/loaders must wear:
- long-sleeved shirt and long pants
- chemical-resistant footwear
- chemical-resistant gloves
- chemical-resistant coveralls

Mixers and loaders using products in water-soluble packaging must have immediately available for use in emergency (such as broken package, spill or equipment breakdown) additional PPE. These PPE include coveralls and chemical-resistant footwear and a non-powered air purifying respirator equipped with an R- or P-series filter.

Applicators using airblast equipment with a closed cab must wear:
- long-sleeved shirt and long pants
- socks and shoes

Applicators using airblast equipment with an open cab must wear:
- long-sleeved shirt and long pants
- chemical-resistant footwear
- chemical-resistant gloves
- chemical-resistant coveralls and head protection
- an air purifying respirator equipped with an R- or P-series filter

Applicators using ground equipment with an open cab must wear:
- long-sleeved shirt and long pants
- socks and shoes

Applicators using handheld equipment must wear:

- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves

8.1.3 Proposed interim measures to minimize exposure to workers re-entering the treated areas

- Limit the maximum number of applications per season as follows:
  apple – Eastern Canada 2; Western Canada 5
  carrot – 1
  celery – 1

- Reduce the rate on apples for control of codling moth in British Columbia from 1875 to 1625 g a.i./ha.

- Require the following agronomically feasible REIs as proposed in the USEPA IRED document for phosmet (see Appendix III, Table 3).
  alfalfa – 5 days
  apple – 3 days
  blueberry – 3 days
  carrot – 5 days
  celery – 5 days
  cherry (sour) – 3 days
  cranberry – 3 days
  grape – 7 days
  peach – 3 days
  pear – 3 days
  plum – 3 days
  potato – 5 days
  floriculture crops – 3 days

- Require PPE (long-sleeved shirt, long pants and chemical-resistant gloves) for critical postapplication activities performed by workers within 30 days of phosmet application.

- Require that wash stations be available for re-entry workers.

- Require that field workers be provided with double notification (i.e., written notice on posted signs and verbal notification to those re-entering the field) that the area has been treated with phosmet and that phosmet is a cholinesterase inhibitor. This should include a brief description of the signs and symptoms of cholinesterase inhibition and ways to minimize exposure.

8.1.4 Proposed regulatory action relating to environment

Environmental Hazards

DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.

TOXIC to birds.

TOXIC to wild mammals.

TOXIC to aquatic organisms.

RUNOFF
To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil and poorly draining soil (e.g. soils that are compacted, fine textured, or low in organic matter such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip (buffer strip) between the treated area and the edge of the water body.

DIRECTIONS OF USE

GENERAL
DO NOT apply this product directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposing of wastes.

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty.

AIRBLAST APPLICATION
DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows.

DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply this product by air.

BUFFER ZONES
The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of (1) sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), and (2) estuarine or marine habitats.

Table 8.1.4.1 Buffer zones (in metres) for the protection of aquatic habitat of various water depths for ground application of phosmet in different crops

Method of application	Buffer zone (metres) required for the protection of aquatic habitat with water depth of*:		
	< 1 metres	1–3 metres	> 3 metres
Field sprayer	50	40	30
Airblast (early growth stage)	65	50	40
Airblast (late growth stage)	55	40	30

* With the use of shrouds or cones on field sprayers (for reducing drift), buffer zones can be reduced by 70% (shrouds) or 30% (cones).

TANK MIX
When using a tank mixture, consult the labels of the tank-mix partners and use the largest (most restrictive) buffer zone recommended for any of the products.

CRANBERRIES
To minimize surface water contamination by phosmet applied on cranberries, all effluent water must be impounded and released only when levels of phosmet are $\leq$ 0.2 µg a.i./L.

STORAGE
To prevent contamination store this product away from food or feed.

8.2 Definition of the residue of concern

Division 15, Table II, of the Food and Drug Regulations currently defines the parent compound phosmet (O,O-dimethyl S-phthalimidomethyl phosphorodithioate) as the residue of concern (ROC). It is recommended that the ROC be defined as the sum of parent phosmet and its oxon metabolite (O,O-dimethyl S-phthalimidomethyl phosphorothioate). This ROC definition is consistent with that of the USEPA.

