

US EPA ARCHIVE DOCUMENT



US Environmental Protection Agency Office of Pesticide Programs

Reregistration Eligibility Decision for Phosmet

When EPA concluded the organophosphate (OP) cumulative risk assessment in July 2006, all tolerance reassessment and reregistration eligibility decisions for individual OP pesticides were considered complete. OP Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs. OP tolerance reassessment decisions (TREDs) also are considered completed.

Combined PDF document consists of the following:

- Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006)
- Phosmet IRED



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

SUBJECT: Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides

FROM: Debra Edwards, Director
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Office of Pesticide Programs

TO: Jim Jones, Director
Office of Pesticide Programs

As you know, EPA has completed its assessment of the cumulative risks from the organophosphate (OP) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual OPs have also been subject to review through the individual-chemical review process. The Agency's review of individual OPs has resulted in the issuance of Interim Reregistration Eligibility Decisions (IREDs) for 22 OPs, interim Tolerance Reassessment and Risk Management Decisions (TREDs) for 8 OPs, and a Reregistration Eligibility Decision (RED) for one OP, malathion.¹ These 31 OPs are listed in Appendix A.

EPA has concluded, after completing its assessment of the cumulative risks associated with exposures to all of the OPs, that:

(1) the pesticides covered by the IREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) are indeed eligible for reregistration; and

¹ Malathion is included in the OP cumulative assessment. However, the Agency has issued a RED for malathion, rather than an IRED, because the decision was signed on the same day as the completion of the OP cumulative assessment.

(2) the pesticide tolerances covered by the IREDs and TREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) meet the safety standard under Section 408(b)(2) of the FFDCA.

Thus, with regard to the OPs, EPA has fulfilled its obligations as to FFDCA tolerance reassessment and FIFRA reregistration, other than product-specific reregistration.

The Special Review and Reregistration Division will be issuing data call-in notices for confirmatory data on two OPs, methidathion and phorate, for the reasons described in detail in the OP cumulative assessment. The specific studies that will be required are:

- 28-day repeated-dose toxicity study with methidathion oxon; and
- Drinking water monitoring study for phorate, phorate sulfoxide, and phorate sulfone in both source water (at the intake) and treated water for five community water systems in Palm Beach County, Florida and two near Lake Okechobee, Florida.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

Attachment A:
Organophosphates included in the OP Cumulative Assessment

Chemical	Decision Document	Status
Acephate	IREDD	IREDD completed 9/2001
Azinphos-methyl (AZM)	IREDD	IREDD completed 10/2001
Bensulide	IREDD	IREDD completed 9/2000
Cadusafos	TREDD	TREDD completed 9/2000
Chlorethoxyphos	TREDD	TREDD completed 9/2000
Chlorpyrifos	IREDD	IREDD completed 9/2001
Coumaphos	TREDD	TREDD completed 2/2000
DDVP (Dichlorvos)	IREDD	IREDD completed 6/2006
Diazinon	IREDD	IREDD completed 7/2002
Diclotophos	IREDD	IREDD completed 4/2002
Dimethoate	IREDD	IREDD completed 6/2006
Disulfoton	IREDD	IREDD completed 3/2002
Ethoprop	IREDD	IREDD completed 9/2001 IREDD addendum completed 2/2006
Fenitrothion	TREDD	TREDD completed 10/2000
Malathion	RED	RED completed 8/2006
Methamidophos	IREDD	IREDD completed 4/2002
Methidathion	IREDD	IREDD completed 4/2002
Methyl Parathion	IREDD	IREDD completed 5/2003
Naled	IREDD	IREDD completed 1/2002
Oxydemeton-methyl	IREDD	IREDD completed 8/2002
Phorate	IREDD	IREDD completed 3/2001
Phosalone	TREDD	TREDD completed 1/2001
Phosmet	IREDD	IREDD completed 10/2001
Phostebupirim	TREDD	TREDD completed 12/2000
Pirimiphos-methyl	IREDD	IREDD completed 6/2001
Profenofos	IREDD	IREDD completed 9/2000
Propetamphos	IREDD	IREDD completed 12/2000
Terbufos	IREDD	IREDD completed 9/2001
Tetrachlorvinphos	TREDD	TREDD completed 12/2002
Tribufos	IREDD	IREDD completed 12/2000
Trichlorfon	TREDD	TREDD completed 9/2001



EPA 738-R-01-010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 30, 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide phosmet. The public comment period on the revised risk assessment phase of the reregistration process is closed. The Agency held a Technical Briefing on February 10, 2000, in Pasco, Washington, where the results of the revised human health and environmental effects risk assessments were presented to the general public. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on March 20, 2000. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on March 20, 2000, and closed on May 19, 2000.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current uses of phosmet. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the 45 current uses of phosmet and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for phosmet will be finalized once the cumulative assessment for all of the organophosphate pesticides is considered. The enclosed "Interim Reregistration Eligibility Decision for Phosmet," which was approved on October 30, 2001, contains the Agency's decision on the individual chemical phosmet."

A Notice of Availability for this Interim Reregistration Eligibility Decision for phosmet is being published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic

copies of the interim RED and all supporting documents are available on the Internet. See <http://www.epa.gov/pesticides/op>.

The interim RED is based on the updated technical information found in the phosmet public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for phosmet, and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For phosmet, a proposal was submitted by Gowan Company, the technical registrant. Comments on mitigation or mitigation suggestions were also submitted by environmental organizations, agricultural extension agents, and various other organizations.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for these pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphate pesticides are following this new process.

Please note that the phosmet risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's conclusions on the dietary (food and drinking water) risks posed by exposure to phosmet alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of phosmet. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing the risk assessments for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of phosmet. The Agency will issue the final tolerance reassessment decision for phosmet and finalize decisions on reregistration eligibility once the cumulative assessment for all of the organophosphates is considered.

Interim RED DCIs: This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, is being sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of required responses is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

In this interim RED, the Agency has determined that phosmet will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. This interim RED identifies risk concerns associated with current uses of phosmet. Other phosmet uses with remaining risks have been determined to have significant benefits associated with their continued use. These risks are mitigated to the extent possible. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this interim RED describe labeling amendments for end-use products, data requirements necessary to implement these mitigation measures and discuss the benefits associated with the use of phosmet on various crops. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this interim RED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, even in light of the benefits derived from its use, the Agency will continue to have concerns about the risks posed by phosmet. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. Accordingly, pesticides containing phosmet may not be eligible for reregistration absent the labeling changes.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Diane Isbell at (703) 308-8154. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Barbara Briscoe at (703) 308-8177.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

**Interim Reregistration Eligibility Decision
for
Phosmet**

Case No. 0242

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GLOSSARY OF TERMS AND ABBREVIATIONS

AGDCI	Agricultural Data Call-In
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOD	Limit of Detection
MATC	Maximum Acceptable Toxicant Concentration
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate

OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WPS	Worker Protection Standard
Fg/g	Micrograms Per Gram
Fg/L	Micrograms Per Liter

Executive Summary

EPA has completed its review of public comments on the revised phosmet risk assessments and is issuing its risk management decisions for phosmet. This document supercedes the Partial Interim RED (PIRED) signed on August 31, 2001. This document contains both the 17 decisions in the PIREDD as well as decisions on the 28 remaining uses. The decisions outlined in this document do not include the final tolerance reassessment decision for phosmet; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. Four tolerances will be revoked now, for corn commodities, because the registrant is not supporting these uses. It should be noted that the Partial Interim RED proposed that citrus tolerances would also be revoked. The Agency received a request from the State of Florida for a Special Local Need registration under FIFRA Section 24(c). The Agency is in the process of assessing the risks and benefits associated with this use. A final determination on the citrus use will be made at the close of the comment period on this IRED, scheduled to be completed 60 days after this document is issued. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is considered. The Agency may need to pursue further risk management measures for phosmet once the cumulative assessment is considered.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on phosmet. The Agency considered the revised risk assessments and the mitigation options proposed by the Gowan Company, the technical registrant of phosmet, as well as comments and mitigation suggestions from other interested parties including Wellmark International, the Natural Resources Defense Council, several grower organizations, and an agricultural extension agent. After considering these comments and suggestions, the EPA developed its risk management decision for uses of phosmet. This decision is discussed fully in this document.

Phosmet is an organophosphate insecticide used on a variety of insects, first registered in 1966 for use on the following crops: fruit trees (apple, pear, peach, nectarine, plum, prune, apricot, cherry) and nut trees (almond, walnut, pecan, filbert, pistachio), grapes, kiwi, blueberries, cotton, peas (succulent and dried), potato, and sweet potato (foliar and post-harvest). In addition, phosmet is registered for direct animal treatments to control fleas, lice, hornflies, sarcoptic mange, and ticks on cattle, swine, and dogs. There are other uses such as in forestry and for ornamentals, including residential sites, that can be treated by professional applicators. Phosmet can also be used by homeowners to treat trees, shrubs, ornamental plants, pets (dogs only) and home gardens. Use data from 1988 to 1997 indicate an average of approximately 1,000,000 pounds of phosmet are applied to approximately 402,000 acres per year.

Overall Risk Summary

EPA's human health risk assessment for phosmet indicates some risk concerns. However, food risks, both acute and chronic, are well below the Agency's level of concern. Similarly, drinking water risk estimates are based on screening models, from both ground and surface water for acute and chronic exposures, are not of concern for all populations. There are, however, concerns for workers who mix, handle or load phosmet in the wettable powder form for aerial and chemigation applications to fruit and nut trees, field and vegetable crops, grapes, and ornamental plants and forestry. Worker handler risks are largely due to dermal exposure. Following application of phosmet, there are also concerns for workers re-entering treated fields. Additionally, there are concerns for homeowners who apply phosmet to ornamental plants and fruit trees with a low pressure hand wand, and for adults and youth-aged children harvesting and maintaining these fruit trees. There are significant risk concerns for toddlers exposed to phosmet residues following contact with treated dogs.

Phosmet was found to be moderately to practically non-toxic to avian species (acute); however, the application rates for some crops result in levels of concern that are slightly exceeded. Use on most crops appears to pose a chronic risk to birds and for all crops, there is a high chronic risk for mammals. For mammals, the acute levels of concern are exceeded mainly on short grass for smaller animals. Acute and chronic risk to both freshwater and estuarine/marine fish is relatively low. The acute risk to both freshwater and estuarine/marine invertebrates are of concern for some crops. All crops (with potential for marine exposure) appear to be a chronic concern for marine invertebrates. Use of phosmet on many crops appears to be a chronic risk to freshwater invertebrates. In addition, phosmet is highly toxic to honey bees, and incidents of honey bee toxicity have been reported.

To mitigate risks of concern posed by the uses of phosmet, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties, and has decided on a number of label amendments to address the worker, residential, and ecological concerns. Results of the risk assessments, and the necessary label amendments to mitigate those risks, are presented in this interim RED.

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water are not of concern; therefore, no mitigation is warranted at this time for any dietary exposure to phosmet.

Occupational Risk

Occupational exposure to phosmet is of concern to the Agency, and it has been determined that a number of mitigation measures are necessary. For the agricultural uses of phosmet, the Agency has risk concerns for occupational handlers mixing and loading wettable powder products for aerial and chemigation applications to fruit and nut trees, field and vegetable crops, grapes, and forestry, i.e., MOEs are less than 100. The EPA believes most of

these risks can be mitigated to an acceptable level by using additional personal protective equipment, or closed loading systems, in addition to label restrictions and amendments detailed in Section V of this document. The Agency also has concerns about workers re-entering the agricultural field within 24 hours after treatment with phosmet, which is the restricted entry interval on current labels. To mitigate those risks, the Agency is proposing to extend the current REIs for all crops. Even after taking into account all feasible mitigation for these uses, there are some phosmet uses with risks of concern. In situations where there are non-dietary risk concerns, FIFRA allows the Agency to consider benefits derived from using a pesticide when evaluating the risks. The EPA has conducted a benefits assessment for phosmet use on many crops, and considered the benefits of continued use, as well as the risks, in its risk management decisions. The crops with remaining risks have significant benefits associated with their continued use. The benefits associated with these uses are summarized in Section IV of this interim RED. Full benefits assessments are available in the docket and on the internet.

Residential Risk

Based on the phosmet use pattern, residential handler exposure is expected to occur through treatment of a dog or use on ornamental plants in a home garden. The homeowner handler scenarios that involve the use of a low-pressure handwand are of concern. There are concerns for continuous post-application exposure to adults and youth in residential settings over an extended period of time (greater than 30 days); however, there is little information to determine if such extended exposures actually occur. There are also concerns for short-term exposure to adults and youths harvesting and maintaining fruit trees. In addition, there are risk concerns for toddlers exposed to phosmet residues following contact with treated dogs, regardless of the duration of exposure. To mitigate the residential risks of concern, the registrant has agreed to cancel all products that are used in or around the home or on pets.

Ecological Risk

The Agency has some concerns with the estimated ecological risks. Studies suggest that on certain crops, where there is a high application rate and frequent application of phosmet, expected environmental concentrations can lead to acute risk for mammals; chronic risk for birds and mammals; and acute and chronic risks to invertebrates. In addition, phosmet is highly toxic to honey bees.

With the implementation of the mitigation measures detailed in this document, the Agency has determined that, until the outcome of the cumulative assessment of all of the organophosphates has been considered, these uses may continue; the use on dogs and the homeowner use of phosmet on ornamentals and fruit trees and high pressure hose use on cattle will be voluntarily canceled.

The Agency is issuing this interim Reregistration Eligibility Document (RED) for phosmet, as announced in a Notice of Availability published in the *Federal Register*. This interim RED document includes guidance and time frames for complying with any necessary

label changes for products containing phosmet. Note that there is a 60-day comment period for this document, and that the time frames for compliance with the label changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for phosmet have already been subject to numerous public comment periods. Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. In this case, because of demonstrated interest in the risk management decision and content of the benefits assessments, the Agency is allowing a 60-day public comment period. With regard to complying with the risk mitigation measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for phosmet can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further risk mitigation measures for phosmet.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Phosmet belongs to a group of pesticides called organophosphates, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency’s reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency’s revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the interim decision on the reregistration eligibility of phosmet. It is intended to be only the first phase in the reregistration process for phosmet. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for phosmet.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-Fold Safety Factor;
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments ;
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments;

- Refining Dietary (Food) Exposure Estimates;
- Refining Dietary (Drinking Water) Exposure Estimates;
- Assessing Residential Exposure;
- Aggregating Exposure from all Non-Occupational Sources;
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity;
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates; and
- Whether and How to Use Data Derived from Human Studies.

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

In addition to the policy issues that resulted from the TRAC process, the Agency issued, on September 29, 2000, a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides, and the Agency expects that other types of chemicals will be handled similarly. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals will be necessary for most uses where current assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the risks associated with the use of this chemical. The measures included in this interim RED are consistent with the Worker Pesticide Registration Notice.

This document consists of six sections. Section I (this section) contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II, Chemical Overview, provides a profile of the use and usage of the chemical. Section III, Summary of Phosmet Risk Assessment, gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV, Interim Risk Management and Reregistration Decision, presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV, Related Documents and How to Access Them. Section VI provides information on how to access related documents. Finally, the Appendices list the uses that will be eligible for reregistration, pending the cumulative assessment for the organophosphate pesticides, data that support this decision and Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page

www.epa.gov/pesticides/op, and in the Public Docket located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

II. Chemical Overview

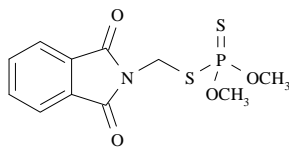
A. Regulatory History

Phosmet was first registered in the United States in 1966 as a broad-spectrum insecticide for control of a wide variety of pests including the alfalfa weevil, boll weevil, codling moth, grape berry moth, leafrollers, plum curculio, and oriental fruit moth. In addition, phosmet is registered for direct animal treatments to control fleas, lice, hornflies, sarcoptic mange, and ticks on cattle, swine and dogs. There are other uses such as in forestry and for ornamental plants, including residential sites that can be treated by professional applicators. Phosmet can also be used by homeowners to treat trees, shrubs, ornamental plants, home gardens and dogs.

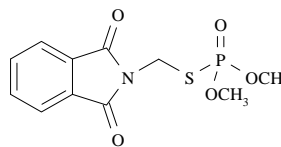
Although there are existing tolerances for residues in sweet corn and citrus, the registrant had indicated these uses would not be supported. Therefore, they were excluded from the risk assessment. It should be noted that the Partial Interim RED proposed that citrus tolerances would also be revoked. The Agency received a request from the State of Florida for a Special Local Need registration for citrus under FIFRA Section 24(c). The Agency is in the process of assessing the risks and benefits associated with this use. A final determination on the citrus use will be made in the final IRED, after the 60-day comment period for this document has ended.

B. Chemical Identification

N-(mercaptomethyl) phthalimide-S-(O,O-dimethyl phosphorodithioate):



Phosmet



Phosmet oxon

!	Common Name:	Phosmet
!	Chemical Name:	N-(mercaptomethyl) phthalimide-S-(O,O-dimethyl phosphorodithioate):
!	Chemical family:	Organophosphate

! Case number:	0242
! CAS registry number:	732-11-6
! OPP chemical code:	059201
! Empirical formula:	C ₁₁ H ₁₂ NO ₄ PS ₂
! Molecular weight:	317.32
! Trade and other names:	Imidan
! Basic manufacturer:	Gowan Company and Schering-Plough Animal Health Inc.

Technical phosmet is a pink to white crystalline solid with a melting point of 66-69 C. Phosmet is slightly soluble in water (20 mg/L at 20-25 C), more soluble in ethanol and kerosene (<1.0 g/100 mL), and readily soluble in acetone, chloroform, and xylene (>100 g/100 mL). Phosmet has a relatively low vapor pressure of 3.72×10^{-7} mm Hg at 25 C.

C. Use Profile

The following information is based on the currently registered uses of phosmet.

Type of Pesticide: Insecticide.

Summary of Use Sites:

Food: Fruit trees (apple, pear, peach, nectarine, plum, apricot, tart cherry) and nut trees (almond, beechnut, brazil nut, butternut, cashew, chestnut, filbert, macadamia, pecan, pistachio, walnut), grapes, kiwi, blueberries, cranberries, cotton, peas (succulent and dried), potato, sweet potato (foliar and post-harvest), cattle, and swine.