8.3 Maximum residue limits for phosmet in food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian maximum residue limits (MRLs) and to remove MRLs that are no longer supported. The Agency recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the PMRA requires residue data (MOR trials) that are representative of use conditions in exporting countries, in the same manner that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the Agency may determine whether the requested MRLs are needed, and to ensure they would not result in unacceptable health risks.

After the revocation of an MRL or where there is no specified MRL, the general MRL of 0.1 ppm, as specified in subsection B.15.002 (1) of the Food and Drug Regulations, applies for enforcement purposes. Changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

As indicated in Table 8.3.1, the Food and Drug Regulations specify MRLs for phosmet residues in apples, grapes, peaches, pears, cherries, blueberries, plums and kiwi. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specified MRL (i.e. cranberries, carrots, celery, potatoes, beef cattle and hogs), must not exceed the general MRL of 0.1 ppm.

With the exception of cranberries, residue data were available to indicate the existing MRLs should not be exceeded if phosmet is used according to good agricultural practice (GAP), as described by the current product labels. However, in most cases the existing residue data are dated, and do not fully satisfy the requirements as described in Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*. The technical registrant is asked to provide confirmation that residue field trial data for all commodities meet contemporary standards by submitting the appropriate data and/or American Data Evaluation Reports (DERs).

There were no residue data on file for cranberries following the label specified 30 day PHI. The technical registrant is required to provide this data. Extrapolation of available residue data for residues on cranberries following shorter PHIs indicated that residues should not exceed the 0.1 ppm general MRL if phosmet is used according to GAP.

Parties interested in supporting a phosmet MRL should contact the PMRA during the comment period of this document to discuss the submission of appropriate data.

Table 8.3.1 Phosmet MRLs for commodities approved for treatment in Canada and for import commodities with specified MRLs

Commodity	MRL (ppm)
Apples	10
Blueberries	5
Cherries	7
Grapes	10
Kiwi fruit	1*
Peaches	10
Pears	10
Plums	5
Carrot (field)	0.1**
Celery (field)	0.1**
Cranberries	0.1**
Potatoes	0.1**
Cattle	0.1**
Hogs	0.1**

* For import purposes, edible portion only

** By virtue of subsection B.15.002(1) of the Food and Drug Regulations, the maximum residue limit of foods for which MRLs have not specifically been established is 0.1 ppm.

9.0 Additional data requirements

9.1 Information required to refine the occupational exposure assessment

The technical registrant is required to provide, by 1 December 2006, information that demonstrates acceptable MOEs for workers. The PMRA will finalize the re-evaluation decision on phosmet after reviewing the submitted data. If no data are received, the PMRA will consider appropriate measures (e.g., longer REIs, cancellation of uses) to address concerns regarding postapplication risks to workers. The type of data needed to refine the exposure assessment could include, but is not limited to, the following:

- typical rate and number of application/season;
- critical worker activities and their timing with respect to the stage of growth of the crop and application of phosmet;
- data being developed by the ARTF;
- other exposure data such as passive dosimetry, biological monitoring
- additional DFR data;
- feasibility of lower rate of application;
- feasibility of longer REIs;
- feasibility of additional protective clothing and/or other mitigation measures for selected postapplication worker activities; and

- feasibility of any other risk mitigation measures.

9.2 Other data requirements

Data needed to support continued registration of existing uses of phosmet are noted hereafter. Scientifically based rationales for data waivers may be acceptable for some of the following data requirements.

9.2.1 Data requirements relating to chemistry

A. Technical grade active ingredient:

- No additional chemistry data are required for the technical product.

B. End-use product:

- A Statement of Product Specification Form for all registered EPs in accordance with Table 1 in Section 3.3 of DIR98-03, following conversion of the TGAI to a nominal guarantee.
- Quality control data of active ingredient from 10 batches of EPs to support the nominal active value, if nominal guarantee of pure active ingredient is the same as the original minimum guarantee.

The guarantee of the product will be revised to the nominal value after submission of these data.