Residential: Trees, shrubs, ornamentals, pets (dogs only), home gardens and fire ant mounds.

Public Health: Fire Ants.

Other Nonfood: Forestry and ornamental plants. Direct animal treatments to dogs.

Target Pests: Moths, various beetles, various weevils, leafrollers, plum curculio, lice, flies, ticks and sarcoptic mange.

Formulation Types Registered: Dust, emulsifiable concentrate, soluble concentrate, and wettable powder.

Method and Rates of Application:

Equipment - In agriculture, groundboom, airblast and aerial applications. Other applications, commercial dusting equipment, handheld equipment such as low pressure handwand sprayers and backpack sprayers. Post-harvest application to sweet potatoes can be made by hand held dusting equipment. Direct dermal application to livestock is permitted via sprays and a backrubber. Dogs can be treated with a dip or a dust.

Method and Rate - In agriculture, use rates range from 0.7 to 6 lb a.i./A, depending on the crop. Multiple foliar applications can be made to some crops in a growing season. Applications can generally be made up to 7 to 14 days prior to harvest. Post-harvest application of a dust formulation to sweet potatoes is permitted, using 0.0125 lb a.i./50 lb bushel. Direct dermal applications to livestock range from 0.4 - 2.0 lb a.i./100 gallons spray. Backrubber application to cattle rate range is 1 lb a.i./50 gallons fuel oil. The use rate for dusting dogs is 0.5 g dust/kg animal weight. The use rate for dipping dogs is 0.0076 lb a.i./gallon dip solution.

Timing - Delayed dormant, foliar applications for agricultural crops and post-harvest use on sweet potatoes.

Use Classification: General classification.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of phosmet, based on available pesticide usage information for 1990 to 1999. A full listing of all uses of phosmet, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 1,250,000 pounds active ingredient (a.i.) of phosmet are used annually, according to Agency and registrant estimates.

Table 1. Phosmet Estimated Usage for Representative Sites

Crop	Lbs. Active Ingredient Applied (Wt. Avg.) ¹	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Alfalfa	35,000	0.5	0.2
Almonds	75,000	16	5.3
Apples	440,000	38	25
Apricots	13,000	42	19
Beef Cattle	-	0.22	0.11
Blueberries	19,000	30	20
Canine (Dog)	10,000	-	-
Cattle & Swine	19,000	-	-
Cherries	35,000	26	15
Cotton	2,000	0.18	0.04
Dairy Herd	-	0.56	0.28
Grapes	21,000	5	2
Kiwifruit	54	4	1
Nectarines	13,000	27	14
Other Crops	5,000	-	-
Peaches	110,000	23	13
Pears	54,000	33	20
Peas, Green	7,000	6	3
Peas, Dry	12,000	27	13
Pecans	30,000	10	3
Plums & Prunes	15,000	7	4
Potatoes	28,000	4	1
Sweet Potatoes	14,000	7	4
Walnuts	87,000	25	9
Woodland	0	0.02	0.01

¹ Weighted Average is based on data for 1988 to 1997; the most recent years and more reliable data are weighted more heavily.

III. Summary of Phosmet Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide phosmet, as fully presented in the documents, "Phosmet (Chemical ID No. 059201/List A Reregistration Case No. 0242). HED Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED). DP Barcode No. D262365," dated February 9, 2000; "Phosmet: Revised Occupational Post-Application Exposure and Risk Calculations [DP Barcode D268141, Chemical Code 059201, Case 818976]," dated August 15, 2000; and "Environmental Fate and Effects Division RED Chapter for Phosmet," dated April 24, 1998. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

These risk assessments for phosmet were presented at a February 10, 2000 Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments summarized here form the basis of the Agency's risk management decision for phosmet only; the Agency must consider the cumulative assessment of the risks of all the organophosphate pesticides before any final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for phosmet on January 15, 1999, (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are based on the following data: USDA Pesticide Data Program; FDA Surveillance Monitoring Program Data; 21-day dermal toxicity study; the sub-chronic neurotoxicity study, a recalculation of restricted entry intervals based on new data from the Agricultural Reentry Task Force (ARTF) and inclusion of a worker risk assessment for the liquid formulations.

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of phosmet can be found in the February 9, 2000, Human Health Risk Assessment.

Cancer Risk

Based on all available data for phosmet, the HED Cancer Assessment Review Committee (CARC) concluded that phosmet should be classified as having "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential". In a mouse carcinogenicity study, phosmet caused increases in liver carcinomas/adenomas in males and increased mammary gland tumors in females. Phosmet was not carcinogenic in rats. The CARC conducted a weight-of-evidence evaluation of the mutagenicity and carcinogenicity data for phosmet (in accordance with the 1997 draft Cancer Guidelines) on September 1, 1999.

Additional data regarding tumor counts in the mouse carcinogenicity study were discussed along with additional mutagenicity data submitted by the registrant. The CARC recommended against completing a quantitative cancer risk assessment for phosmet. This recommendation is consistent with the previous recommendation to use the reference dose (RfD) approach, in which chronic risks assessed using the RfD are considered to be protective of any carcinogenic effect, in addition to systemic or other chronic effects.

Human Data

The Agency is currently evaluating an acute (ascending single oral dose) study with phosmet in humans that was conducted by Inveresk Research in Scotland in 1999. The following observations can be made on the potential impact of these data on the phosmet risk assessment. Because the study is a single oral dose, it could be used in a weight-of-evidence approach to inform the selection of the inter-species uncertainty factor for acute risk assessments. That is, assuming it was conducted according to appropriate scientific and ethical standards, the acute human study could be compared to existing acute animal data to determine if the full ten-fold inter-species uncertainty factor is needed to account for variation between species in the acute dietary assessment for phosmet and could provide a basis for reduction of the uncertainty factor for acute dietary risk. However, because of its limited duration, the human study would not likely be appropriate for use in short-term or intermediate-term assessments, such as those used to estimate worker risk from phosmet use, nor would it be appropriate for the chronic dietary assessment.

1. Dietary Risk from Food

a. Toxicity

A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 below.

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1 X. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute in utero exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the 10X factor as required by FQPA was reduced to 1, for both acute and chronic risk

assessments for all subpopulations. A developmental neurotoxicity study (DNT) study has been required and is considered confirmatory.

c. Population Adjusted Dose (PAD)

The PAD is a term that expresses the dietary risk of a chemical, and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of phosmet, the FQPA safety factor is 1; therefore, the acute or chronic RfD is equal to the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of phosmet

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	PAD
Acute Dietary	LOAEL of 22.5 mg/kg/day NOAEL of 4.5 mg/kg/day	Red blood cell, plasma and brain cholinesterase inhibition and decreased motor activity	Oral Acute Neurotoxicity Study on Rats	100	1	0.045 mg/kg/day
Chronic Dietary	LOAEL of 1.8 mg/kg/day NOAEL of 1.1 mg/kg/day	Red blood cell, and serum cholinesterase inhibition	Oral Chronic Toxicity/ Carcinogenicity Study on Rats	100	1	0.011 mg/kg/day

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for phosmet were calculated using the Dietary Exposure Evaluation Model (DEEM™). The regulated residues consist of parent phosmet and its metabolite, phosmet oxygen analog (oxon). For the revised phosmet risk assessment, the Agency conducted highly refined (Tier 3) acute (probabilistic) and chronic dietary exposure analyses which were based almost entirely on the available monitoring data, and incorporated additional refinements such as processing and cooking factors and percent of crop treated. Typically, the Agency cannot use monitoring data which do not include all residues of toxicological concern. Although both the PDP and FDA monitoring programs reported data for parent phosmet only, these data have been used in the revised risk assessment for the following reasons: (i) field trial data indicate that oxon residues, when detected, are generally an order of magnitude lower than parent residues; (ii) residues in both PDP and FDA monitoring samples were significantly less than tolerance-level residues; and (iii) phosmet oxon is relatively unstable in numerous commodities. Using the monitoring data in acute and chronic dietary exposure analyses is not expected to underestimate risk.

The acute dietary risk analyses for phosmet were calculated using a probabilistic analysis (Monte Carlo), incorporating percent crop treated data, USDA's Pesticide Data Program data (PDP monitoring data), the Food and Drug Administration's monitoring data, residue field trial data, cooking study data, and processing factors, where available, and consumption information from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1989 to 1991. Chronic dietary risk was calculated by using the average consumption and residue values for foods.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concerns. The phosmet acute dietary risk from food is well below the Agency's level of concern; that is, less than 100% of the acute PAD is utilized. For example, for the most exposed population subgroups, children (1-6 years) and infants (<1 year), the % acute PAD values are 7.5% and 6.5%, respectively, at the 99.9th percentile of exposure.

The chronic dietary risk from food alone is well below the Agency's level of concern. For the most exposed population subgroup, children (1 - 6 years), the % chronic PAD value is 0.7%.

The Agency has refined the dietary analyses to the extent currently possible.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. In the case of phosmet, only limited monitoring data for either ground or surface water were available; therefore, modeling was used to estimate drinking water risks from these sources.

The PRZM-EXAMS model was used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. Both models are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than SCI-GROW.

Phosmet oxon is the only degradate of toxicological concern and was identified in a number of environmental fate studies conducted. Phosmet oxon appears to be less mobile than phosmet, as evidenced by its absence in leachates in the aged and unaged mobility study. In addition phosmet oxon was limited to the upper soil layer in the field studies while phosmet was detected as low as the 10.5-inch soil layer. Phosmet was found to be moderately mobile to mobile in four different soil classes.

The estimated concentrations for drinking water are for phosmet only. Phosmet oxon, which has been included in the tolerance expression, is not included in the modeling due to the absence of fate information. Considering the limited presence of phosmet oxon in the laboratory and field studies (soil extract of the mobility study and upper 0 - 3-inch soil layer in the field dissipation studies), phosmet oxon should not add appreciably to the concentration of parent compound in ground or surface water in most use areas.

a. Surface Water

A Tier II PRZM-EXAMS screening model was used to estimate the upper-bound concentrations of phosmet in drinking water derived from surface water. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model.

Phosmet can contaminate surface water via runoff if runoff-producing rain events occur within the first few days to weeks post application. Phosmet's water solubility (25 mg/l) and its partition coefficient ($K_{ads} = 1.17 - 15.8$) suggest that it will enter surface water via runoff. It appears that the persistence of phosmet in surface water may be limited by its susceptibility to biodegradation especially in water with moderate to high microbial activity and by abiotic hydrolysis under neutral to alkaline conditions. In flowing water, its persistence is limited by the flow rate of the system more than by either metabolism or hydrolysis. However, its persistence in lakes and reservoirs will be greater and controlled more by metabolism and hydrolysis.

Limited monitoring data indicate that phosmet has been detected in surface water in known use areas. However, these data suggest that phosmet concentrations do not exceed the very low ppb range, well below the DWLOC. The three crops with the highest phosmet surface water concentrations are pears, kiwi and cotton applied at 5, 2 and 1 lb a.i./A, respectively. The EECs range from 0.4 ppb for application to apples at the western-low rate (1.5 lb a.i./A) to 140 ppb for application to pears (5 lb a.i./A).

b. Ground Water

A Tier I screening model, SCI-GROW, was used to estimate the upper-bound drinking water concentrations of phosmet in ground water. The SCI-GROW model is based on the fate properties of the pesticide, the annual application rate, and the existing body of data from small-scale ground water monitoring studies. The model assumes that the pesticide is applied at its maximum rate in areas where ground water is particularly vulnerable to contamination. In most cases, a considerable portion of any use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimates. The estimated maximum concentration derived using these modeled estimates should be considered a high-end to bounding estimate of acute and chronic exposure.

The maximum concentration (acute and chronic) for parent phosmet estimated using

SCI-GROW is approximately 0.4 ppb. No phosmet residues were reported in ground water monitoring data at concentrations above the detection limits of 0.1 and 10 ppb. Phosmet is not expected to pose a threat to ground water resources.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a “drinking water level of comparison”(DWLOC) to determine whether modeled or monitored levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water where sufficient water monitoring data are not available. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The results of the Agency’s drinking water analysis are summarized here. Details of this analysis, which used screening models, are found in the Environmental Fate and Effects Assessment, dated April 24, 1998, and the Human Health Risk Assessment, dated February 9, 2000.

For acute risk, the potential drinking water exposure derived from either ground or surface water is not of concern for all populations. The table below presents the calculations for the acute drinking water assessment.

Table 3. Summary of DWLOC Calculations for Phosmet Acute Risk

Population Subgroup	Ground Water EECs (ppb) (SCI-GROW)	Surface Water EECs (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.4	3 - 140	1523
Females 20+	0.4	3 - 140	1308
Children 1-6	0.4	3 - 140	416

For chronic risk, potential exposure to drinking water derived from either groundwater or surface water is not of concern for all populations. The table below presents the calculations for the chronic drinking water assessments.

Table 4. Summary of DWLOC Calculations for Phosmet Chronic Risk

Population Subgroup	Ground Water EECs (ppb) (SCI-GROW)	Surface Water EECs (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.4	1	384
Children 1 - 6	0.4	1	110
Females 13 - 19	0.4	1	330

3. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities in treated areas. Occupational handlers of phosmet include: individual farmers or growers who mix, load, or apply pesticides, and professional or custom agricultural applicators. Residential handlers include homeowner applicators treating their own home garden or their dogs. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

a. Toxicity

The toxicity of phosmet is integral to assessing the occupational and residential risk. All risk calculations are based on the most current toxicity information available for phosmet, including a 21-day dermal toxicity study in rats. An acceptable dermal absorption study conducted in rats indicates a dermal absorption factor of 10 percent is appropriate for the phosmet risk assessment. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for phosmet are listed in Table 5a.

In the preliminary risk assessment for phosmet, the Agency selected a LOAEL of 1.5 mg/kg/day established in the subchronic oral neurotoxicity study in rats for the intermediate-term dermal and inhalation exposures of >30 days in duration. In this study, a NOAEL was not established at the termination of the study. Therefore, the Agency used the LOAEL in the risk assessment and added an uncertainty factor of 3. The use of this uncertainty factor established the target MOE of 300 for these assessments and lead to a value (0.5 mg/kg/day) lower than the one used for the chronic dietary RfD (1.1 mg/kg/day). Based on a consideration of the entire toxicity database, EPA determined that the 0.5 mg/kg/day value was not a representative subchronic endpoint. For this reason, the Agency selected the chronic rat study with a NOAEL of 1.1 mg/kg/day for the intermediate term >30 days exposure in the risk assessment. This is appropriate because the same endpoint (cholinesterase inhibition) was observed in both studies in the same species (rat) and the LOAEL of 1.5 mg/kg/day in the subchronic study is comparable to the LOAEL of 1.8 mg./kg/day in the chronic study.

Table 5a. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessments for Phosmet

Assessment	Dose	Endpoint	Study	Absorption Factor
Short-term dermal (Up to 7 days)	NOAEL = 15 mg/kg/day	Cholinesterase Inhibition [brain (females), plasma (males)] at the LOAEL of 22.5 mg/kg/day	21-Day Dermal Toxicity in Rats	Not Relevant
Intermediate-term dermal (>7 and #30 days)	NOAEL = 15 mg/kg/day	Cholinesterase Inhibition [brain (females), plasma (males)] at the LOAEL of 22.5 mg/kg/day	21-Day Dermal Toxicity in Rats	Not Relevant
Intermediate-term dermal (>30 days)	NOAEL = 1.1 mg/kg/day	Cholinesterase Inhibition (RBC and Serum) at the LOAEL of 1.8 mg/kg/day	Oral Chronic Toxicity/ Carcinogenicity in Rats	10%
Short-term inhalation (Up to 7 days)	NOAEL= 4.5 mg/kg/day	Cholinesterase Inhibition (Plasma, RBC, Brain) and Decreased Motor Activity at the LOAEL of 22.5 mg/kg/day	Oral Acute Neurotoxicity in Rats	100 %
Intermediate - term inhalation (>7 and # 30 days)	NOAEL= 1.5 mg/kg/day (At 3 week interval)	Cholinesterase Inhibition [brain (females), plasma (males)] at the LOAEL of 2.7 mg/kg/day	Oral Subchronic Neurotoxicity in Rats	100 %
Intermediate - term inhalation (>30 days)	NOAEL= 1.1 mg/kg/day	Cholinesterase Inhibition (RBC and Serum) at the LOAEL of 1.8 mg/kg/day	Oral Chronic Toxicity/ Carcinogenicity in Rats	100 %
Non-dietary ingestion - Acute (children)	NOAEL = 4.5 mg/kg/day	Cholinesterase Inhibition (Plasma, RBC, Brain) and Decreased Motor Activity at the LOAEL of 22.5 mg/kg/day	Oral Acute Neurotoxicity in Rats	Not Relevant
Non-dietary ingestion - Intermediate-term (children)	NOAEL = 1.1 mg/kg/day	Cholinesterase Inhibition (RBC and Serum) at the LOAEL of 1.8 mg/kg/day	Oral Chronic Toxicity/ Carcinogenicity in Rats	Not Relevant

In acute toxicity studies, phosmet exhibits severe toxicity via the oral and inhalation routes of exposure. Phosmet is not acutely toxic in rats via the dermal route, is non-irritating to the skin, and is not an eye irritant in the rabbit.

Table 5b. Acute Toxicity Profile for Phosmet

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
870.1100/§81-1	Acute Oral - rat	00046189	LD ₅₀ = 113 mg/kg	II
870.1200/§81-2	Acute Dermal - rabbit	00046190	LD ₅₀ >5000 mg/kg	III
870.1300/§81-3	Acute Inhalation - rat	00063197	LC ₅₀ >0.152 mg/L	II
870.2400/§81-4	Primary Eye Irritation	00046192	moderate eye irritant	III
870.2500/§81-5	Primary Skin Irritation	00046191	not a skin irritant	IV
870.2600/§81-6	Dermal Sensitization	no study		N/A
870.6100/§81-7	Delayed Neurotoxicity	44587601	unsteadiness, subdued behavior, recumbency, salivation; no ataxia; no decreases in brain or spinal cord NTE; brain ChE decreased 63%; no neuropathology. [All hens were dosed at 600 mg/kg by oral gavage]	N/A
870.6200/§81-8	Acute Neurotoxicity	44673301	NOAEL 4.5 mg/kg LOAEL 22.5 mg/kg, based on cholinesterase inhibition [plasma, RBC, brain] and decreased motor activity in both sexes.	N/A

b. Exposure

Chemical-specific exposure data for pesticide handling activities were not submitted to the Agency for phosmet. Therefore, daily dermal and inhalation handler doses were calculated using the Pesticide Handlers Exposure Database (PHED), Version 1.1. The database contains exposure values for over 1,700 monitored exposure events, which have been evaluated by the Agency in order to characterize the quality of the data.