9.2.2 Data requirements relating to toxicology

The following confirmatory data are required to support the continued registration of phosmet and to support any expansion of phosmet use:

- A developmental neurotoxicity study (DACO 4.5.14)

9.2.3 Data requirements relating to food residue exposure

The following confirmatory data are required to support the continued registration of phosmet and to support any expansion of phosmet use:

- Residue field trials following GAP for cranberries (DACO 7.4.1)
- Freezer storage stability tests or USEPA DERs for all commodities on which phosmet is registered for use (DACO 7.3)
- Livestock and plant metabolism studies or USEPA DERs (DACO 6.2 and 6.3)
- Confirmation that residue data for all commodities meet contemporary standards, as per PMRA Residue Chemistry Guidelines (DACO 7.4 to 7.6)

9.2.4 Data requirements relating to environmental risks

- Toxicity to beneficial predators and predatory mites (DACO 9.2.5)
- Toxicity of phosmet oxon (transformation product of toxicological concern) to *Daphnia magna* (DACO 9.3.2; if toxicity to Daphnia is evident, toxicity studies for other organisms may be required)
- Aerobic aquatic biotransformation (20–30°C) for phosmet oxon (DACO 8.2.3.5.2)
- Anaerobic water/sediment biotransformation (20–30°C) for phosmet oxon (DACO 8.2.3.5.6)
- Aerobic soil biotransformation (20–30°C) for phosmet oxon (DACO 8.2.3.4.2)
- Adsorption/desorption for phosmet oxon (DACO 8.2.4.2)

10.0 Re-evaluation conclusions

By way of this document, the Agency is soliciting, from interested parties, comments on the proposed interim regulatory decision for phosmet. In particular, the PMRA is soliciting comments on the feasibility of lengthening the proposed interim REIs prior to finalizing this interim decision. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document.

List of abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
atm	atmospheres
bw	body weight
CC	closed cab tractor
cm	centimetre(s)
DEEM®	Dietary Exposure Evaluation Model
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DT_{50}	dissipation time to 50%
DWLOC	drinking water level of comparison
DNA	deoxyribonucleic acid
EEC	expected environmental concentration
EP	end-use product
EXAMS	Exposure Analysis Modeling System
F_0	parental animals
F_1	first filial generation
GAP	good agricultural practice
g	gram(s)
ha	hectare(s)
IRED	Interim Reregistration Eligibility Decision
K_d	adsorption coefficient
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	octanol–water partition coefficient
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
L	litre(s)
LOAEL	lowest observed adverse effect level
LOEC	lowest observed effect concentration
LOEL	lowest observed effect level
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
mm	millimetre(s)
mm Hg	millimetre(s) mercury
MOE	margin of exposure
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OP	organophosphate
PCPA	*Pest Control Products Act*

PDI	potential daily intake
PDP	Pesticide Data Program
PHI	preharvest interval
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
pK_a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
Q*	cancer potency factor
REI	restricted entry interval
ROC	residue(s) of concern
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration

Appendix I Phosmet products currently registered

Registrant	Registration number	Guarantee	Product name	Class
Dispar, Division of Vétoquinol North America Inc.	15359	11.6%	Louse Kill Pour-on Emulsifiable Liquid	Commercial
Gowan Company	23006	50%	Imidan 50-WP Instapak Agricultural Insecticide	Commercial
Gowan Company	23055	94%	Phosmet Technical	Technical
Schering-Plough Animal Health	27478	11.6%	Del-Met Emulsifiable Liquid Insecticide	Commercial

Appendix II Toxicology endpoints for health risk assessment for phosmet

Exposure scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE[a]
Acute dietary	NOAEL = 4.5	Brain and erythrocyte cholinesterase inhibition, decreased motor activity	Acute oral neurotoxicity—rat	100
	ARfD = 0.045 mg/kg bw			
Chronic dietary	LOAEL = 1.0	Brain cholinesterase inhibition (interim sacrifice)	2-year dietary oncogenicity—mouse	300
	ADI = 0.0033 mg/kg bw/day			
Short- and intermediate-term[b] Dermal	Dermal NOAEL = 15	Brain cholinesterase inhibition	21-day dermal toxicity—rat	100
Short-, and intermediate-term[b] inhalation[c]	Oral NOAEL = 1.5	Brain cholinesterase inhibition	Subchronic dietary neurotoxicity—rat	100
Cancer		Liver tumours in males	2-year dietary oncogenicity—mouse	$Q_1^* = 1.06 \times 10^{-2}$ $(mg/kg\ bw/day)^{-1}$

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments

[b] Duration of exposure is 1–30 days

[c] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) should be used in route-to-route extrapolation

Appendix III Occupational risk estimates for phosmet

Table 1 shows non-cancer risks expressed as combined MOEs estimated from dermal and inhalation unit exposure values from PHED with the specified PPE; the target MOE is 100. Cancer risks assume exposure from the maximum number of applications every year for 35 years of a 70-year lifetime. The table includes the assumptions for area treated or litres used per day.