The post-application risk assessment for phosmet has been developed using chemical-specific dislodgeable foliar residue data on pears and grapes. In addition, the Agency used chemical-specific exposure data for homeowner exposures resulting from tending and harvesting treated pear trees.

Residential Exposure

Phosmet may be used for direct animal treatments on dogs. Dogs may be treated by either a dust or a dip solution. For the dog dust, the application rate is 0.5 grams of formulated dust per kilogram of animal body weight. For the dog dip, the application rate is 0.0076 lb a.i. per gallon of dip solution.

For homeowner application, the rates are: 0.0098 lb a.i. per gallon and 10 gallons of water per fruit and nut tree; 0.012lb a.i. per 100 square feet for vegetables; 0.0075 lb a.i. per gallon on ornamental plants; and 0.009 lb a.i. per square foot of fire ant mound. In addition, dogs may be treated by homeowners; for the dust, the application rate is 0.5 grams of formulated

dust per kilogram of animal body weight and for the dog dip, the application rate is 0.0076 lb a.i. per gallon of dip solution.

Because phosmet is used in a residential setting, post-application exposure could occur. Homeowners, other adults or children could be exposed to phosmet by entering treated areas, harvesting or maintaining fruit or nut trees, or gardens. In addition, toddlers and others could be exposed to phosmet after coming in contact with a treated dog.

Agricultural Exposure

The quality of the data and exposure factors represent the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from phosmet labels. In addition, typical use rates are also represented in the assessment. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others are considered low quality, but all are the best available data. The quality of the data used for each scenario assessed is discussed in the Revised Human Health Risk Assessment for Phosmet, dated February 9, 2000, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling and information on common practices, as provided by Gowan Company and various growers and research organizations. Application rates specified on phosmet labels range from 0.7 to 6 pounds of active ingredient per acre in agricultural settings. For agricultural applications, the Agency typically uses acres treated per day values that are thought to represent 8 solid hours of application work for specific types of application equipment. Phosmet may be used for direct animal treatments on livestock. The application rates for the farm animal spray range from 0.4 to 2.0 lb a.i. per 100 gallons. For the cattle backrubber, the application rate is 1 lb a.i. per 50 gallons of fuel oil.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) and engineering controls (EC)). The levels of protection that formed the basis for calculations of exposure from phosmet activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Label: Long-sleeved shirt and long pants, waterproof gloves, shoes plus socks, chemical resistant headgear for overhead exposure, and dust/mist filtering respirator (most labels).

- Minimum PPE: Baseline + chemical resistant gloves and a PF 5 respirator (dust mist).
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical-resistant footwear plus socks, chemical resistant headgear for overhead exposures, and a PF 10 respirator (OV) if risk is driven by inhalation.
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a closed mechanical transfer system for liquids or a packaged based system (e.g., water soluble packaging for wettable powders). Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures).

In addition to the tasks and activities associated with pesticide application and post-application exposures, the Agency considers the expected duration and route of exposure and the associated potential toxic effects as determined in the required toxicity testing. Based on the phosmet use pattern, short-and intermediate-term exposures are expected to occur. For the phosmet risk assessment, short-term exposures are from one to seven days; intermediate-term exposures were separated into two distinct time-frames of between eight and thirty days and greater than thirty days in duration. The reason for these distinctions is that the results of the toxicity testing indicate that effects associated with exposure to phosmet become more severe over time (greater than 30 days).

For the residential handler risk assessment, all application of phosmet by homeowners to fruit and nut trees, ornamental plants, vegetable plants, fire ant mounds and dogs is considered to be short-term, and assumes that no protective clothing is used. The Agency does not require protective clothing for residential handlers because there is no mechanism to ensure that the protective clothing is cleaned and maintained appropriately or that it would routinely be used.

Post-application exposure is a term used to describe those individuals who can be exposed to pesticides after entering areas previously treated with pesticides and performing certain tasks or activities. As with handler risk assessment, the Agency believes that there are distinct tasks that occur in areas previously treated with phosmet in addition to non-work related activities, e.g., children playing with a companion animal, that may contribute to exposure. The Agency also believes that the resulting exposures can vary depending upon the specifics of each task or activity and the levels of chemical residue available in the environment. The nature of the treated area such as the type of foliage on the plant or tree and the duration of activity can also cause exposure levels to differ in a manner specific to each setting considered. For occupational uses, the following post-application scenarios are assessed: adults harvesting tree fruits and nuts; adults harvesting and maintaining nuts;

c. Occupational & Residential Handler Risk Summary

Based on the phosmet use pattern, a total of **23** occupational handler scenarios were identified. No chemical-specific handler exposure data were submitted for phosmet, and therefore daily dermal and inhalation handler doses were calculated using data from the *Pesticide Handlers Exposure Database (PHED), Version 1.1*. The database contains exposure values for over 1,700 monitored exposure events, which have been evaluated by the Agency in order to characterize the quality of the data.

Assumptions regarding the application rate and acres treated (including an assumption of an 8-hour workday for occupational scenarios) were used in conjunction with the PHED unit exposure values to determine phosmet handler exposures. For agricultural handler scenarios, the number of acres treated per day assumed in the phosmet risk assessment are those typically used in risk assessments. For pet handler exposures (vets and professional groomers), the Agency assumed that a maximum of 8 dogs/day are dipped/dusted; risks were calculated for a range of dog body weights (5-120 lbs). In addition, it was assumed that 10% of the active ingredient applied during dipping/dusting represented the total dose; this is a standard assumption taken from the 1997 *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment*. The average body weight of an adult handler was assumed to be 70 kg, which is standard for these risk assessments. The hose-end sprayer data were used to assess exposures associated with the fire ant mound treatment scenario. Since there were no data to assess potential handler exposure associated with “charging” the cattle backrubber, data for open mixing of liquids were used; however, the Agency believes this approach may underestimate exposure, based on information submitted about the operation of the cattle backrubber by the registrant, Schering-Plough Animal Health Inc. about the operation of the cattle backrubber.

(1) Occupational Handler Risk

The occupational handler scenarios are listed below:

Mixing/Loader

- (1a) mixing/loading liquid formulations for high pressure handwand applications;
- (1b) mixing/loading liquid formulations for airblast sprayer application;
- (1c) mixing/loading liquid formulations for groundboom sprayer;
- (1d) mixing/loading liquid formulations for aerial application;
- (2) mixing/loading wettable powders for treating pine seedlings
- (2a) mixing/loading wettable powders for aerial application and chemigation;
- (2b) mixing/loading wettable powders for groundboom application
- (2c) mixing/loading wettable powders for airblast sprayer application;
- (2d) mixing/loading wettable powders for high pressure handwand applications;

Applicator

- (3) applying sprays with an airblast sprayer
- (4) applying sprays with a groundboom sprayer;

- (5) aerial application of sprays with a fixed wing aircraft (fixed wing aircraft also accounts for helicopter pilot exposure);
- (6) applying using a high-pressure handwand;
- (7) applying using a right-of-way sprayer;
- (8) dipping pine seedlings;

Mixer/Loader/Applicator

- (9) mixing/loading/applying with dusting equipment;
- (10) dusting a dog;
- (11) dipping a dog;
- (12) use of a cattle backrubber;
- (13a) mixing/loading/applying liquids with a backpack sprayer;
- (13b) mixing/loading/applying wettable powders with a backpack sprayer;
- (14a) mixing/loading/applying liquids with a low pressure handwand;
- (14b) mixing/loading/applying wettable powders with a low pressure handwand;
- (15) mixing/loading/applying soluble concentrates for sprinkling; and

Flagger

- (16) flagging for aerial spray application.

The Agency completes occupational handler assessments using different levels of personal protection. Minimal protection is assumed at first, and a tiered approach to adding protective measures is used until an appropriate MOE is obtained, or until all options are exhausted. The lowest tier is defined as the baseline exposure scenario; higher tiers include measures such as personal protective equipment (PPE, e.g., gloves, extra clothing, and respirators) and engineering controls (e.g., closed cabs and closed loading systems). The most practical option for risk reduction is generally considered to be the minimal level of protection adequate to address the risks identified in the risk assessment. MOE calculations are shown in the table below. The footnotes describe the level of PPE used in the assessment. The last column of the table indicates the level of PPE or engineering controls required on labels.

Table 6. Occupational Uses: Risk Concerns (combined dermal & inhalation MOEs)

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
Occupational Mixer/Loader Estimates for MOE 100 or Highest Achievable MOE							
(1a) mixing/loading liquid formulations for high pressure handwand applications	livestock	1000 gal	0.004	9722 ¹	7500 ¹	5500 ¹	Baseline + Gloves
	livestock	1000 gal	0.02	1994 ¹	1500 ¹	1100 ¹	Baseline + Gloves
	ornamentals	400gal	0.008	121 ¹	120 ¹	7333 ¹ + gloves	Baseline + Gloves
(1b) mixing/loading liquid formulations for airblast sprayer application	ornamentals	50	0.06	121 ¹	120 ¹	7333 ¹ + gloves	Baseline + Gloves
(1c) mixing/loading liquid formulations for groundboom application	blueberries	80	0.47	1034 ¹ + gloves	798 ¹ + gloves	585 ¹ + gloves	Baseline + Gloves
	blueberries	80	0.94	517 ¹ + gloves	399 ¹ + gloves	293 ¹ + gloves	Baseline + Gloves
	potatoes, alfalfa, cotton	80	1.02	477 ¹ + gloves	368 ¹ + gloves	270 ¹ + gloves	Baseline + Gloves
	alfalfa	80	0.78	623 ¹ + gloves	481 ¹ + gloves	353 ¹ + gloves	Baseline + Gloves
(1c) mixing/loading liquid formulations for groundboom application	alfalfa	200	0.78	249 ¹ + gloves	192 ¹ + gloves	141 ¹ + gloves	Baseline + Gloves

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	alfalfa, cotton	200	1.02	191 ¹ + gloves	147 ¹ + gloves	108 ¹ + gloves	Baseline + Gloves
	Cotton	80	0.23	2114 ¹ + gloves	1630 ¹ + gloves	1196 ¹ + gloves	Baseline + Gloves
	Cotton	200	0.23	845 ¹ + gloves	652 ¹ + gloves	478 ¹ + gloves	Baseline + Gloves
(1d) mixing/loading liquid formulations for aerial application and chemigation	Blueberries	350	0.47	236 ¹ + gloves	182 ¹ + gloves	134 ¹ + gloves	Engineering Controls
	Blueberries	350	0.94	118 ¹ + gloves	126 ²	115 ² + double layer	Engineering Controls
	Potatoes, Cotton, Alfalfa	350	1.02	109 ¹ + gloves	116 ²	106 ² + double layer	Engineering Controls
	Alfalfa	350	0.78	143 ¹ + gloves	110 ¹ + gloves	111 ²	Engineering Controls
	Alfalfa	1200	0.78	126 ⁴	119 ⁴	87 ⁴	Engineering Controls
(1d) mixing/loading liquid formulations for aerial application and chemigation	Alfalfa, Cotton	1200	1.02	97 ⁴	91 ⁴	67 ⁴	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	cotton	350	0.23	483 ¹ + gloves	373 ¹ + gloves	273 ¹ + gloves	Engineering Controls
	cotton	1200	0.23	141 ¹ + gloves	109 ¹ + gloves	110 ²	Engineering Controls
(2) mixing/loading wettable powders for high pressure handwand application	pine seedlings	100	0.35	151 ²	117 ²	103 ² + respirator	Engineering Controls
(2a) mixing/loading wettable powders for aerial application and chemigation	various nut trees	350	5.95	23 ⁴	22 ⁴	16 ⁴	Engineering Controls
	pears	350	5	28 ⁴	26 ⁴	19 ⁴	Engineering Controls
	apples	350	4	34 ⁴	32 ⁴	24 ⁴	Engineering Controls
	fruit & nuts	350	3	46 ⁴	43 ⁴	31 ⁴	Engineering Controls
	grapes, fruit trees & vegetables	350	1.5	92 ⁴	86 ⁴	63 ⁴	Engineering Controls
(2a) mixing/loading wettable powders for aerial application and chemigation	grapes, & fruit trees	350	1	138 ⁴	128 ⁴	94 ⁴	Engineering Controls
	cotton	1200	0.4	100 ⁴	94 ⁴	69 ⁴	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5 (dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10 (OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	forestry	1200	1	40 ⁴	37 ⁴	27 ⁴	Engineering Controls
(2b) mixing/loading wettable powders for groundboom application	noncrop/field perimeters	10	2	168 ¹ + gloves	205 ²	150 ²	Engineering Controls
	grapes, vegetables	80	1.5	401 ⁴	374 ⁴	274 ⁴	Engineering Controls
	grapes, vegetables	80	1	602 ⁴	561 ⁴	411 ⁴	Engineering Controls
	cotton	200	0.4	602 ⁴	561 ⁴	411 ⁴	Engineering Controls
(2c) mixing/loading wettable powders for airblast sprayer application	various nut trees	40	5.95	202 ⁴	189 ⁴	138 ⁴	Engineering Controls
	pears	40	5	241 ⁴	224 ⁴	165 ⁴	Engineering Controls
	apples	40	4	301 ⁴	280 ⁴	206 ⁴	Engineering Controls
(2c) mixing/loading wettable powders for airblast sprayer application	fruit & nut trees	40	3	401 ⁴	374 ⁴	274 ⁴	Engineering Controls
	grapes, fruit trees & vegetables	40	1.5	110 ² + double layer	101 ³	548 ⁴	Engineering Controls
	grapes, tree fruit	40	1	132 ²	103 ²	111 ³	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	ornamentals	50	0.06	1117 ¹ + gloves	583 ¹ + gloves	428 ¹ + gloves	Engineering Controls
(2d) mixing/loading wettable powders for high pressure handwand applications	ornamentals	400	0.008	1117 ¹ + gloves	583 ¹ + gloves	428 ¹ + gloves	Engineering Controls
Occupational Applicator Estimates							
(3) applying sprays with an airblast sprayer	various nut trees	40	5.95	215 ⁴	188 ⁴	138 ⁴	Engineering Controls
	pears	40	5	256 ⁴	223 ⁴	164 ⁴	Engineering Controls
	apples	40	4	320 ⁴	279 ⁴	205 ⁴	Engineering Controls
	fruit & nuts trees	40	3	427 ⁴	372 ⁴	273 ⁴	Engineering Controls
(3) applying sprays with an airblast sprayer	grapes, fruit trees & vegetables	40	1.5	854 ⁴	745 ⁴	546 ⁴	Engineering Controls
	grapes & tree fruit	40	1	103 ¹ + gloves	105 ²	819 ⁴	Engineering Controls
	ornamentals	50	0.06	933 ¹	864 ¹	634 ¹	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
(4) applying sprays with a groundboom sprayer	noncrop/ field perimeters	10	2	3188 ¹	2453 ¹	1799 ¹	Baseline
	grapes, fruit trees & vegetables	80	1.5	531 ¹	409 ¹	300 ¹	Baseline
	grapes & vegetables	80	1	797 ¹	613 ¹	450 ¹	Baseline
	cotton	200	0.4	797 ¹	613 ¹	450 ¹	Baseline
	blueberries	80	0.47	1696 ¹	1305 ¹	957 ¹	Baseline
	blueberries	80	0.94	848 ¹	653 ¹	479 ¹	Baseline
	potatoes, alfalfa, cotton	80	1.02	781 ¹	601 ¹	441 ¹	Baseline
	alfalfa	80	0.78	1022 ¹	786 ¹	577 ¹	Baseline
	alfalfa	200	0.78	409 ¹	315 ¹	230.6	Baseline
(4) applying sprays with a groundboom sprayer	alfalfa, cotton	200	1.02	313 ¹	241 ¹	176 ¹	Baseline
	cotton	80	0.23	3466 ¹	2667 ¹	1956 ¹	Baseline
	cotton	200	0.23	1386 ¹	1067 ¹	782 ¹	Baseline

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
(5) aerial application of sprays with a fixed wing aircraft (fixed wing aircraft also accounts for helicopter pilot exposure)	various nut trees	350	5.95	97 ⁴	89 ⁴	65 ⁴	Engineering Controls
	pears	350	5	115 ⁴	106 ⁴	78 ⁴	Engineering Controls
	fruit & nut trees	350	3	191 ⁴	176 ⁴	129 ⁴	Engineering Controls
	grapes, fruit trees & vegetables	350	1.5	383 ⁴	352 ⁴	258 ⁴	Engineering Controls
	grapes & fruit trees	350	1	574 ⁴	528 ⁴	387 ⁴	Engineering Controls
	cotton	1200	0.4	418 ⁴	385 ⁴	282 ⁴	Engineering Controls
	forestry	1200	1	167 ⁴	154 ⁴	113 ⁴	Engineering Controls
	blueberries	350	0.47	1221 ⁴	1124 ⁴	824 ⁴	Engineering Controls
(5) aerial application of sprays with a fixed wing aircraft (fixed wing aircraft also accounts for helicopter pilot exposure)	blueberries	350	0.94	611 ⁴	562 ⁴	412 ⁴	Engineering Controls
	potatoes, alfalfa, cotton	350	1.02	563 ⁴	518 ⁴	380 ⁴	Engineering Controls
	alfalfa	350	0.78	736 ⁴	677 ⁴	497 ⁴	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	alfalfa	1200	0.78	215 ⁴	198 ⁴	145 ⁴	Engineering Controls
	alfalfa	1200	1.02	164 ⁴	151 ⁴	111 ⁴	Engineering Controls
	cotton	350	0.23	2496 ⁴	2296 ⁴	1684 ⁴	Engineering Controls
	cotton	1200	0.23	728 ⁴	670 ⁴	491 ⁴	Engineering Controls
	cotton	1200	1.02	164 ⁴	151 ⁴	111 ⁴	Engineering Controls
(6) applying using a high-pressure handwand	livestock	1000	0.004	127 ¹	101 ¹	135 ¹ + gloves	Use Canceled
	livestock	1000	0.02	127 ² + double layer	101 ² + double layer	88 ³	Use Canceled
	ornamentals	400	0.008	170 ¹	135 ¹	188 ¹ + gloves	Baseline + Gloves
(7) applying using a right-of-way sprayer	ornamentals	400	0.008	267 ¹	261 ¹	192 ¹	Baseline
(8) dipping pine seedlings	pine seedlings	100	0.35	no data	no data	no data	Maximum
Occupational Mixer/Loader/Applicator Estimates							
(9) mixing/loading/applying with a dusting equipment	sweet potatoes	no data	0.013lb/a.i./bushel	no data	no data	no data	Maximum
(10) dusting on animal	dog	8 animals	0.003	468,750 ¹	468,750 ¹	343,750 ¹	Use Canceled