Table 2 identifies the REIs calculated to provide a MOE of 100 for selected re-entry activities (i.e., weeding, scouting and harvesting).

Table 3 shows non-cancer risks as MOEs and lifetime cancer risks per million, estimated at agronomically feasible REIs for low- and high-exposure re-entry activities. Risk estimates for harvesting are calculated at the PHI, if it is longer than the agronomically feasible REI.

Table 1 Summary of occupational mixer/loader/applicator risks

Activity type	Scenario/ formulation	Area treated/ litres used per day	Non-cancer		Cancer[2]	
			Required PPE[7]	MOE[1]	Required PPE[7]	Risk
USC 8 Livestock for Food						
Livestock application	Liquid pour-on[3]	48 L	Minimum PPE	21500	Minimum PPE	2.0×10^{-9}
USC 13 Terrestrial Feed Crops						
alfalfa	groundboom	65 ha	Baseline	160	Baseline	4.1×10^{-7}
	custom groundboom – M/L	300 ha	Minimum PPE	130	Maximum PPE	2.0×10^{-6}
	custom groundboom – A		Maximum PPE	100	CC [8]	2.5×10^{-6}
	custom – M/L/A		Max/Max + resp.[8]	100	Max/Max + resp.[8]	6.7×10^{-6}
USC 14 Terrestrial Food Crops						
apple	airblast	16 ha	Min/CC	490	Min/CC	2.2×10^{-7}
blueberry	groundboom	32 ha	Baseline	320	Baseline	1.4×10^{-7}
	airblast	16 ha	Min/Max	100	Maximum PPE	4.1×10^{-7}
carrot	groundboom	32 ha	Baseline	320	Baseline	1.4×10^{-7}
celery	groundboom	32 ha	Baseline	320	Baseline	1.4×10^{-7}
cherry (sour)	airblast	16 ha	Min/CC	490	Min/CC	1.8×10^{-7}
cranberry	groundboom	32 ha	Baseline	330	Baseline	2.6×10^{-7}
	airblast[4]	16 ha	Min/Max	100	Maximum PPE	8.1×10^{-7}
	chemigation[3]	60 ha	Baseline	330	Baseline	2.6×10^{-7}
grape	airblast	16 ha	Min/CC	600	Min/CC	1.1×10^{-7}

Activity type	Scenario/ formulation	Area treated/ litres used per day	Non-cancer		Cancer[2]	
			Required PPE[7]	MOE[1]	Required PPE[7]	Risk
	groundboom	32 ha	Baseline	230	Baseline	2.8×10^{-7}
peach	airblast	16 ha	Min/CC	490	Min/CC	1.8×10^{-7}
pear	airblast	16 ha	Min/CC	490	Min/CC	8.8×10^{-8}
plum	airblast	16 ha	Min/CC	490	Min/CC	1.3×10^{-7}
potato	groundboom	65 ha	Baseline	160	Baseline	6.9×10^{-7}
	custom groundboom - M/L	300 ha	Minimum PPE	130	Maximum PPE	2.0×10^{-6}
	custom groundboom - A		Maximum PPE	100	CC[8]	2.5×10^{-6}
	custom - M/L/A		Max/Max + resp.[8]	100	Max/Max + resp.[8]	6.7×10^{-6}
USC 27 Ornamentals Outdoor						
ornamentals	groundboom	32 ha	Baseline	580	Baseline	1.1×10^{-7}
	airblast	16 ha	Baseline	110	Baseline	5.8×10^{-7}
	low-pressure hand wand[6]	150 L	Minimum PPE[5]	8000	Minimum PPE[5]	8.1×10^{-9}
	backpack[6]	150 L	Minimum PPE[5]	1800	Minimum PPE[5]	3.5×10^{-8}
	high-pressure hand wand[6]	1500 L	Minimum PPE[5]	160	Minimum PPE[5]	4.1×10^{-7}

1 Combined MOE calculated using a dermal NOAEL of 15 mg/kg bw/day and an inhalation NOAEL of 1.5 mg/kg bw/day.

2 Assuming yearly maximum number of applications for 35 years of a 70-year life span; custom operators assumed 30 days per year.

3 Risk estimates include mixing and loading only. No data are available for the pour-on or chemigation application scenarios.

4 Airblast data were used to represent fogger/mister application over cranberry bogs.

5 No data are available for the bare hands baseline for these mixer/loader/applicator scenarios; minimum PPE includes chemical-resistant gloves.

6 Risk estimates calculated for use of liquid open pour since no reliable data were available for use of the WSP formulation.

7 PPE as described in the text; where there is one designation it applies to mixing/loading/applying, while two designations refer to PPE required for mixing/loading and applying, separately.

8 Custom applicators wearing maximum PPE applying in an open cab tractor have a cancer risk of 6.4×10^{-6} or 4.6×10^{-6} with maximum PPE and a respirator. Custom M/L/A must wear maximum PPE and, if not applying from a closed cab tractor, a respirator.

M/L/A mixer/loader/applicator

CC closed cab tractor for applicators

Table 2 Calculated restricted entry intervals (REIs) to reach target MOE for some crop/activity combinations

Crop	PHI[1] (days)	Weeding[2] (days)	Scouting[3] (days)	Harvesting[3] (days)
alfalfa	7	—	12	—
apple	1	4	18	24
blueberry	15	0	0	16—low bush 34—high bush
carrot	40	0	0	24
celery	40	0	16	24
cherry (sour)	7	4	13	19
cranberry	30	0	0	0
grape	7	0	12	36
peach	1	4	14	20
pear	1	4	12	18
plum	1	4	13	19
potato	7	0	20	—
floriculture crops	—	9	26—full foliage	33
residential floriculture use[4] not supported by the registrant (Section 3.2.2)	—	0	0	0

[1] Current PHI according to product labels.
[2] Following a single application of phosmet.
[3] Following the maximum number of applications of phosmet.
[4] Assumes postapplication exposure duration of 40 minutes/day.

Table 3 Risk estimates for short-term (≤ 30 days) exposures at 8 hours/day

Crop	REI[1]/ PHI[2]	Low exposure[3]		High exposure[3]		Harvesting[2]	
		MOE	LCR[6]	MOE	LCR[6]	MOE	LCR[6]
alfalfa	5/7	62	406	—	—	5	5
apple	3/1	39	7.5	13	23	26	11
blueberry (low)	3/15	155	1.9	41	7	94	3.1
blueberry (high)	3/15	124	2.3	12	23	28	10
carrot [7]	5/40	236	1.2	28	10	311	0.92
celery [7]	5/40	142	2	28	10	311	0.92
cherry (sour)	3/7	54	5.4	18	16	47	6.2
cranberry	3/30	126	2.3	126	2.3	799	0.36
grape	7/7	115	2.5	23	12	23	12
peach	3/1	49	5.9	16	18	33	8.9
pear	3/1	58	5	19	15	39	7.6
plum	3/1	53	5.5	18	17	35	8.3
potato [5]	5/7	36	7.9	—	—	5	5
floriculture crops	3	44	6.6	16	18	n/a	n/a
residential floriculture use[4] not supported by the registrant (Section 3.2.2)	0	427	0.67	153	1.9	n/a	n/a

1 Agronomically feasible REIs based on USEPA assessment for phosmet.
2 When PHI > REI , label PHIs remain as REIs pertinent to harvesting scenario.
3 Low-exposure activities: scouting, irrigating; and high-exposure activities: thinning, pruning.
4 Homeowners gardening 40 minutes per day, 7 days per year for 35 years.
5 Restrict to mechanical harvesting only.
6 Lifetime cancer risk (LCR), per million, based on 30 days of activity, on average, per year for 35 years.
7 REI based on consultations with growers groups and extention workers.

Appendix IV Use standard for commercial class products containing phosmet

(**NOTE:** The information in this appendix summarizes the acceptable uses, limitations and minimum PPE for the commercial class products containing phosmet resulting from this re-evaluation. This use standard does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary PPE that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this use standard.)

COMMON NAME: phosmet

CHEMICAL NAME: O,O-dimethyl S-phthalimidomethyl phosphorodithioate

FORMULATION TYPES: Wettable powder (in water-soluble packaging)
Emulsifiable concentrate

SITE CATEGORIES:

8	Livestock for Food
13	Terrestrial Feed Crops
14	Terrestrial Food Crops
27	Ornamentals Outdoor

GENERAL LIMITATIONS:

TOXICOLOGICAL INFORMATION:
Phosmet is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician

For those products that contain greater than 10% petroleum distillates, the following text should also be added to the Toxicological Information section (placed at the end of the paragraph presented above), as an additional aid to the attending physician:

"NOTE: Product contains a petroleum distillate solvent."