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	dog	8 animals	0.066	19,886 ¹	19,886 ¹	14,583 ¹	Use Canceled
(11) dipping a dog	dog	8 animals	0.0076	172,697 ¹	172,697 ¹	126,645 ¹	Use Canceled
(12) use of a cattle backrubber	cattle	50 animals	0.02	362 ¹	361 ¹	264 ¹	Baseline
(13a) mixing/loading/applying liquids with a backpack sprayer	livestock	100 animals	0.004	26,250 ¹	8750 ¹	6417 ¹	Baseline
	livestock	100 animals	0.02	5250 ¹	1750 ¹	1283 ¹	Baseline
	ornamentals	40	0.008	35,000 ¹	11,667 ¹	8556 ¹	Baseline
(13b) mixing/loading/applying wettable powders with a backpack sprayer	ornamentals	40	0.008	35,000 ¹	11,667 ¹	8556 ¹	Baseline
(14a) mixing/loading/applying liquids with a low pressure handwand	livestock	100	0.004	4953 ¹	3596 ¹	2637 ¹	Baseline + Gloves
	livestock	100	0.02	991 ¹	719 ¹	527 ¹	Baseline + Gloves
	ornamentals	40	0.008	6604 ¹	4795 ¹	3516 ¹	Baseline + Gloves
(14b) mixing/loading/applying wettable powders with a low pressure handwand	ornamentals	40	0.008	285 ¹	179 ¹	131 ¹	Baseline + Gloves
(15) mixing/loading/applying soluble concentrates for sprinkling	fire ants	24	0.009	158 ¹	158 ¹	115 ¹	Baseline
Occupational Flagger Estimates							
(16) flagging for aerial spray application.	various nut trees	350	5.95	2072 ⁴	1739 ⁴	1275 ⁴	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	pears	350	5	2466 ⁴	2069 ⁴	1517 ⁴	Engineering Controls
	fruit & nut trees	350	3	4110 ⁴	3448 ⁴	2529 ⁴	Engineering Controls
	grapes, fruit trees & vegetables	350	1.5	164 ¹	138 ¹	101 ¹	Engineering Controls
	grapes & fruit trees	350	1	247 ¹	207 ¹	152 ¹	Engineering Controls
	cotton	1200	0.4	180 ¹	151 ¹	111 ¹	Engineering Controls
	forestry	1200	1	3596 ⁴	3017 ⁴	2213 ⁴	Engineering Controls
	blueberries	350	0.47	525 ¹	440 ¹	323 ¹	Engineering Controls
(16) flagging for aerial spray application.	blueberries	350	0.94	262 ¹	220 ¹	161 ¹	Engineering Controls
	potatoes	350	1.02	242 ¹	203 ¹	149 ¹	Engineering Controls
	alfalfa	350	0.78	316 ¹	265 ¹	195 ¹	Engineering Controls
	alfalfa	1200	0.78	4610 ⁴	3868 ⁴	2837 ⁴	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Combined MOEs (dermal and inhalation)			Necessary level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	Intermediate Term > 30 days	
	alfalfa	350	1.02	242 ¹	203 ¹	149 ¹	Engineering Controls
	alfalfa	1200	1.02	3525 ⁴	2958 ⁴	2169 ⁴	Engineering Controls
	cotton	350	0.23	1072 ¹	900 ¹	660 ¹	Engineering Controls
	cotton	1200	0.23	313 ¹	262 ¹	192 ¹	Engineering Controls
	cotton	350	1.02	242 ¹	203 ¹	149 ¹	Engineering Controls
	cotton	1200	1.02	3525 ⁴	2958 ⁴	2169 ⁴	Engineering Controls

1 Baseline PPE which represents typical work clothing with no respiratory protection. No chemical-resistant gloves are included in this scenario.

2 Minimum PPE which represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.(dust-mist respirator).

3 Maximum PPE which represents the baseline scenario with the use of an additional layer of clothing, chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.(OV respirator).

4 Engineering controls which represent the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods.

(2) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture. All of the post-application risk calculations completed in this assessment are included in the human health risk assessment and the August 15, 2000, update entitled "Phosmet: Revised Occupational Post-Application Exposure and Risk Calculations (DP Barcode D268141, Chemical Code 059201, case 818976)", which takes into account the most recent revisions of the policy on agricultural transfer coefficients and information recently collected by the Gowan Company with regard to post-application exposures.

Based on the phosmet use pattern, there is potential for both short-and intermediate-term (< 30 days) post-application exposure to phosmet residues for workers. Only dermal exposures were considered in the post-application assessment, since the physical properties of phosmet suggest post-application inhalation exposures would be minimal.

Agricultural post-application scenarios assessed for phosmet consist of adults harvesting and maintaining fruit trees, grapes, field and vegetable crops. The MOEs were calculated using chemical specific residue dissipation data for pears and grapes. All of the chemical-specific data generated for post-application exposure and risk assessment included residues of phosmet and the oxygen analog metabolite, which were assumed to be equivalent in terms of toxicity. The results of the revised post-application assessment are summarized in Tables 7 through 13, this assessment reflects the updated transfer coefficients as established in the *HED Science Policy for Exposure 3.1: Agricultural Transfer Coefficients*, dated August 7, 2000. These calculations indicate a concern for workers reentering treated fields following the 24-hour REI on current labels for some scenarios. In addition, in the memorandum titled "Phosmet : Further Revisions to the Occupational Exposure and Risk Calculations [DP Barcode D277160, Chemical Code 059201, Case 818976]", dated August 20, 2001, the Agency discusses an additional change to the transfer coefficients used to calculate post-application exposure to workers performing thinning on fruit trees.

It should be noted that the transfer coefficient being used for calculating exposure for fruit tree thinners is the same as that used for calculating fruit tree harvester exposure. However, the Agency does not believe, at this time, that fruit tree thinner data should be grouped with harvester data to calculate an overall weighted average transfer coefficient, as proposed by the ARTF and Bayer.

(3) Occupational Reentry Risk Estimates for Phosmet

Table 7: Low Berry Transfer Coefficient Group:

Post-application Risks For Phosmet On Low Bush Blueberries and Cranberries				
Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)	
			Low Exposure Activities: scouting, hand weeding, irrigation (early season, low foliage), hand pruning (early season, low foliage), and thinning (early season, low foliage)	High Exposure Activities: hand pruning (late season, full foliage) and hand harvesting.
Low Bush Blueberries and Cranberries				
0	Grape data at 1 lb a.i./acre, not adjusted for application rate	Blueberries - 3 Cranberries - 14	193	52 (blueberries only)
10				102 (blueberries only)
Cranberries				
0	Grape data at 1 lb a.i./acre, adjusted for application rate of 4 lb a.i./acre	Cranberries - 14	48	Not Applicable
11			102	Not Applicable

Table 8: Field/Row Crop Transfer Coefficient Group (low/medium height):

Post-application Risks For Phosmet on Alfalfa, Cotton and Peas					
Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)		
			Low Exposure Activities: irrigation and scouting of immature plants	Medium Exposure Activities: irrigation and scouting of mature plants	High Exposure Activities: hand harvesting
0	Grape data at 1 lb a.i./acre, not adjusted for application rate	Alfalfa 7 - 14	772	52	31
10		Cotton - 21		102	61
18		Peas - 7			105

Table 9: Deciduous Tree Fruit Transfer Coefficient Group:

Post-application Risks For Phosmet On Deciduous Tree Fruit Transfer Coefficient Group						
Crop	Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)		
				Very Low Exposure Activities: propping	Low Exposure Activities: irrigation & scouting	High Exposure Activities: hand harvesting, & hand thinning
Pears	0	Pear data at 5 lb a.i./acre, not adjusted for application rate	7	260	26	9
	21				105	
	37					101
West Coast Apples	0	Pear data at 5 lb a.i./acre, adjusted for application rate of 4 lb a.i./acre	7	325	33	11
	17				100	
	34					103
Apricots, nectarines, peaches, plums/prunes	0	Pear data at 5 lb a.i./acre, adjusted for application rate of 3 lb a.i./acre	Apricots - 14 Nectarines - 14 Peaches - 14 Plums - 7 Prunes - 7	434	43	15
	13				103	
	30					105
East Coast Apples	0	Pear data at 5 lb a.i./acre, adjusted for application rate of 1.5 lb ai/acre	7	868	87	29
	3				106	
	19					102

Table 10: Evergreen Tree Transfer Coefficient Group:

Post-application Risks For Phosmet On Christmas Trees, Evergreen Trees and Pine Seed Orchards				
Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)	
			Low Exposure Activities: Irrigation, scouting, hand weeding, thinning small trees	Medium Exposure Activities: pruning, thinning, cone pruning, cone harvesting, hand harvesting, shaking, topping, training
0	Pear data at 5 lb a.i./acre, adjusted for application rate of 1 lb a.i./acre	Not Specified	130	43
13				103

Table 11: Tree Nut Transfer Coefficient Group:

Post-application Risks For Phosmet on Tree Nut Transfer Coefficient Group					
Crop	Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)	
				Low Exposure Activities: irrigation and scouting	High Exposure Activities: hand harvesting, poling, pruning
Beech nut, brazil nut, butternut, cashew, chestnut, macadamia, walnuts	0	Pear data at 5 lb a.i./acre, adjusted for application rate of 5.95 lb a.i./acre	14	44	9
	13			104	
	37				101
Almonds, pistachios, pecans	0	Pear data at 5 lb a.i./acre, adjusted for application rate of 3 lb a.i./acre	Almonds - 30 Pistachios - 14 Pecans - 14	87	17
	3			106	
	27				104

Table 12: Root Vegetable Transfer Coefficient Group:

Post-application Risks For Phosmet On Potatoes and Sweet Potatoes					
Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)		
			Low Exposure Activities: irrigation and scouting of immature plants	Medium Exposure Activities: irrigation and scouting of mature plants	High Exposure Activities: hand harvesting only for sweet potatoes
0	Grape data at 1 lb a.i./acre, not adjusted for application rate	Potatoes - 7	257	52	31
10				102	
18					105

Table 13: Vine/trellis Transfer Coefficient Group:

Post-application Risks For Phosmet On Highbush Blueberries, Grapes, Kiwi, and Trellised Sweet Peas						
Days After Treatment (DAT)	Dislodgeable Foliar Residue Source	Pre-Harvest Interval on Current Label (days)	MOEs (100 target)			
			Low Exposure Activities: hedging, irrigation, scouting blueberries, hand weeding, training/tying blueberries	Medium Exposure Activities: grape/kiwi scouting, training grapes, tying kiwi	High Exposure Activities: hand harvesting, thinning, pruning, training/tying grapes	Very High Exposure Activities: grape girdling and cane turning
0	Grape data at 1 lb a.i./A, not adjusted for application rate	Blueberries 3	154	77	15	8
4		Grapes 7 - 14		101		
28		Kiwi 21			104	
38		Sweet Peas 7				103

(4) Residential (Homeowner) Handler Risk

- The Agency is concerned about exposures associated with treatment of dogs because the majority of the serious cases reported in the incident data involved systemic illnesses to pet owners, groomers and veterinary assistants.
- EPA's comparative analysis of incident data shows that residential exposures to phosmet are more likely to result in treatment in a health care facility than other organophosphate insecticides; phosmet ranked third for hospitalizations, and first for admission to intensive care units.

In 1996 several mitigation measures were implemented in an attempt to reduce the number of incidents to homeowners, veterinary workers and pets, associated with the use of phosmet. Specifically, product labels were amended to discourage application to certain dog breeds, and to smaller dogs and specifically exclude use on cats.

For homeowner handler exposure assessments, the Agency does not believe a tiered mitigation approach like that used for assessing occupational handler risk is appropriate. Homeowners often lack access to personal protective equipment (PPE) and also do not possess expertise in the proper use of PPE. As a result, homeowner handler assessments are completed using a single scenario based on the use of short-sleeved shirts and short pants (i.e., common homeowner attire during the pesticide application season). In addition, only short-term exposures were assessed, as the Agency does not believe homeowners who apply phosmet will be exposed for more than 7 days. The exposure scenarios are:

Residential (homeowner) Direct Animal Treatments:

- (1) dusting a dog;
- (2) dipping a dog;

Residential (homeowner) Use on Terrestrial Crops:

- (3b) mixing/loading/applying wettable powders with a backpack sprayer;
- (4b) mixing/loading/applying wettable powders with a low pressure handwand sprayer;
- (5b) mixing/loading/applying wettable powders with a hose-end sprayer;

Residential (homeowner) Treatments on Ornamental Plants:

- (3a) mixing/loading/applying liquids with a backpack sprayer;
- (3b) mixing/loading/applying wettable powders with a backpack sprayer;
- (4a) mixing/loading/applying liquids with a low pressure handwand sprayer;
- (4b) mixing/loading/applying wettable powders with a low pressure handwand sprayer;
- (5a) mixing/loading/applying liquids with a hose-end sprayer;
- (5b) mixing/loading/applying wettable powders with a hose-end sprayer; and
- (6) mixing/loading/applying soluble concentrates to fire ant mounds.

Combined dermal and inhalation MOEs for mixing/loading/applying phosmet to fruit trees and ornamentals using a low pressure handwand were of concern (42 and 83, respectively). Very

limited data were available to assess exposure risks for handlers for the direct application to dogs scenario (dip/dust); therefore, data and procedures specified in the 1997 SOPs for Residential Exposure Assessment were used. The SOPs assume combined dermal and inhalation exposure of 10% of the amount applied. This assessment estimated that handler risks for direct application to dogs (dip/dust) were not a concern.

Table 14. Homeowner Uses:

Phosmet MOEs Attributable to Combined Short-term Homeowner Handler Dermal and Inhalation Exposures						
Scenario	Scenario Description	Assumptions Used in Assessment	Crop Type or Target	Dermal MOEs (Target 100)	Inhalation MOEs (Target 100)	Combined MOEs (Target 100)
1	Dusting an Animal	1 dog/day	Dog	3,750,000	No Data	No Data
		1 dog/day	Dog	159,091	No Data	No Data
2	Dipping a Dog	1 dog/day	Dog	1,381,579	No Data	No Data
3a	Mixing/loading/applying Liquids With a Backpack Sprayer	5 gallons	Ornamentals	5,490	280,000	5,385
3b	Mixing/loading/applying Wettable Powders With a Backpack Sprayer	5 gallons	Ornamentals	4,118	210,000	4,038
		150 ft ²	Peas	11,438	583,333	11,218
		250 ft ²	Potatoes	11,438	583,333	11,218
		10 gallons	Fruit Trees	2,101	107,143	2,060
4a	Mixing/loading/applying Liquids With a Low Pressure Handwand	5 gallons	Ornamentals	280	280,000	280
4b	Mixing/loading/applying Wettable Powders With a Low Pressure Handwand	5 gallons	Ornamentals	84	5,727	83
		150 ft ²	Peas	233	15,909	230
		250 ft ²	Potatoes	233	15,909	230
		10 gallons	Fruit Trees	43	2,922	42
5a	Mixing/loading/applying Liquids With a Garden Hose-End Sprayer	5 gallons	Ornamentals	933	884,211	932
5b	Mixing/loading/applying Wettable Powders With a Garden Hose-End Sprayer	5 gallons	Ornamentals	700	663,158	699
		150 ft ²	Peas	1,944	1,842,105	1,942
		250 ft ²	Potatoes	1,944	1,842,105	1,942
		10 gallons	Fruit Trees	357	338,346	357
6	Mixing/loading/applying Soluble Concentrates For Sprinkling	20 gallons (5 - 2 ft ² mounds at 4 gallons per mound)	Fire Ants	389	368,421	388

(5) Residential Post-Application Risk

Phosmet can be used on residential fruit and nut trees, home gardens, ornamental plants, and dogs where exposure to adults and children may occur. Exposure may result from entering the treated garden; maintaining fruit or nut trees; harvesting fruits, nuts or vegetables; or petting treated dogs. As a result, both toddler and adult risks were considered in the risk assessment.

Residential post-application scenarios assessed for phosmet consist of adult homeowners and children (aged 10-12) harvesting and maintaining pears and apples at maximum application rates, and toddlers after dermal contact with treated dogs, including incidental hand-to-mouth transfer. There are concerns for continuous post-application exposure to adults and youth in residential settings over an extended period of time (greater than 30 days); however, there is little information to determine if such extended exposures actually occur. There are also concerns for short-term post-application exposure to adults and youths harvesting and maintaining fruit trees. In addition, there are significant risk concerns for toddlers exposed to phosmet residues following contact with treated dogs, regardless of the duration of exposure.

For short- and intermediate-term (less than 30 days) exposures to adults and youths harvesting and maintaining apples and pears in home gardens, the MOEs were less than 100 on the day of phosmet application, with the exception of apples treated at 1.5 lb a.i./A. An MOE greater than 100 was achieved 4-8 days after application for adults and 3-6 days after application for youths. For this residential post-application scenario, the Agency assumes that home gardening activities would take place for 0.67 hours per day. The Agency does not have enough information to determine if intermediate-term (more than 30 days) exposures to phosmet occur in home gardens. However, empirical dissipation data suggest that phosmet residues persist, and that it may be possible for individuals to be exposed over an extended period of time.

The Agency has concerns for short- and immediate-term (less than 30 days) post-application risk for toddlers exposed to phosmet through dermal contact with treated dogs, as well as through non-dietary ingestion of residues associated with hand-to-mouth behaviors. For this assessment, the Agency has assumed that toddlers would engage in hand-to-mouth activity for 2 hours per day. The Day 0 MOEs calculated for petting small and large dogs ranged from <1 to 8, with the target MOE being 100. An MOE of more than 100 was not achieved even after 30 days, when re-treatment could occur. For toddler mouthing behaviors, as well as for combined exposure to dogs (i.e., dermal + hand-to-mouth exposures), Day 0 MOEs were 1 or less than one after contact with small and large dogs, and did not go above 100 after 30 days. Intermediate-term (more than 30 days) aggregate (i.e., dermal + hand-to-mouth) MOEs calculated for toddlers following contact with treated dogs were <1.

4. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and residential exposure (dermal exposure, inhalation exposure for homeowner applicators, and incidental oral exposure for toddlers who pet treated dogs and engage

in hand-to-mouth activities). The aggregate dietary (food and water) risks are not of concern. Generally, all risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency.

Results of the aggregate risk assessment are summarized here, and are discussed extensively in the HED chapter, dated February 9, 2000. Aggregate risks including food, water, and residential exposure were not of concern except for the following residential scenarios: toddler contact with treated dogs; harvesting from home gardens treated at higher application rates; and homeowners applying wettable powder to ornamentals and fruit trees using low-pressure handwand sprayers.

5. Incident Data Review

Incidents involving exposure to phosmet are reported in the four sources reviewed; OPP's Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), and the National Pesticides Telecommunications Network (NPTN). In addition, the EPA has reviewed several literature studies, two of which describe an exposure incident in detail, and one which consists of a telephone survey of animal groomers/veterinary workers to determine the type of products used, PPE used, and incidents associated with exposure to flea control products.

- The Agency is concerned about exposures associated with treatment of dogs because the majority of the serious cases reported in the incident data involved systemic illnesses to pet owners, groomers and veterinary assistants.
- EPA's comparative analysis of incident data shows that residential exposures to phosmet are more likely to result in treatment in a health care facility than other organophosphate insecticides; phosmet ranked third for hospitalizations, and first for admission to intensive care units.

In 1996 several mitigation measures were implemented in an attempt to reduce the number of incidents to homeowners, veterinary workers and pets, associated with the use of phosmet. Specifically, product labels were amended to discourage application to certain dog breeds, and to smaller dogs and specifically exclude use on cats.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated April 24, 1998, available in the public docket.

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various species. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the

chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies. The higher the RQ the greater the concern. Reported incidents to nontarget organisms, such as fish and birds, involving the use of a pesticide can provide meaningful information to confirm the results of risk assessments and to help characterize ecological risks.

1. Environmental Fate and Transport

Phosmet is stable to soil photolysis and appears to be stable to aqueous photolysis. Phosmet is subject to rapid hydrolysis under alkaline and neutral conditions and to a much lesser extent, under acidic conditions. Microbial degradation is a major route of dissipation. In soils where microbial activity is minimal, leaching may be a significant route of dissipation for this chemical. Phosmet degrades rapidly under aerobic conditions in soil (3 days) and more slowly under anaerobic conditions (15 days). Phosmet was not detected below the 10.5-inch soil layer in any of three field dissipation studies and dissipated to, or below, the level of detection prior to the study's completion.

Phosmet oxon is the only known degradate of toxicological concern identified in a number of environmental fate studies conducted. Studies have indicated that phosmet oxon is less mobile than phosmet because it was not detected in the leachate in aged and unaged mobility studies. In addition, phosmet oxon was limited to the upper soil layer in field studies while phosmet was detected as low as the 10.5-inch soil layer.

Based on laboratory studies and field studies, phosmet and phosmet oxon might appear to pose a threat to groundwater resources. However, the short time-frame in which these chemicals degrade, reduces the migration in most microbially active soils and it does not appear that phosmet or phosmet oxon will pose a significant threat to ground water resources. Phosmet and possibly phosmet oxon, may contaminate surface waters in the dissolved phase, mainly as a result of runoff-producing storm events shortly after field applications. Surface and ground water monitoring data were very limited for phosmet and were not used in the risk assessment.

2. Risk to Birds and Mammals

Phosmet was found to be moderate to practically non-toxic to avian species (acute). However, the application rates and number of applications for various crops have produced acute RQ values that are in the 0.3 to 2.9 range. Use on most crops appears to pose a chronic risk to birds with RQ values that range from 0.3 (for alfalfa seed) to 19.9 (for apples at high rates in short grass).

For mammals, the acute levels of concern are exceeded mainly on short grass for smaller animals. The highest acute RQs are for pears (RQ = 10) and walnuts (RQ = 12). The application rates and frequency of applications result in very high chronic risk concerns for all crops (RQs for short grass, the worst scenario, range from 13 - 73).

3. Risk to Aquatic Species

Acute and chronic risk to both freshwater and estuarine/marine fish is relatively low. The highest RQ is 3.4, for chronic risk to estuarine/marine fish, using the eastern apple high application rates.

The RQs for acute risk to both freshwater and estuarine/marine invertebrates range from 0.2 for apples (low western rate) to 13.4 for apples (high eastern rate), excluding the two highest values. The two highest RQ values are 68.7 and 70 for acute risk to freshwater invertebrates for application to kiwi and pears, respectively.

All crops, which have the potential to expose marine environments, appear to be a chronic concern for marine invertebrates (except alfalfa and cherries) with RQs ranging from 0.39 to 10.5. Chronic risk to freshwater invertebrates appears to be of concern for the following crops: apples, grapes, kiwi, peaches, pears, pecans and sweet potatoes.

4. Risk to Honey Bees

Phosmet is highly toxic to honey bees. Incidents of toxicity to honey bees have been reported.

IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing phosmet active ingredients.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient phosmet, as well as a phosmet-specific dietary (food + drinking water) risk assessment that has not considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient phosmet, EPA has sufficient information on the human health and ecological effects of phosmet to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. Taking into account the benefits of phosmet use where appropriate, the Agency has determined that phosmet is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risk assessment for the organophosphates support a final reregistration eligibility decision. Label changes are described in

Section IV. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of phosmet, and lists the submitted studies that the Agency found acceptable.

Although the Agency is in the process of conducting its cumulative risk assessment for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of phosmet.

Based on its current evaluation of phosmet alone, the Agency has determined that phosmet products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of phosmet.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For phosmet, if all changes outlined in this document are incorporated into the labels, then most current risks will be mitigated. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for phosmet after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing phosmet food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has considered the cumulative assessment, phosmet tolerances will be reassessed in that light. At that time, the Agency will reassess phosmet along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical phosmet, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the RED, that any of the determinations described in this interim RED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this interim RED.

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Fifty two comments were received during the public comment period that closed on May 19, 2000. Of these, comments specific to phosmet were received from the registrants (Gowan Company and Wellmark International Corporation), and the remaining fifty comments were from various organizations and private citizens. Many of these comments were testimonials to the effectiveness of phosmet. Commentors emphasized that phosmet is an important tool for integrated pest management, and that without it, resistance would develop quickly because of limited effective alternatives. Many commentors indicated that phosmet is not harmful to beneficial insects. In addition, the Natural Resources Defense Council submitted comments that were specific to phosmet, but also included comments related to other OPs being reviewed and to any pesticide used on food.

A Partial IRED (PIRED) for phosmet was signed on August 31, 2001; a 60-day comment period for that document closes on October 30, 2001. Because the IRED for phosmet will be issued before the end of the comment period, and there would not be sufficient time to incorporate all comments before issuing the interim RED, there will be a 60-day comment period on this interim RED for phosmet. The comment period for this document ends 60 days after publication of the Notice of Availability in the *Federal Register*.

One comment on the PIREP has been received to date. A summary of the comment is noted here. The state of Florida sent in a Special Local Need (SLN) request, consistent with Section 24(c) of FIFRA, to use phosmet on citrus to control the apopka weevil. There is an existing tolerance for phosmet use on citrus. The Agency will review the risks and benefits associated with phosmet use on citrus and include the results in the Agency's response to comments. Other comments on the benefits assessments have been received. These comments are being evaluated. Changes to the IRED resulting from these comments will be discussed in the Agency's response to comments.

C. Regulatory Position

EPA has determined that the continued use of phosmet is warranted under the conditions specified in this document. Dietary (food and drinking water) risks are not of concern. Residential risks have been addressed by voluntary cancellation of phosmet uses in the home. Further, the Agency finds that the risks posed to workers and the environment by the uses addressed in this document are currently acceptable taking into account mitigation measures and the benefits of phosmet use. In arriving at these decisions, EPA has considered all relevant risk mitigation options. In addition to personal protective equipment and engineering controls for workers, EPA has considered reductions in the rate and frequency of applications and precautionary labeling. Despite

these mitigation measures, residual risks are still of concern, (e.g., MOEs <20) for some worker activities for nine uses (apples, crabapples, apricots, nectarines, peaches, pears, plums/prunes, highbush blueberries, and grapes). Although EPA has determined that the benefits of these uses currently exceed the mitigated risks, these mitigated risks are still high enough that they would outweigh the benefits if the benefits changed appreciably. EPA is, therefore, requiring that after October 30, 2006, the reentry intervals for phosmet products registered for these 9 uses shall be extended as specified in the risk mitigation tables below. These longer reentry intervals (13 to 29 days) should bring the MOEs to approximately 70, substantially easing EPA's remaining risk concerns.

According to EPA's worker risk management policy (PR Notice 2000- 9), when calculated MOEs are below the target MOE after all mitigation has been considered, in this case 100, EPA will characterize uncertainties in the risk assessment, assess the potential of additional data to reduce the uncertainty, and consider benefits, i.e., the cost, availability and relative risk of alternatives in making its regulatory decisions. These factors are addressed below.

Uncertainty in the Occupational Risk Assessment

In the case of phosmet, the uncertainty associated with its toxicity is relatively low. The endpoint used for the short and intermediate-term (≤ 30 days) worker assessment is cholinesterase inhibition in both blood and brain. The 21-day dermal rat study that was used for this assessment is appropriate both in terms of route and duration of likely exposures. There is less than a 2-fold difference between the LOAEL (22.5 mg/kg/day) and the NOAEL (15 mg/kg/day). Additional toxicity data such as biological monitoring or workers' cholinesterase levels could allow further refinement.

On the exposure side, EPA's assessment reflects the most recently updated transfer coefficients based on the Agricultural Reentry Task Force data and dislodgeable foliar residue (DFR) data from a phosmet-specific study. Additional regional DFR data could impact exposure assessments. There are some protective assumptions built into the post-application exposure assessment for phosmet. For example, EPA assumes that no protective clothing is worn, that workers may be exposed for up to 30 days, and that every field a worker enters has been treated with phosmet at the same maximum rate. User survey information provided by the registrant and others indicates that the actual frequency and duration of some post application activities such as scouting and irrigation tasks may be more intermittent, i.e., generally less than standard assumptions, and that maximum application rates are not always used.

For other activities such as hand thinning and hand harvesting, EPA's assumptions are less conservative. Data provided by growers and others confirm that these workers frequently enter recently treated areas and continually work 30 days, sometimes longer.

Benefits

Table 16 contains a brief summary of benefits information for each site and proposed decision. The complete benefits assessments are available in the OPP public docket and on the Internet. In general, EPA's assessments have found little or no impact on crop production from the measures proposed in this document. However, USDA, the registrant and others have voiced the concern that extending the REI for some uses could have the effect of growers shifting to more hazardous alternatives. Stakeholders are urged to provide EPA with factual information related to potential shifts in use and the impacts of these shifts, e.g., increased cost, increased pesticide use, environmental impacts, etc., as well as any appropriate documentation during the comment period.

EPA is providing a 60-day public comment period on the risk management decisions contained in this interim RED.

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to phosmet is within its own "risk cup." In other words, if phosmet did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for phosmet meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to phosmet "fit" within the individual risk cup. Therefore, the phosmet tolerances remain in effect until a full reassessment of the cumulative risk from all organophosphates is considered.

b. Tolerance Summary

In the individual assessment, tolerances for residues of phosmet in/on plant commodities [40 CFR §180.261] are presently expressed in terms of the combined residues of phosmet and its oxygen analog. Metabolism and field trial residue data indicate parent phosmet is the most significant residue in fruit; when detected, phosmet oxon residues are generally an order of magnitude less than the parent residues. Combined phosmet and oxon residues were below the limit of quantitation of 0.05 ppm in cottonseed, nuts and potatoes (following foliar use). Monitoring data indicate that residues in fruits and vegetables are expected to be significantly lower than the established tolerances.

The residue chemistry database for phosmet is largely complete; additional studies are being reviewed to reassess the tolerance for residues in sweet potatoes following post harvest application of the dust formulation; supporting storage stability data must also be submitted. Geographically representative field trial data for blueberries are required. The data gaps do not preclude completion of a dietary exposure analysis, since there are adequate monitoring data available for these commodities.

According to current Agency practice, the name for the tolerance “alfalfa” will be separated into two tolerance names, “alfalfa forage” and “alfalfa hay”. Likewise, the name for the tolerance “peas” will be separated into two tolerance names, “peas, dry” and “peas, succulent”.

Table 15. Tolerance Summary for Phosmet

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment/Correct Commodity Definition
Tolerances Listed Under 40 CFR §180.261 (a)			
Alfalfa	40	20	A separate tolerance is needed for residues in alfalfa hay/ alfalfa, forage. The tolerance is reduced to 20 ppm, consistent with the 1986 Registration Standard. [<i>alfalfa, forage</i>]
	40	40	A separate tolerance is needed for residues in alfalfa hay/ alfalfa, forage [<i>alfalfa, hay</i>]
Almond Hulls	10	10	[<i>almond, hulls</i>]
Apples	10	10	[<i>apple</i>]
Apricots	5	5	[<i>apricot</i>]
Blueberries	10	To be determined	Additional residue data required [<i>blueberry</i>]
Cattle, fat	0.2	0.2	[<i>cattle, fat</i>]
Cattle, MBYP	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [<i>cattle, meat byproducts</i>]
Cattle, meat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [<i>cattle, meat</i>]

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment/Correct Commodity Definition
Cherries	10	10	[cherry]
Citrus Fruits	5	TBD	To Be Determined**
Corn, fodder	10	Revoke	Not Supported
Corn, forage	10	Revoke	Not Supported
Corn, fresh	0.5	Revoke	Not Supported
Corn, grain	0.5	Revoke	Not Supported
Cotton, seed	0.1	0.1	[cotton seed, undelinted]
Cranberries	10	10	[cranberry]
Goats, fat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [goat, fat]
Goats, MBYP	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [goat, meat byproducts]
Goats, meat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [goat, meat]
Grapes	10	10	[grape]
Hogs, fat	0.2	0.2	Tolerance based on dermal treatment [hog, fat]
Hogs, MBYP	0.2	0.04	Revised tolerances based on dermal treatment [hog, meat byproducts]
Hogs, meat	0.2	0.04	Revised tolerances based on dermal treatment [hog, meat]
Horses, fat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [horse, fat]
Horses, MBYP	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [horse, meat byproducts]
Horses, meat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [horse, meat]
Kiwifruits	25	25	[kiwifruit]
Nectarines	5	5	[nectarine]
Nuts	0.1 (N)	0.1	It is current Agency administrative practice to remove the “N” designation, which means negligible residues, from all entries. [nut, tree, group]
Peaches	10	10	[peach]
Pears	10	10	[pear]
Peas	10	10	Separate tolerances are needed for residues in dry and succulent pea/dry pea. [pea, forage]

Peas

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment/Correct Commodity Definition
	10	20	Separate tolerances are needed for residues in dry and succulent pea/dry pea. The available data indicate that the tolerance should be increased to 20 ppm. [<i>pea, hay</i>]
Peas	0.5	1	Separate tolerances are needed for residues in dry and succulent pea/dry pea. The available data indicate that the tolerance should be increased to 1 ppm. [<i>pea, succulent</i>]
	0.5	0.5	Separate tolerances are needed for residues in dry and succulent pea/dry pea. [<i>pea, dry</i>]
Plums	5	5	[<i>plum</i>]
Potatoes	0.1	0.1	[<i>potato</i>]
Sheep, fat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [<i>sheep, fat</i>]
Sheep, MBYP	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [<i>sheep, meat by products</i>]
Sheep, meat	0.2	0.1	The available data indicate that the tolerance should be reduced to 0.1 ppm. [<i>sheep, meat</i>]
Sweet Potatoes (post harvest)	10	To Be Determined	Residue data is being developed by the registrant.
Tolerances Needed under 40 CFR §180.261 (a)			
Cotton gin byproducts	None	To be determined	Additional data required.
Cotton seed, refined oil	None	0.2	
Milk	None	0.1	Based on the combined limits of quantitation (LOQs) for phosmet and phosmet oxon
Tolerances Listed Under 40 CFR §180.261 (c)			
Crabapples	20	20	[<i>crabapple, (post harvest)</i>]
Pistachios	0.1	Revoke	Tolerance should be revoked once a 0.1 ppm tolerance is established for <i>nut, tree, group</i> .

* The term "reassessed" here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be reassessed only upon completion of the cumulative risk assessment of all organophosphates, as required by this law. Rather, it provides a tolerance level for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data.

**The Agency has received an application for a Special Local Need registration under FIFRA Section 24(c) from Florida for control of the Apopka Weevil in oranges and grapefruit. Additional data may be required for this use.

The Agency will commence proceedings to revoke the four existing tolerances for phosmet use on corn. The establishment of a new tolerance or raising tolerances will be deferred, pending the consideration of the cumulative assessment. The Agency received a request from the State of

Florida for a Special Local Need registration under FIFRA Section 24(c). The Agency is in the process of assessing the risks and benefits associated with this use. A final determination on the citrus use will be made after the comment period.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, phosmet may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Labels

The following risk mitigation measures are necessary to mitigate the risks identified in the phosmet risk assessment to workers who handle phosmet and workers re-entering fields treated with phosmet.

Label amendments, in addition to the existing label requirements, are necessary in order for phosmet products to be eligible for reregistration.

Provided the risk mitigation measures described in the following section are incorporated in their entirety into labels for phosmet-containing products, the Agency finds that 33 of the 45 currently registered uses of phosmet would be eligible for reregistration, and 9 uses are being reregistered on a time-limited basis, pending a cumulative assessment of the organophosphates. The registrant has requested voluntary cancellation of the remaining three uses of phosmet (pets, household ornamentals, household fruit trees, and high pressure hose application method to cattle). It should be noted that other application methods for cattle will remain. The regulatory rationale for each of the mitigation measures is also discussed.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the current use of phosmet. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Mitigation

a. Dietary (food and water) Mitigation

(1) Acute Dietary (Food)

Taking into account all currently registered uses of phosmet, dietary (food and water) risks are not of concern. However, additional studies have been required to reassess the tolerance for residues in sweet potatoes following post harvest application of the dust formulation. The Agency has received this data and is in the process of reviewing it. In addition, the following data is required: geographically representative field trial residue data for blueberries; representative storage stability studies for phosmet oxon in an oil seed or nut matrix; and residue data for cotton gin byproducts.

(2) Chronic Dietary (Food)

No risk mitigation is necessary.

(3) Drinking Water

No risk mitigation is necessary.

b. Residential

All residential uses of phosmet, including treatment of dogs, are being voluntarily canceled. However, Pest Control Operators will be permitted to apply phosmet to fire ant mounds in a residential setting, because fire ants are a public health pest and risks to mixers, loaders, applicators and residents are not of concern.

c. Occupational Risk Mitigation

(1) Agricultural Risk Mitigation

To reduce risks to workers who mix and load phosmet, the Agency is requiring the use of closed mixing and loading systems, e.g., water soluble bags.

The risks associated with the dipping of pine seedlings and post harvest application to sweet potatoes have not been quantified, but the Agency believes that it is prudent to require handlers to

wear a long-sleeved shirt and long pants, shoes, socks, an additional layer of clothing, an apron, chemical-resistant gloves, and an air purifying (OV) respirator to mitigate risks.

To reduce risks to workers harvesting potatoes and sweet potatoes, phosmet is only to be used on potatoes and sweet potatoes that will be harvested by machine.

Liquid products are limited to use on the following crops: alfalfa, cotton, blueberries, and potatoes, thus reducing exposure to workers who mix and load phosmet.

EPA has determined that worker risks from exposure to phosmet in the scenarios listed below would be adequately mitigated through use of the following PPE: long-sleeved shirt and long pants, shoes and socks.

- Applying sprays with a groundboom sprayer;
- Applying using a right-of-way sprayer;
- Use of a cattle backrubber
- Mixing/loading/applying liquids with a backpack sprayer;
- Mixing/loading/applying wettable powders with a backpack sprayer;
- Mixing/loading/applying soluble concentrates for sprinkling.

EPA has determined that worker risks from exposure to phosmet in the scenarios listed below would be adequately mitigated through use of the following PPE: long-sleeved shirt and long pants, shoes, socks and chemical-resistant gloves.

- Mixing/loading liquid formulations for high pressure handwand application;
- Mixing/loading liquid formulations for airblast sprayer application;
- Mixing/loading liquid formulations for groundboom application;
- Mixing/loading/applying wettable powders with a low pressure handwand;
- Mixing/loading/applying liquids with a low pressure handwand; and
- Applying using a high-pressure handwand.

EPA has determined that worker risks from exposure to phosmet in the scenarios listed below would be adequately mitigated through use of the following PPE: long-sleeved shirt and long pants, shoes, additional layer of clothing, socks, chemical-resistant gloves, and an air purifying respirator (OV) to mitigate risks from exposure to phosmet.

- Dipping pine seedlings; and
- Mixing/loading/applying a dust formulation.

EPA has determined that worker risks from exposure to phosmet in the scenarios listed below would be adequately mitigated through use of engineering controls such as a closed tractor cab or closed loading system for granulars or liquids.

- Mixing/loading wettable powders for aerial application and chemigation;

- Mixing/loading wettable powders for groundboom application;
- Mixing/loading wettable powders for airblast sprayer application;
- Mixing/loading wettable powders for high pressure handwand application;
- Mixing/loading liquids for aerial application and chemigation;
- Applying sprays with an airblast sprayer;
- Aerial application of sprays with a fixed wing aircraft (fixed wing aircraft also accounts for helicopter pilot exposure); and
- Flagging for aerial spray application.

The only mixer/loader/applicator scenarios that remain of concern after the standard mitigation of PPE and engineering controls are considered include:

- mixing/loading liquid formulations for aerial application and chemigation; and
- mixing/loading wettable powder formulations for aerial application and chemigation.

The risks and benefits associated with these activities are discussed in greater detail in the table below in the context of each registered crop and use pattern.

Postapplication Exposure

EPA completes exposure assessments on postapplication workers for various crops and activities at intervals following the application until risk falls below a target level. For phosmet, the target level for dermal risk concerns is an MOE of 100 and for inhalation risk concerns, it is an MOE of 100.

In order to determine the REI for a crop, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk to a worker falls below the target MOE. Occupational risks are regulated under the FIFRA section 3(c)(5) standard - "without unreasonable adverse effects on the environment" - which means that both risks and benefits must be considered in making a risk management decision. This standard may be met at a level below the target MOE when there are significant benefits associated with a specific activity. As the worker exposure database has improved, risk assessments are now conducted for a variety of postapplication activities based on the level of exposure for each worker activity, see Tables 7 - 13, "Occupational Postapplication Risk from Phosmet: Days After Treatment at Which the MOE is \$100". For a specific crop/pesticide combination, the duration required to achieve the target MOE can vary depending on the activity assessed.

In general, EPA prefers to set a single REI for all activities related to a crop or crop group without additional activity-based labeling. This approach is favored because handlers and workers are more likely to understand and comply with simpler labels. Also, permitting entry for some activities during the REI could cause confusion and compromise the effectiveness of the Worker Protection Standard (WPS). However, when the consideration of risks and benefits indicate that a single REI is unworkable, EPA may consider either setting an REI with early entry exceptions for one or more critical tasks or establishing an entry prohibition for a specific task after the REI has

expired. For phosmet, no critical activities have been identified to warrant the use of an activity-based exception or prohibition. However, during the 60-day comment period for this interim RED, EPA will accept further comments from growers regarding needs for additional REI exceptions for specific activities, and will consider such exceptions where needed if there are adequate MOEs and/or benefits associated with such activities.

In weighing worker risks and benefits, the Agency considered the timing of field activities that are critical to crop production. For many of the phosmet uses discussed below, scouting and irrigation are critical activities in crop production, and these activities routinely need to be performed soon after application. In evaluating the restricted entry intervals, the Agency considered the exceptions to the WPS that could inform the decision. EPA's proposed REIs take into account the flexibility already provided by these exceptions. Scouting is a handler activity under the WPS, so anyone performing this activity may legally enter the treated field during the REI provided they use the handler personal protective equipment (PPE) specified on the label. In addition, if the scout is a certified crop advisor as defined in the WPS (40 CFR 170.204(b)), the individual can determine the appropriate PPE to be used. For many of these crops, irrigation equipment is not routinely moved by hand. For these methods, the primary activity involves entering the field to turn the watering equipment on and off. This activity is allowed during the REI under the no contact exception to WPS (40 CFR 170.112(b)). This exception also usually applies to mechanical harvesting, to tree shaking for nut crops using vehicles with enclosed cabs, and often applies to mowing. Should irrigation equipment need unexpected repairs during the REI, WPS allows workers to enter a treated field provided early entry PPE is used (40 CFR 170.112(c)).

Time-Limited Registration

EPA has designated 9 of the 45 phosmet decisions in the following table as time-limited. They are apples, crabapples, apricots, high-bush blueberries, peaches, pears, plums/prunes, nectarines, and grapes. These uses are eligible for reregistration, under the conditions specified in this IRED. However, despite imposition of all feasible risk mitigation measures, calculated re-entry worker risks remain high and are still of concern to the Agency. Although EPA has determined that the risks of these 9 phosmet uses (with the mitigation measures identified in this IRED) are currently reasonable, taking into account their economic, social, and environmental costs and benefits, EPA remains concerned about the worker risks. EPA believes that the worker risks for these 9 uses would outweigh the benefits if the benefits changed appreciably, and that the current benefits are likely to diminish over time as new, safer alternatives become available and are adopted by growers. The risk picture could also change with the development of monitoring or other toxicity data.

For these reasons the Agency has reached agreement with the registrants, on a mechanism to reconsider both the risks and benefits of these 9 uses in five years. Under this agreement, the reentry intervals for phosmet products registered for these 9 uses shall be extended as specified in the Agreement with Gowan Company, effective October 30, 2006, unless the registrant or other stakeholders can demonstrate that a lesser REI would continue to meet the standards for registration.

The Agency has taken this approach for these 9 uses because both the risk to re-entry workers and the benefits of phosmet use on these crops are high. "High benefits" means that the withdrawal of phosmet from the market would result in significant economic impacts on the fruit industry. These impacts are largely determined by the lack of alternative methods to control pest pressure effectively and economically. In the case of phosmet, lengthening the REIs on these 9 crops to 13 - 29 days* would substantially address the Agency's risk concerns. However, under current cropping practices lengthening the restricted entry intervals beyond what is indicated in this document would preclude key activities and result in substantial losses. For a complete discussion of the benefits of phosmet use on these crops see EPA's website: www.epa.gov/pesticides/op/phosmet.htm

In order to ensure that risks are no greater than currently estimated, registrants have agreed to conduct a controlled study to provide data on reentry workers' cholinesterase levels under the conditions of use set forth in this IRED. They have also agreed to provide updated usage and benefits information related to phosmet, and investigate the feasibility and work on developing additional protective equipment, specifically, gloves, for reentry workers. While EPA considers data in these areas to be key, registrants may also provide other data that they believe would be relevant to the Agency's risk-benefit deliberations.

For the nine commodities that are included in the five-year reevaluation of phosmet, growers and commodity organizations are encouraged to develop Pest Management Strategic Plans (PMSPs), or expand existing plans. PMSPs are commodity-specific plans that identify current and emerging pest management practices. PMSPs also state a commodity's priorities for research, regulatory activities, and education/training programs to support transition to alternative pest management practices. For more information about PMSPs, see: <http://www.pmcenters.org> or contact USDA's Office of Pest Management Policy on (202) 720-4074.

As appropriate, EPA, USDA and other stakeholders, including worker and growers groups, are encouraged to participate in discussions of feasibility of protective equipment, adequacy of alternatives and ways to overcome barriers to adoption of alternative pest control methods. Additionally, all affected stakeholders will be invited to comment on the design and implementation of the cholinesterase monitoring study. These key studies and any other relevant data must be completed and provided to EPA no later than October 30, 2005, in order for EPA to ensure their consideration prior to the deadline for reevaluation, October 30, 2006.

*Apples (1.5 lb ai/A), REI=13-days; Apples (4 lb ai/A), REI=28-days; Pears, REI=28-days; Peaches, REI=24-days; Nectarines, REI=24-days; Apricots, REI=24-days; Plums/Prunes, REI=24-days; Grapes, REI=29-days; and Highbush Blueberries, REI=23-days.