PRECAUTIONARY STATEMENTS:

PROTECTIVE CLOTHING AND EQUIPMENT:

Liquid pour-on formulations

Mixers/loaders/applicators must wear:
- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves

Wettable powder formulations (must be in water-soluble packaging)

Mixers/loaders must wear:
- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves

Custom mixers/loaders must wear:
- long-sleeved shirt and long pants
- chemical-resistant footwear
- chemical-resistant gloves
- chemical-resistant coveralls

Mixers and loaders using products in water-soluble packaging must have immediately available for use in emergency (such as broken package, spill or equipment breakdown) additional PPE. These PPE include coveralls and chemical-resistant footwear and a non-powered air purifying respirator equipped with an R- or P-series filter.

Applicators using airblast equipment with a closed cab must wear:
- long-sleeved shirt and long pants
- socks and shoes

Applicators using airblast equipment with an open cab must wear:
- long-sleeved shirt and long pants
- chemical-resistant footwear
- chemical-resistant gloves
- chemical-resistant coveralls and head protection
- an air purifying respirator equipped with an R- or P-series filter

Applicators using ground equipment with an open cab must wear:
- long-sleeved shirt and long pants
- socks and shoes

Applicators using handheld equipment must wear:
- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves

Postapplication

Workers performing critical postapplication activities within 30 days of phosmet application must wear:
- long-sleeved shirt and long pants
- chemical-resistant gloves

Wash stations must be available for re-entry workers.

RESTRICTED ENTRY INTERVAL:

Field workers must be provided with double notification (i.e., written notice on posted signs and verbal notification to those re-entering the field) that the area has been treated with phosmet and that phosmet is a cholinesterase inhibitor. This should include a brief description of the signs and symptoms of cholinesterase inhibition and ways to minimize exposure.

The following REIs must be observed by workers re-entering the treated areas for these crops.

- alfalfa – 5 days
- apple – 3 days
- blueberry – 3 days
- carrot – 5 days
- celery – 5 days
- cherry (sour) – 3 days
- cranberry – 3 days
- grape – 7 days
- peach – 3 days
- pear – 3 days
- plum – 3 days
- potato – 5 days
- floriculture crops – 3 days

ENVIRONMENTAL HAZARDS:

DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.

TOXIC to birds.

TOXIC to wild mammals.

TOXIC to aquatic organisms.

RUNOFF

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil and poorly draining soil (e.g., soils that are compacted, fine textured or low in organic matter such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip (buffer strip) between the treated area and the edge of the water body.

DIRECTIONS OF USE

GENERAL

DO NOT apply this product directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposing of wastes.

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty.

AIRBLAST APPLICATION

DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows.

DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply this product by air.

BUFFER ZONES

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of (1) sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), and (2) estuarine or marine habitats.

Buffer zones (in metres) for protection of aquatic habitat of various water depths for ground application of phosmet in different crops

Method of application	Buffer zone (metres) required for the protection of aquatic habitat with water depth of*:		
	< 1 metres	1–3 metres	> 3 metres
Field sprayer	50	40	30
Airblast (early growth stage)	65	50	40
Airblast (late growth stage)	55	40	30

* With the use of shrouds or cones on field sprayers (for reducing drift), buffer zones can be reduced by 70% (shrouds) or 30% (cones).

TANK MIX

When using a tank mixture, consult the labels of the tank-mix partners and use the largest (most restrictive) buffer zone recommended for any of the products.

CRANBERRIES

To minimize surface water contamination by phosmet applied on cranberries, all effluent water must be impounded and released only when levels of phosmet are $\leq$ 0.2 µg a.i./L.

STORAGE

To prevent contamination store this product away from food or feed.

ACCEPTABLE COMMERCIAL USES FOR PHOSMET:

General			**Wettable Powder** Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
cattle (non-lactating), swine	lice, sarcoptic mange	11.6 mg a.i./kg bw	**Emulsifiable concentrate** **Pour-on:** Pour phosmet-water solution down the centre line of the animal's back. Do not use on lactating cattle. Dandruff may appear on treated areas, which may be a blemish in show animals. Do not use this product on cattle which are likely to be infested with grubs as host parasite reaction may occur. Symptoms of host parasite reaction usually appear 24–96 hours after treatment and include staggering, or rarely posterior paralysis, salivation or bloat. Consult your veterinarian should these symptoms occur. Atropine is contraindicated. Solvent irritation may occur in sensitive skinned animals, symptoms are increased activity, a repeated getting up and down, tail swishing and twitching of the skin. Symptoms occur within 5–15 minutes after treatment and subside within one hour without complications. Cattle lice: A second application 3 weeks later may be necessary. Hog lice: If necessary, re-treat once. Do not re-treat within 7 days of the first application. Hog mange: A second application 14 days later may be necessary. Do not apply within 7 days of slaughter. Maximum of 2 applications.

General			Wettable Powder Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
alfalfa	alfalfa weevil, alfalfa blotch leafminer	1125	**Wettable powder** **Spray:** Do not apply during bloom. Apply in 200–500 L of water per hectare. Alfalfa weevil: Consult local agricultural authorities regarding proper time of spray applications. Alfalfa blotch leafminer: Apply when first signs of infestation are visible. Do not apply within 7 days of harvest. Do not apply more than 1 time per cutting. Do not make more than 3 applications per season.

General			**Wettable Powder** Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
apple	codling moth, redbanded leaf roller, plum curculio, apple maggot, apple aphid, spotted tentiform leafminer, obliquebanded leafroller, green fruitworm, tarnished plant bug, eye-spotted bud moth, San Jose scale, eastern tent caterpillar, elm spanworm, gypsy moth, Japanese beetle, spring cankerworm Suppresses European red mite, twospotted spider mite	codling moth: Eastern Canada: 1875 Western Canada: 1625 other pests: 1875	**Wettable powder** **Air blast:** Use sufficient water to provide thorough coverage. Obliquebanded leafroller: Begin sprays within 7–10 days after first moths are trapped. Other pests: Consult local agricultural authorities regarding proper time of spray applications. Do not apply within 3 days of harvest. Eastern Canada: Do not apply more than 2 applications. Western Canada: Do not apply more than 5 applications.

General			**Wettable Powder** Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
blueberry	blueberry maggot, blueberry spanworm	blueberry maggot: 1125 blueberry spanworm: 1120	**Wettable powder** **Spray:** Apply in 1000 L of water per hectare. Blueberry maggot: Applications may be made when indicated by insect infestations and local or provincial spray programs. Apply between July 15 and 30. Blueberry spanworm: Apply from mid-April to mid-June for both sprouting and fruiting field sections. First application to be made when insects reach damaging levels; repeat application if necessary. Consult local crop specialists for detailed recommendations. Do not apply within 15 days of harvest. Maximum 2 applications per season.
carrot, celery	carrot weevil	1125	**Wettable powder** **Spray:** Apply in sufficient water to provide good coverage for carrot and up to 1000 L per hectare for celery. Consult local agricultural authorities regarding proper timing of spray applications. Do not make more than 1 application per season. Do not apply within 40 days of the harvest.

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Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
cherry, sour (tart)	peach twig borer, plum curculio, redbanded leaf roller, cherry fruit fly, eastern tent caterpillar, elm spanworm, gypsy moth, Japanese beetle, spring cankerworm. Suppresses European red mite, twospotted spider mite	1875	**Wettable powder** **Spray, air blast:** Consult local agricultural authorities regarding proper time of spray applications. Use sufficient water to provide thorough coverage. Do not apply within 7 days of harvest. Do not make more than 4 applications per season.
cranberry	blackheaded fireworm	1100	**Wettable Powder** **Spray and chemigation:** Apply the first application after egg hatch and the second application 5–7 days later if necessary. Cranberry growers in British Columbia are advised to obtain and follow the *Chemigation Guidelines for British Columbia* available from the British Columbia Ministry of Agriculture, Fisheries and Food (Abbotsford). Do not apply within 30 days of harvest. Maximum of 4 applications per season.
grapes	grape berry moth, eastern tent caterpillar, elm spanworm, gypsy moth, Japanese beetle, spring cankerworm	950, 1250 and 1550	**Wettable powder** **Spray, air blast:** Apply 950 g a.i./ha at prebloom, 1250 g a.i./ha at postbloom and 1550 g a.i./ha at the first cover. Apply in sufficient water to provide good coverage. Do not apply within 7 days of harvest. Maximum of 3 applications.