Table 16: Risk Mitigation

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Kiwifruit (1 lb a.i./A rate)	21	<p>High exposure activities (hand harvesting): MOE = 17 at current REI of 24 hours MOE 100 @ 28 days MOE 65 @ 21 days</p> <p>Medium exposure activities (scouting and tying kiwifruit): MOE = 83 at current REI of 24 hours MOE 100 @ 4 days</p>	Because the boxelder bug is an early season pest, a 28-day pre-harvest interval (PHI) is not expected to have an impact on kiwifruit production.	<p>28-day PHI (high exposure: harvesting), MOE >100)</p> <p>7-day REI (medium exposure: scouting and tying, MOE > 100)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: For Kiwifruit, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations.</p> <p>The boxelder bug sporadically appears in kiwifruit (CA), and no alternative controls exist. This pest can cause bud and fruit drop and malformation to the fruit, resulting in yield and quality losses. Because of the low volume of use (54 lbs of phosmet used estimated per year), benefits are generally considered to be low; however, for one sporadic but serious pest, there is no similarly efficacious alternative.</p> <p>With a 28-day pre-harvest interval, risks from harvesting are not of concern. With a 7-day REI for the remaining activities, risks from postapplication exposures are not of concern.</p> <p>Rationale for Ecological Risk Mitigation: Although only an average of 54 pounds of phosmet are applied to kiwifruit annually, spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Peas (Green) (1 lb a.i./A rate)	7	<p>High exposure activities (hand harvesting): MOE = 33 at current REI of 24 hours MOE 100 @ 18 days</p> <p>Medium exposure activities (irrigation and scouting of mature plants): MOE = 55 at current REI of 24 hours MOE = 100 @ 10 days</p>	<p>Little phosmet use is reported on this crop. Extending the PHI to 18 days is expected to have little impact on harvesting of green peas. Increasing the REI to 5 days for all activities other than hand harvesting is expected to have little impact on the crop.</p>	<p>18 day PHI (MOE>100)</p> <p>5-day REI (MOE = 72 for irrigation, scouting, all other worker activities >100)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: For green peas, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. With a 18-day PHI and a 5-day REI, risks from postapplication exposures are not of concern.</p> <p>Stakeholder comments have suggested that scouts have minimal contact with treated foliage because of use of all terrain vehicles during scouting activities. However, the Agency has received a study conducted in conjunction with the Agricultural Re-entry Task Force (ARTF) that indicates that there is exposure to scouts performing those activities. Therefore, scouting and irrigating mature plants is considered a "medium" exposure activity in the risk mitigation.</p> <p>Under the Worker Protection Standard, scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. Irrigation is often fixed in place, which is a no contact activity as defined by the Worker Protection Standard.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Peas (Dry) (1 lb a.i./A rate)	7	<p>High exposure activities (hand harvesting): MOE = 33 at current REI of 24 hours MOE 100 @ 18 days</p> <p>Medium exposure activities (irrigation and scouting of mature plants): MOE = 55 at current REI of 24 hours MOE = 100 @ 10 days</p>	<p>Use of phosmet on dry peas (ID) has high benefits for control of the pea weevil and the pea leaf weevil.</p> <p>Increasing the REI to 5 days is expected to have little impact on the crop.</p>	<p>5-day REI (MOE = 72 for irrigation and scouting of mature plants, all other worker activities >100)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: For dry peas, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. With a 5-day restricted entry interval, risks from postapplication exposures are not of concern.</p> <p>Phosmet controls the pea weevil and the pea leaf weevil. Adult leaf weevils cause significant damage and economic loss by damaging leaves, terminate buds, and ultimately destroying the plants.</p> <p>Stakeholder comments have suggested that scouts have minimal contact with treated foliage because of use of all terrain vehicles during scouting activities. However, the Agency has received a study conducted in conjunction with the Agricultural Re-entry Task Force (ARTF) that indicates that there is exposure to scouts performing those activities. Therefore, scouting mature plants is considered a "medium" exposure activity in the risk mitigation.</p> <p>Phosmet use will be limited to dry peas that are mechanically harvested, which is a no contact activity as defined by the Worker Protection Standard Under the Worker Protection Standard. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. Irrigation is often fixed in place, which is a no contact activity as defined by the Worker Protection Standard.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Sweet Potatoes (1 lb a.i./A rate)	7	Medium exposure activities (irrigation scouting of mature plants) MOE = 55 at current REI of 24 hours MOE 100 @ 10 days	Benefits very high for control of the white fringe weevil, spotted and banded cucumber beetle. Quarantine use: for control of the sweet potato weevil. Increasing the REI to 5-days is expected to have little impact on the crop.	5-day REI (medium. exposure: irrigation and scouting of mature plants, MOE = 72) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: For sweet potatoes, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations.</p> <p>Because sweet potatoes are mechanically harvested, the estimated risk for hand harvesting is not considered for setting the REI; therefore, exposures to individuals performing scouting tasks on mature plants have calculated MOEs <100. However, EPA believes a 5-day REI is acceptable with an MOE of 72 because of the low volume of phosmet use and scouting activities occur intermittently.</p> <p>Phosmet is essential in controlling the sweet potato weevil, white fringe weevil, banded and spotted cucumber beetle. All other worker exposures have MOEs over 100 and thus are not of concern.</p> <p>Phosmet is also used post-harvest on stored sweet potatoes for controlling the sweet potato weevil, a quarantine pest. Phosmet is the only effective pesticide for controlling the sweet potato weevil in stored sweet potatoes. The risks associated with the post-harvest application to sweet potatoes have not been quantified, but the Agency considers it prudent to require handlers to wear long-sleeved shirt and long pants, shoes, socks, an additional layer of clothing, an apron chemical-resistant gloves, and an air purifying (OV) respirator to mitigate applicator risks associated with the use of the 5% dust product.</p> <p>All sweet potatoes are mechanically harvested, which is a no contact activity as defined by the Worker Protection Standard. Under the Worker Protection Standard, scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. Little irrigation is needed for sweet potatoes.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Alfalfa/Clover (1 lb a.i./A rate)	7-14	M/L Aerial MOE = 97 @ 1 lbs. Medium exposure activities (irrigation and scouting of mature plants) MOE = 55 at current REI of 24 hours MOE 100 @ 10 days	Usage of phosmet on this field crop is extremely low. Increasing the REI to 5 days is expected to have little impact on crop production.	5-day REI (medium exposure: scouting and irrigation of mature plants, MOE = 72) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: For alfalfa or clover, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. For mixing and loading for aerial application, it is unlikely that the use of phosmet would exceed 7 days (MOE = 97) because of the low volume of phosmet used. Therefore, risks to mixers and loaders are not of concern.</p> <p>With a 5-day restricted entry interval (MOE=72), risks from postapplication exposures (scouting and irrigation of mature plants) are not of concern because phosmet is not frequently used on alfalfa or clover and most of the irrigation systems used are stationary thus resulting in no worker contact with treated foliage, allowing re-entry consistent with the Worker Protection Standard. No impact on alfalfa or clover production is expected from extending the REI to 5 days because of the limited use and few hand activities that would occur during this period.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Blueberries (lowbush) (1 lb a.i./A rate)	3	High exposure activities (hand harvesting) MOE = 55 at current REI of 24 hours MOE 100 @ 10 days	Benefits are high to medium high, because alternatives are less effective than phosmet.	7-day PHI (high exposure: hand harvesting MOE = 83) 3-day REI (MOE>100 for remaining activities) Limit phosmet applications to 2.8 lb a.i./A per year.* Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: For lowbush blueberries, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations.</p> <p>Growers have indicated a need to re-enter treated fields to monitor pest infestations and replace pheromone traps, consistent with Integrated Pest Management Programs and that the use of alternatives (malathion and carbaryl) requires more frequent treatments.</p> <p>*The Agency has received comments indicating that the seasonal maximum application rate of 2.8 lb a.i./A per season is adequate if azinphos-methyl is available for pest control; however, the rate reduction would impact blueberry production if the use pattern for azinphos-methyl is changed. The Agency is interested in receiving additional comments on the seasonal maximum application rate for blueberries.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Cherries, Sweet (1.5 lb a.i./A rate)	7	<p>M/L Aerial MOE = 92 High exposure activities (hand harvesting): MOE = 31 at current REI of 24 hours MOE 100 @ 19 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 93 at current REI of 24 hours MOE 100 @ 3 days</p>	<p>Benefits are high to growers in OR for Syneta beetle use. Limited alternatives. (24(c) registration in OR)</p> <p>Increasing the PHI to 19 days and the REI to 3 days is expected to have little impact on crop production.</p>	<p>19-day PHI (MOE > 100)</p> <p>3-day REI (remaining activities, MOE >100)</p> <p>Limit to 5.25 lb a.i./A per year.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that they would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated short-term MOE of 92. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Damage from syneta beetle is fruit-scarring, and causes deformed fruit. Application to control this beetle is early-season (end of bloom). Because critical activities are not anticipated in the early season, a 19-day pre-harvest interval is not expected to have an impact on sweet cherry production. With a 3-day REI, the risks are not of concern for all other activities. The 3-day REI is not expected to have any impact on sweet cherry production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Cherries, Tart (1.5 lb a.i./A rate)	7	<p>M/L Aerial MOE = 92 High exposure activities (hand harvesting): MOE = 31 at current REI of 24 hours MOE 100 @ 19 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 93 at current REI of 24 hours MOE 100 @ 3 days</p>	Benefits are high for the use of phosmet in tart cherries. Pests are the cherry fruit flies.	<p>3-day REI (low exposure: irrigation and scouting) for all activities -no hand harvesting, MOE >100</p> <p>Limit to 5.25 lb a.i./A per year.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 92. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Pests are the cherry fruit flies. Truckloads with maggots are rejected at the distributor level. Many alternatives are less efficacious and most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for tart cherry growers. In addition, scale infestations have become common in tart cherry orchards. The scale infestations cause lower yields, lower fruit quality, and most significantly, can kill cherry trees within two years if untreated.</p> <p>Exposure to workers is limited because all tart cherries are mechanically harvested. Consequently, the re-entry exposures of concern are scouting and irrigation. With a 3-day REI, these risks are not of concern and the increased REI is not expected to have any impact on tart cherry production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Apples/ Crabapples (Eastern U.S.) 1.5 lb a.i./A rate	7	<p>M/L Aerial MOE = 92 High exposure activities (hand harvesting, hand thinning): MOE = 31 at current REI of 24 hours MOE 100 @ 19 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 93 at current REI of 24 hours MOE 100 @ 3 days</p>	<p>Benefits are very high for the use of phosmet in apples. Increasing the REI beyond 3 days is expected to significantly impact apple production by limiting the ability to perform critical activities, such as thinning and harvesting.</p> <p>Pests are: Eastern Region: codling moth, plum curculio, apple maggot, oriental fruit moth, leafrollers, tarnished plant bug, European apple sawfly, and San Jose Scale.</p> <p>Western Region: codling moth, grape mealybug, green fruitworms, oblique-banded leafrollers, and Western tussock moth.</p>	<p>3-day REI (high exposure: hand harvesting and hand thinning, MOE = 35; low exposure: irrigation and scouting, MOE>100) for all activities.</p> <p>Time-limited Registration (5 years)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are preformed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 92. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Phosmet is often used for early season control of pest outbreaks during thinning operations and late in the season because of the 7-day PHI, which is shorter than some alternatives. With the removal of methyl-parathion and the restrictions placed on chlorpyrifos limiting its use to before bloom, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. The benefits for phosmet use on apples are very high because there are few alternatives available that allow for timely entry into treated orchards to perform thinning and other orchard maintenance activities. None of the alternatives provide adequate control for the target pests. Thinning operations are completed early in the growing season. Many of the pests such as oriental fruit moth are most active during the thinning time-frame. If thinning is not completed in a timely manner, the apples do not grow large enough to be profitable.</p> <p>Most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for apple growers. Scale infestations cause lower yields, lower fruit quality, and most significantly, reduced orchard longevity. Orchards are typically productive for approximately 30 - 45 years (depending on the type of tree), taking from 2 - 10 years for the trees to bear fruit. Heavy scale infestations can shorten the productive life of the orchard by 1 to 2 years.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforcesecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases.</p> <p>The re-entry exposures of concern for workers are scouting, irrigation, hand harvesting, and hand thinning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. With an REI longer than 3 days significant impacts are likely to apple production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p> <p>In light of the benefits of phosmet use on apples, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				
Apples/ Crabapples (Western U.S.) 4 lb a.i./A rate	7	M/L Aerial MOE = 34 High exposure activities (hand harvesting, hand thinning): MOE = 12 at current REI of 24 hours MOE 100 @ 34 days Low exposure activities (irrigation and scouting): MOE = 35 at current REI of 24 hours MOE 100 @ 17 days	Benefits are very high for the use of phosmet in apples. Increasing the REI beyond 3 days is expected to significantly impact apple production by limiting the ability to perform critical activities, such as thinning and harvesting. Pests are: Eastern Region: codling moth, plum curculio, apple maggot, oriental fruit moth, leafrollers, tarnished plant bug, European apple sawfly, and San Jose Scale. Western Region: codling moth, grape mealybug, green fruitworms, oblique-banded leafrollers, and Western tussock moth.	3 day REI (high exposure: hand harvesting and hand thinning, MOE = 13; low exposure: irrigation and scouting, MOE = 40) for all activities. Time-limited Registration (5 years) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 34. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>The pest complex for the Western United States is different from the pest complex in the Eastern United States. The most important pest in western apples is codling moth. For adequate control under heavy pest pressure, the 4 lb a.i./A rate is necessary; however, typical rates in the west range from 2.0 - 2.3 lb a.i./A.</p> <p>Phosmet is often used for early season control of pest outbreaks during thinning operations and late in the season because of the 7-day PHI, which is shorter than some alternatives. With the removal of methyl-parathion and the restrictions placed on chlorpyrifos limiting its use to before bloom, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. The benefits for phosmet use on apples are very high because there are few alternatives available that allow for timely entry into treated orchards to perform thinning and other orchard maintenance activities. None of the alternatives provide adequate control for the target pests. Thinning operations are completed early in the growing season. Many of the pests such as oriental fruit moth are most active during the thinning time-frame. If thinning is not completed in a timely manner, the apples do not grow large enough to be profitable.</p> <p>Most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for apple growers. Scale infestations cause lower yields, lower fruit quality, and most significantly, reduced orchard longevity. Orchards are typically productive for approximately 30 - 45 years (depending on the type of tree), taking from 2 - 10 years for the trees to bear fruit. Heavy scale infestations can shorten the productive life of the orchard by 1 to 2 years.</p> <p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforcesecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases. The re-entry exposures of concern for workers are scouting, irrigation, hand harvesting, and hand thinning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. With an REI longer than 3 days significant impacts are likely to apple production.</p> <p>Rationale for Ecological Risk Mitigation:</p> <p>Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p> <p>In light of the benefits of phosmet use on apples, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Apricots 3 lb a.i./A rate	14	<p>M/L Aerial MOE = 46</p> <p>High exposure activities (hand harvesting, hand thinning): MOE = 16 at current REI of 24 hours</p> <p>MOE 100 @ 30 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days</p>	<p>Benefits are very high for the use of phosmet in apricots. Increasing the REI beyond 3 days is expected to significantly impact apricot production by limiting the ability to perform critical activities.</p> <p>Pests are: fruit tree leafroller, green fruitworm, orange tortrix, and peach twig borer.</p>	<p>3 day REI (high exposure: hand harvesting and hand thinning, MOE = 18; low exposure: irrigation and scouting, MOE = 53) for all activities.</p> <p>Limit to 9.1 lbs a.i. per year.</p> <p>Time-limited Registration (5 years)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than predicted by the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Phosmet is often used for early season control of pest outbreaks during thinning operations and late in the season because of the 14-day PHI, which is shorter than some alternatives. The benefits for phosmet use on apricots are very high because there are few alternatives available that allow for timely entry into treated orchards to perform thinning and other orchard maintenance activities. With the removal of methyl-parathion, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. None of the alternatives provide adequate control for the target pests. Thinning operations are completed early in the growing season. Many of the pests are most active during the thinning time-frame. If thinning is not completed in a timely manner, the apricots do not grow large enough to be competitive in the marketplace.</p> <p>Most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly increases the cost of apricot production.</p> <p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforcesecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>The re-entry exposures of concern for workers are scouting, irrigation, hand harvesting, and hand thinning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. Thinning activities in apricots may be performed by hand or by using a handheld stick. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. With an REI longer than 3 days significant impacts are likely to apricot production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p> <p>In light of the benefits of phosmet use on apricots, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				
Blueberries (high bush) 1 lb a.i./A rate	3	High exposure activities (hand harvesting) MOE = 17 at current REI of 24 hours MOE 100 @ 28 days	Benefits are very high for the use of phosmet in blueberries, many alternatives are less effective than phosmet. Increasing the REI beyond 3 days is expected to significantly impact blueberry production by limiting the ability to perform critical activities. Pests: fruitworms, blueberry maggot, Japanese beetle, oblique banded leaf rollers, plum curculio, and spanworm.	3-day PHI (high exposure: hand harvesting) MOE = 19. 3-day REI (low exposure: irrigation, scouting, hand weeding, and training) MOE >100. Limit phosmet applications to 2.8 lb a.i./A per year.* Time-limited Registration (5 years) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Rationale for Worker Risk Mitigation:</p> <p>For high bush blueberries, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Growers have indicated a need to re-enter treated fields to monitor pest infestations and replace pheromone traps, consistent with Integrated Pest Management Programs and that the use of alternatives are not as effective.</p> <p>There is zero tolerance for blueberry maggot or Japanese beetle infestation. These pests have the potential to cause significant economic damage to blueberries. With a 3-day REI, there are significant benefits for using phosmet on high bush blueberries and risks of concern for re-entry workers.</p> <p>The re-entry exposure of concern for workers is hand harvesting. With an REI longer than 3 days significant impacts are likely to blueberry production.</p> <p>*The Agency has received comments indicating that the seasonal maximum application rate of 2.8 lb a.i./A per season is adequate if azinphos-methyl is available for pest control; however, the rate reduction would impact blueberry production if the use pattern for azinphos-methyl is changed. The Agency is interested in receiving additional comments on the seasonal maximum application rate for blueberries.</p> <p>Rationale for Ecological Risk Mitigation:</p> <p>Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p> <p>In light of the benefits of phosmet use on blueberries, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Cotton (1 lb a.i./A rate)	21	Aerial MOE M/L 97 @ 1 lb a.i./A Medium exposure activities (irrigation and scouting of mature plants): MOE = 55 at current REI of 24 hours MOE 100 @ 10 days	Usage of phosmet on cotton is extremely low. No impact on cotton production is expected from extending the REI to 5 days.	5-day REI (medium. exposure: scouting and irrigation, MOE = 72) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: Only 5000 acres are treated with phosmet. There is an interest in keeping this use for over wintering boll weevil. For cotton, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. For mixing and loading for aerial application, it is unlikely that the use of phosmet would exceed 7 days (w/ MOE=97) because of the limited use. Therefore, risk to mixers and loaders are not of concern.</p> <p>No field activities are critical within 5 days after application. Because of the extremely low use of phosmet, it is unlikely that a individual would be engaged in scouting and irrigation activities in phosmet treated fields for a number of consecutive days for eight hours a day, so the calculated MOE of 72 probably overstates the actual risk for this crop. No impact on cotton production is expected from extending the REI to 5 days because of the limited use and few hand activities that would occur during this period.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Cranberries (1 lb a.i./A rate) (2.8 lb a.i./A rate)	14	All activities (2.8 lbs a.i./A rate): MOE = 74 at current REI of 24 hours MOE 100 @ 6 days MOE 85 @ 3 days	New use registered in 2000. EPA has no data to determine the importance of phosmet in cranberries.	3-day REI (all activities, MOE = 85) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: For cranberries, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. With a 3-day restricted entry interval, risks from postapplication exposures are not of concern. The calculated MOE of 85 is based on the maximum rate of 2.8 pounds a.i. per acre. This is a new registration and EPA does not have use data for phosmet. Phosmet may be applied at a lower rate, which would result in lower worker exposure (MOEs > 85). The phosmet labeled use rates range from 0.93 to 2.8 lbs a.i. per acre.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Grapes (0.93 lb a.i./A rate) (1.5 lb a.i./A rate)	14 days @ > 0.93 lb a.i./A 7 days @ ≤ 0.93 lb a.i./A	<p>1.5 lb a.i./A rate M/L Aerial MOE = 92</p> <p>High exposure activities (hand harvesting, hand thinning, pruning, tying and vine training): MOE = 11 at current REI of 24 hours MOE 100 @ 34 days</p> <p>Medium exposure activities (scouting and vine training): MOE = 55 at current REI of 24 hours MOE 100 @ 10 days</p> <p>1 lb a.i./A rate High exposure activities (hand harvesting, hand thinning, pruning, tying and vine training): MOE = 17 at current REI of 24 hours MOE 100 @ 28 days</p> <p>Medium exposure activities (scouting and vine training): MOE = 83 at current REI of 24 hours</p>	<p>High benefits for critical late season control of omnivorous leafroller in California, for grape berry moth in North Central and Midwestern regions and for control of Eastern grape leafhopper in Eastern regions. Also effective for controlling Japanese Beetles.</p> <p>Increasing the REI beyond 14 days is expected to significantly impact grape production by limiting the ability to perform critical activities such as hand harvesting, pruning, tying, and vine training.</p> <p>Alternatives, other than azinphos-methyl, are more costly and not as effective.</p>	<p>1.5 lb a.i./A rate: 14-day REI (high exposure: hand harvesting, hand thinning, leaf pulling, pruning, tying and vine training MOE = 27; medium exposure: scouting and training, MOE > 100).</p> <p>1.0 lb ai/A rate: 14-day REI (high exposure: hand harvesting, hand thinning, pruning, tying and vine training MOE = 40; medium exposure: scouting and training, MOE > 100).</p> <p>Time-limited Registration (5 years)</p> <p>Limit to 4.55 lb ai/A per year.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the vineyard floor to the extent that a tractor could not pass through the vineyard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 92. Therefore, risks to mixers and loaders are not of concern.