General			Wettable Powder Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
pear	pear psylla, codling moth, redbanded leafroller, plum curculio, obliquebanded leafroller, green fruitworm, rust mite, eastern tent caterpillar, elm spanworm, gypsy moth, Japanese beetle, spring cankerworm Suppresses European red mite, twospotted spider mite	1875	**Wettable powder** **Air blast:** Apply in sufficient water to provide good coverage. Consult local agricultural authorities regarding proper time of spray applications. For obliquebanded leafroller, begin sprays within 7–10 days after first moths are trapped. May be applied up to 3 days before harvest. Do not apply more than 2 applications per season.

General			**Wettable Powder** Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
peach	plum curculio, peach twig borer, oriental fruit moth, obliquebanded leafroller, tarnished plant bug, eastern tent caterpillar, elm spanworm, gypsy moth, Japanese beetle, spring cankerworm Suppresses European red mite, twospotted spider mite	1875	**Wettable powder** **Air blast:** Apply in sufficient water to provide good coverage. Consult local agricultural authorities regarding proper time of spray applications. For obliquebanded leafroller, begin sprays within 7–10 days after first moths are trapped. May be applied up to 3 days before harvest. Do not apply more than 4 applications per season.
plum	plum curculio, apple maggot, redbanded leafroller, eastern tent caterpillar, elm spanworm, gypsy moth, Japanese beetle and spring cankerworm Suppresses European red mite, twospotted spider mite	1875	**Wettable powder** **Air blast:** Apply in sufficient water to provide good coverage. Consult local agricultural authorities regarding proper time of spray applications. For obliquebanded leafroller, begin sprays within 7–10 days after first moths are trapped. May be applied up to 3 days before harvest. Do not apply more than 3 applications per season.
potato	Colorado potato beetle, potato flea beetle, potato leafhopper, potato aphid	1125	**Wettable powder** **Spray:** Apply in sufficient water to provide good coverage. Do not apply within 7 days of harvest. Maximum of 5 applications pre season.

General			**Wettable Powder** Do not apply by air. Do not use in low-volume, gear-type spray equipment. Do not combine wettable powders with oil or other emulsifiable liquids in the same spray tank unless previous use of the materials combined has proven them to be physically compatible. **Emulsifiable concentrate**
Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
deciduous shade and ornamental trees (ash, beech, oak, dogwood, willow, hickory, hawthorn, birch, elm, maple)	birch leaf miner (birch trees only), gypsy moth, elm spanworm, Japanese beetle, spring cankerworm, eastern tent caterpillar	625	**Wettable powder** **Spray, air blast:** When such insects or their damage occur, spray in sufficient water to thoroughly wet all parts of the affected plants to the point of runoff. The initial application should be made for lepidopterous insects (gypsy moth, elm spanworm, spring cankerworm, eastern tent caterpillar) after most of the eggs have hatched but before heavy feeding damage is noted. Best results are obtained if application can be delayed until the largest larvae are 13 mm long. A second application may be necessary on some species 14–21 days after the first. First generation birch leafminer application should be made in May when the leaves are about half expanded and the small blisters or mines appear noticeable. Make a second application around the first week of July for control of second generation miners. Do not apply more than 3 times per season.

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Site	**Pest**	**Rate (g a.i./ha unless otherwise stated)**	**Application instructions and limitations**
woody evergreen trees and shrubs (arborvitae, azalea, boxwood, camellia, cedar, fir, hemlock, hydrangea, juniper, lilac, pine, privet, rose, spruce, yew) herbaceous plants (chrysanthemum, geranium, zinnia, petunia, portulaca, four-o'clock, marigold, cosmos)	elm spanworm, gypsy moth, Japanese beetle	625	**Wettable Powder** **spray, air blast:** When such insects or their damage occur, apply in sufficient water to thoroughly wet all parts of the affected plants to the point of runoff. The initial application should be made for lepidopterous insects (elm spanworm, gypsy moth) after most of the eggs have hatched but before heavy feeding damage is noted. Best results are obtained if application can be delayed until the largest larvae are 13 mm long. A second application may be necessary on some species 14-21 days after the first. Do not apply more than 3 times per season.