</p> <p>The benefits for phosmet use on grapes are high because there are few alternatives available (with the removal of methyl-parathion use on grapes) and none, other than azinphos-methyl, provide adequate control for omnivorous leafroller, grape berry moth Western grape leaf skeletonizer, or Japanese Beetles, the primary target pests. Carbaryl is also used on grapes; this pesticide is currently undergoing reregistration. There are some risks of concern for the grape use. Because it is too early in the reregistration process, the Agency does not know what impact, if any, that the carbaryl IRED will have on grape production. This issue will be evaluated before the phosmet IRED is finalized.</p> <p>There are significant benefits for using phosmet on grapes and risks of concern for re-entry workers. The re-entry exposures of concern for workers are hand harvesting, hand thinning, pruning, tying and vine training. With an REI longer than 14 days significant impacts are likely to grape production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p> <p>In light of the benefits of phosmet use on grapes, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Nectarines (3 lb a.i./A rate)	14	<p>M/L Aerial MOE = 46</p> <p>High exposure activities (hand harvesting, hand thinning): MOE = 16 at current REI of 24 hours</p> <p>MOE 100 @ 30 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days</p>	<p>Benefits are very high for the use of phosmet in nectarines. Increasing the REI beyond 3 days is expected to significantly impact nectarine production by limiting the ability to perform critical activities. Phosmet is used in IPM programs and for resistance management.</p> <p>Pests: oriental fruit moth, peach twig borer, San Jose scale, omnivorous leafrollers, and katydids.</p>	<p>3-day REI (high exposure: harvesting and hand thinning, MOE = 18; low exposure: irrigation and scouting, MOE = 53) for all activities.</p> <p>Time-limited Registration (5 years)</p> <p>Limit to 9.1 lb a.i./A per year.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Phosmet is often used for early season control of pest outbreaks during thinning operations and late in the season because of the 14-day PHI, which is shorter than some alternatives. The benefits for phosmet use on nectarines are very high because there are few alternatives available that allow for timely entry into treated orchards to perform thinning and other orchard maintenance activities. With the removal of methyl-parathion, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. Thinning operations are completed early in the growing season. Many of the pests such as oriental fruit moth are most active during the thinning time-frame. If thinning is not completed in a timely manner, the nectarines do not grow large enough to be competitive in the marketplace.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for nectarine growers. In addition, scale infestations have become common in nectarine orchards in the southeast. The scale infestations cause lower yields, lower fruit quality, and most significantly, reduced orchard longevity. Orchards are typically productive for approximately 20 years, taking from 5 to 7 of those years to recover the cost of orchard establishment. Heavy scale infestations can shorten the productive life of the orchard by 1 to 2 years.</p> <p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforsecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases.</p> <p>The re-entry exposures of concern for workers are scouting, irrigation, hand harvesting, and hand thinning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. Thinning activities in nectarines are often performed by hand. In addition, nectarine leaves around fruit may be removed to enhance color development in the fruit near harvest.</p> <p>With a 3-day REI, there are significant benefits for using phosmet on nectarines and risks of concern for re-entry workers. With an REI longer than 3 days significant impacts are likely to nectarine production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p> <p>In light of the benefits of phosmet use on nectarines, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Peaches (3 lb a.i./A rate)	14	<p>M/L Aerial MOE = 46</p> <p>High exposure activities (hand harvesting, hand thinning): MOE = 16 at current REI of 24 hours</p> <p>MOE 100 @ 30 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days</p>	<p>Benefits are very high for the use of phosmet in peaches. Phosmet is used in IPM programs and for resistance management.</p> <p>Pests: oriental fruit moth, plum curculio, peach twig borer, San Jose scale, omnivorous leafrollers, and katyids.</p>	<p>3 day REI (high exposure: harvesting and hand thinning, MOE = 18; low exposure: irrigation and scouting, MOE = 53) for all activities.</p> <p>Time-limited Registration (5 years)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Phosmet is often used for early season control of pest outbreaks during thinning operations and late in the season because of the 14-day PHI, which is shorter than some alternatives. The benefits for phosmet use on peaches are very high because there are few alternatives available that allow for timely entry into treated orchards to perform thinning and other orchard maintenance activities. With the removal of methyl-parathion, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. Thinning operations are completed early in the peach growing season. Many of the pests such as plum curculio are most active during the thinning time-frame. If thinning is not completed in a timely manner, the peaches do not grow large enough to be competitive in the marketplace. Peaches that are 1/8 inch smaller than the preferred 2 1/2 to 2 3/4 inch fruit sell for approximately \$4 - \$8 less per 1/2 bushel. Therefore, the amount of profit is directly related to proper thinning of peach trees.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for peach growers. In addition, scale infestations have become common in peach orchards in the southeast. The scale infestations cause lower yields, lower fruit quality, and most significantly, reduced orchard longevity. Southeastern orchards are typically productive for 12 - 14 years, taking from 5 to 7 of those years to recover the cost of orchard establishment. Heavy scale infestations can shorten the productive life of the orchard by 1 to 2 years.</p> <p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforcesecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases.</p> <p>The re-entry exposures of concern for workers are scouting, irrigation, hand harvesting, and hand thinning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. Thinning activities in nectarines are performed by hand.</p> <p>With a 3-day REI, there are significant benefits for using phosmet on nectarines and risks of concern for re-entry workers. With an REI longer than 3 days significant impacts are likely to peach production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p> <p>In light of the benefits of phosmet use on peaches, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Pears (5 lb a.i./A rate)	7	<p>M/L Aerial MOE = 28 M/L Aerial MOE = 34 @ 4 lb a.i./A rate</p> <p>High exposure activities (hand harvesting, hand thinning): MOE = 9 at current REI of 24 hours</p> <p>MOE 100 @ 37 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 28 at current REI of 24 hours MOE 100 @ 21 days</p>	<p>Benefits are very high for the use of phosmet in pears.</p> <p>Pests: codling moth and grape mealy bug (applied post-bloom)</p>	<p>3-day REI (high exposure: harvesting and hand thinning, MOE = 13; low exposure: irrigation and scouting, MOE = 40) for all activities.</p> <p>Reduce application rate to 4 lb a.i./A with a maximum of 11.2 lb a.i./A applied per year.</p> <p>Time-limited Registration (5 years)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 34 (includes rate reduction to 4 lb a.i./A). Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>The benefits for phosmet use on pears are very high because there are few alternatives available and none provide adequate control for the target pests. Most alternative pesticides result in outbreaks of secondary pests such as mites. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for pear growers. With the removal of methyl-parathion, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. Phosmet is often used late in the season because of the 7-day PHI. Because of its short REI, phosmet use is preferred near the time for fire blight removal. There is little to no hand thinning in pears.</p> <p>If the REI for phosmet were extended beyond the 7-day time-frame, significant impacts such as lack of adequate 3rd generation codling moth control. The impacts may include yield losses of 5 - 7% and losses in fruit quality. As a result, growers in the Pacific Northwest region and California could face losses of \$1,238 per acre and \$918 per acre, respectively. This change would result in a reduction in profit of approximately 90%. Fire blight is a disease, which if not controlled by pruning diseased branches, could lead to tree loss and, therefore, significant yield loss.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforcesecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases.</p> <p>The re-entry exposures of concern for workers are scouting, irrigation, pruning for fire blight removal, and hand harvesting. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI.</p> <p>With a 3-day REI, there are significant benefits for using phosmet on pears and risks of concern for re-entry workers. With an REI longer than 3 days significant impacts are likely to pear production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p> <p>In light of the benefits of phosmet use on pears, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Almonds (3 lb a.i./A rate)	30	<p>M/L Aerial MOE = 46</p> <p>High exposure activities (hand harvesting, poling and pruning): MOE = 19 at current REI of 24 hours</p> <p>MOE 100 @ 27 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 93 at current REI of 24 hours MOE 100 @ 3 days</p>	<p>Benefits are moderate for the use of phosmet on almonds, due to the availability of azinphos-methyl in treating many of the same key pests.</p> <p>Pests: navel orange worm, peach twig borer, and San Jose scale.</p>	<p>30-day PHI (high exposure: harvesting, poling and pruning, MOE >100)</p> <p>3-day REI (low exposure: irrigation and scouting), MOE > 100 for all activities.</p> <p>Pruning must occur before dormant applications of phosmet.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 46. Therefore, risks to aerial mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI.</p> <p>Exposure to workers is limited because almonds are mechanically harvested. Exposures to workers re-entering treated almond orchards are not of concern to harvest or perform other activities associated with almond harvest because of the 30-day PHI. With a 3-day REI, low exposure tasks such as irrigation and scouting are not a risk concern and the increased REI is not expected to have any impact on almond production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Pistachios	14	M/L Aerial MOE = 46	Benefits are moderate for the use of phosmet on pistachios, and pecans.	14-day PHI (high exposure: harvesting, poling and pruning), MOE =44.
Pecans (3 lb a.i./A rate)	14	High exposure activities (hand harvesting, poling and pruning): MOE = 19 at current REI of 24 hours MOE 100 @ 27 days Low exposure activities (irrigation and scouting): MOE = 93 at current REI of 24 hours MOE 100 @ 3 days	Pistachio Pests: navel orange worm, flat mite, and leafrollers. Pecan Pests: pecan nut casebearer, hickory shuckworm, and black pecan aphid.	3-day REI (low exposure: irrigation and scouting), MOE > 100 for all activities. Limit applications to 12 lb a.i./A per year for pistachios. Limit applications to 7 lb a.i./A per year for pecans. Pruning must occur before dormant applications of phosmet. Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are preformed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI.</p> <p>Exposures to workers re-entering treated nut orchards are not of concern for harvesting or pruning activities because harvesting is performed mechanically and pruning activities are to be performed during the dormant phase and prior to phosmet treatments. There are some concerns for workers who perform poling activities; however, these activities only take place after harvest, and on a limited basis. The actual MOE is anticipated to be higher than the calculated MOE of 44. With a 3-day REI, low exposure tasks such as irrigation and scouting are not a risk concern. The increased REI is not expected to have any impact on pistachio or pecan production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Walnuts (5.95 lb a.i./A rate)	14	<p>M/L Aerial MOE = 23</p> <p>High exposure activities (hand harvesting, poling and pruning): MOE = 9 at current REI of 24 hours</p> <p>MOE 100 @ 37 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 47 at current REI of 24 hours MOE 100 @ 13 days</p>	<p>Benefits are moderate for the use of phosmet in walnuts, provided that azinphos-methyl is available for use. Harvesting is mechanical and there are no poling activities in walnuts.</p> <p>Pests: codling moth, navel orange worm, walnut husk fly, fall webworm, and redhumped caterpillar.</p>	<p>14-day PHI (high exposure: harvesting and pruning); no high exposure activities are anticipated; (low exposure: irrigation and scouting), MOE = >100 for all activities.</p> <p>7-day REI (low exposure: irrigation and scouting), MOE = 70 for all activities.</p> <p>Pruning must occur before dormant applications of phosmet.</p> <p>Limit applications to 12 lb a.i./A per year.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are preformed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>The re-entry exposures of concern for workers are hand harvesting, poling and pruning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI.</p> <p>Exposures to workers re-entering treated walnut orchards are not of concern for harvesting or pruning activities because harvesting is performed mechanically and pruning activities are to be performed during the dormant season and prior to phosmet treatments. There is no poling in walnut trees. With a 7-day REI, low exposure tasks such as irrigation and scouting, there are some concerns for workers. However, irrigation is often a no contact activity, as defined by the WPS and scouting is performed on a limited basis. The increased REI is not expected to have any impact on walnut production.</p> <p>Rationale for Ecological Risk Mitigation:</p> <p>Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Filberts Brazil nuts Beechnuts Butternuts Cashew Chestnut Chinquapin Hickory nuts Macadamia nuts (5.95 lb a.i./A rate)	14	M/L Aerial MOE = 23 High exposure activities (hand harvesting, poling and pruning): MOE = 9 at current REI of 24 hours MOE 100 @ 37 days Low exposure activities (irrigation and scouting): MOE = 47 at current REI of 24 hours MOE 100 @ 13 days	Benefits not assessed.	28-day PHI (high exposure: harvesting and pruning), MOE = 60; (low exposure: irrigation and scouting), MOE >100. 7-day REI for all activities (low exposure: irrigation and scouting), MOE = 70; (note: high exposure harvesting and pruning take place after 28-day PHI) Pruning must occur before dormant applications of phosmet. Limit applications to 12 lb a.i./A per year. Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Rationale for Worker Risk Mitigation: Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>The re-entry exposures of concern for workers are hand harvesting, poling and pruning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI.</p> <p>Exposures to workers re-entering treated nut orchards are not of concern for harvesting or pruning activities because harvesting is likely to be performed mechanically and pruning activities are to be performed prior to phosmet treatments. There are some concerns for workers who perform poling activities in the various nut trees. Poling activities only take place after harvest (28-day PHI), and on a limited basis, the anticipated MOE is anticipated to be higher than the calculated MOE of 56. With a 7-day REI, low exposure tasks such as irrigation and scouting, there are some concerns for workers. However, irrigation is often a no contact activity, as defined by the WPS and scouting is performed on a limited basis. In addition, the Agency does not have much information on how much phosmet is used on these nut crops. Given the types of activities that are performed in a nut orchard, the increased REI is not expected to have any impact on nut production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Plums/Prunes (3 lb a.i./A rate)	7	<p>M/L Aerial MOE = 46</p> <p>High exposure activities (hand harvesting, hand thinning): MOE = 16 at current REI of 24 hours</p> <p>MOE 100 @ 30 days</p> <p>Low exposure activities (irrigation and scouting): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days</p>	<p>Benefits are very high for the use of phosmet in plums and prunes. Phosmet is used in IPM programs and for resistance management.</p> <p>Western Pests: oriental fruit moth, peach twig borer, codling moth, and citrus cutworm.</p> <p>Eastern Pests: plum curculio and apple maggot.</p>	<p>3 day REI (high exposure: harvesting and hand thinning, MOE = 18; low exposure: irrigation and scouting, MOE = 53) for all activities.</p> <p>Limit to 9.1 lb a.i./A per year.</p> <p>Time-limited Registration (5 years)</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p>
<p>Rationale for Worker Risk Mitigation:</p> <p>Aerial application (using engineering controls) only occurs when rain has softened the orchard floor to the extent that a tractor could not pass through the orchard without damaging the orchard. Given that aerial applications are rarely performed, and when aerial applications are performed, it is unlikely that it would occur for up to seven consecutive days, actual risk is anticipated to be lower than that predicted by the calculated MOE of 46. Therefore, risks to mixers and loaders are not unreasonable given the occasional, yet critical need for aerial application.</p> <p>Phosmet is often used for early season control of pest outbreaks during thinning operations and late in the season because of the 7-day PHI, which is shorter than some alternatives. The benefits for phosmet use on plums and prunes are very high because there are few alternatives available that allow for timely entry into treated orchards to perform thinning and other orchard maintenance activities. With the removal of methyl-parathion, azinphos-methyl and phosmet are the only remaining organophosphate pesticides that provide effective control of key target pests. Thinning operations are completed early in the plum growing season, it should be noted that prunes are often mechanically thinned. If thinning is not completed in a timely manner, the plums and prunes do not grow large enough to be profitable. The amount of profit is directly related to proper thinning of plum and prune trees.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
<p>Most alternative pesticides result in outbreaks of secondary pests such as mites or scale. Stakeholder comments indicate that miticides are expensive (\$45 - \$50/acre) and their use significantly reduces the profit margin for plum and prune growers. The scale infestations cause lower yields, lower fruit quality, and most significantly, reduced orchard longevity. Southeastern orchards are typically productive for 15 - 20 years, taking from 4 - 5 of those years for the trees to bear fruit. Heavy scale infestations can shorten the productive life of the orchard by 1 to 2 years.</p> <p>Other stakeholder comments received by the Agency indicate that the timing of re-entry into treated orchards is critical because of the availability of labor to perform the tasks. Many growers participate with a program administered through the U.S. Department of Labor and the Department of Justice's Immigration and Naturalization Service (INS), called the H-2A program. For a complete discussion of the H-2A program, see the comment from Al Pearson, Big 6 Farm, in the public docket and the U.S Department of Labor website, http://workforcesecurity.doleta.gov/foreign/dflc.asp#h2a. Growers participating in the H2-A program must guarantee a percentage of workers pay. If workers are not effectively utilized for the time they are available, the cost of production increases.</p> <p>The re-entry exposures of concern for workers are scouting, irrigation, hand harvesting, and hand thinning. Scouting is a handler activity which means that scouting can be performed during the REI provided the appropriate handler PPE is used. In addition, certified crop advisors can determine the appropriate level of PPE used during the REI. Thinning activities in plums are often performed by hand, while prunes are generally thinned by mechanical shaking.</p> <p>With a 3-day REI, there are significant benefits for using phosmet on plums and prunes and risks of concern for re-entry workers. With an REI longer than 3 days significant impacts are likely to plum and prune production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited application rate as well as the application method and timing modifications.</p> <p>In light of the benefits of phosmet use on plums and prunes, EPA finds the continued use to be warranted in the near term. A time-limited registration of 5 years with interim mitigation will be allowed.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Potatoes (1 lb a.i./A rate)	7	Medium exposure activities (scouting and irrigation of mature plants): MOE = 55 at current REI of 24 hours MOE 100 @ 10 days	Usage of phosmet is low. No impact on potato production is expected from extending the REI to 5 days.	5-day REI (medium. exposure: irrigation and scouting of mature plants, MOE =72) Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
<p>Rationale for Worker Risk Mitigation: For potatoes, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. Because potatoes are mechanically harvested, the estimated risk for hand harvesting is not relevant for setting the REI; therefore, exposures to individuals performing scouting tasks on mature plants have the risk of greatest concern.</p> <p>The Agency has received comments indicating that scouting has limited exposure because the workers drive around the perimeter of the field, stopping to sample for pests at 3 or 4 sites. Therefore, EPA believes that the calculated MOE of 72 at 5 days may overstate the actual risk to scouts. In addition, comments have indicated that the warm climate would prohibit workers from wearing full PPE to enter treated fields for scouting and irrigating purposes as provided for by the existing low contact exemption in the Worker Protection Standard. No impact on potato production is expected from extending the REI to 5 days.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from these modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Christmas Trees/ Evergreen Trees (1 lb a.i./A rate)	N/A	<p>M/L Aerial MOE = 40, 1,200 acres treated</p> <p>M/L Aerial MOE >100, 350 acres treated</p> <p>High exposure activities (harvesting, staking, topping, and training): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days</p> <p>Low exposure activities (pruning, thinning, cone pruning, and cone harvesting): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days</p>	Benefits not assessed.	<p>13-day REI (high exposure: harvesting, staking, topping, and training) MOE > 100.</p> <p>Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.</p> <p>Limit to 3 applications per year.</p>
<p>Rationale for Worker Risk Mitigation: For Christmas Trees, the risks for workers mixing and loading phosmet for aerial applicators are not of concern, assuming 350 acres or less are treated per day. The Agency has received comments that indicate Christmas Tree farms are generally 350 acres or less. For evergreen trees, the handler risks of concern are for workers mixing and loading phosmet for aerial applications to forestry. Exposure would be reduced provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. These estimates are based on the value for aerial application of 1,200 acres treated per day which is a high-end estimate of the number of acres treated and may not be representative of the actual acreage an applicator would treat in a day. There is not much phosmet use on Christmas trees or evergreen trees.</p> <p>With a 13-day REI, the risks to workers re-entering treated orchards to perform harvesting, staking, topping, and training tasks are not of concern and the increased REI is not expected to have any impact on Christmas tree or evergreen production.</p> <p>Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area, during the bloom phase. Reduced environmental exposure from phosmet use will result from the limited number of applications as well as the application method and timing modifications.</p>				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Pine Seedlings (0.35 lb a.i./A rate)	N/A	M/L/A: No data to assess the risks of this application.	Benefits not assessed.	Long-sleeved shirt and long pants, shoes, socks, additional layer of clothing, chemical-resistant gloves, and an air purifying respirator (OV).
Rationale for Worker Risk Mitigation: The risks associated with the dipping of pine seedlings have not been quantified, but the Agency believes it is prudent to require handlers to wear: long-sleeved shirt and long pants; shoes; socks; additional layer of clothing; apron; chemical-resistant gloves; and an air purifying (OV) respirator to mitigate risks.				
Cattle/Swine (0.02 lb a.i./A rate) (0.004 lb a.i./A rate)	Cattle 3 day pre-slaughter; Swine 1 day pre-slaughter	There are numerous incidents involving the high pressure hose application method.	Benefits not assessed.	Remove the high pressure hose application method from the labels. Do not apply to the point of runoff.
Rationale for Worker Risk Mitigation: Because of the incidents involving workers applying phosmet with a high pressure hose, the registrant has agreed to remove this application method from the labels. The cattle backrubber use will be retained. Removing the high pressure hose from the labels will reduce worker exposure and incidents.				
Pine Seed Orchards (1 lb a.i./A rate)	NA	High exposure activities (hand pollination, harvesting, staking, topping, and training): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days Medium exposure activities (pruning, thinning, cone pruning, and cone harvesting): MOE = 46 at current REI of 24 hours MOE 100 @ 13 days	New use registered in 2001. EPA has no data to determine the importance of phosmet in pine seed orchards.	13-day REI Limit spray drift; turn airblast spray nozzles inward on row ends; and do not apply when bees are in the area.
Rationale for Worker Risk Mitigation: For pine seed orchards, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. These estimates are based on the value for aerial application of 150 - 300 acres treated per day which is a reasonable high-end estimate of the number of acres treated. With a 13-day restricted entry interval, risks from postapplication exposures are not of concern. In pine seed orchards, mowing is a no contact activity and thus could be performed during the REI. The Agency understands that there are some critical low exposure activities that may need to be performed during the 13-day REI. The need for exceptions for such activities will be considered in the comment period.				
Rationale for Ecological Risk Mitigation: Spray drift will be reduced through turning airblast spray nozzles inward on row ends and incidents to honey bees will be avoided if phosmet is not applied when bees are likely to be in the area. Reduced environmental exposure from phosmet use will result from these modifications.				

Crop	Current PHI	Risks of Concern	Benefits	Proposed Mitigation
Ornamental (Nursery) (0.008 lb a.i./A rate)	NA	MOE \geq 100 at current REI of 24 hours for low exposure activities	Benefits not assessed, risks not of concern.	Acceptable with engineering controls Limit to 3 applications per year.
Rationale for Worker Risk Mitigation: For ornamental trees in nurseries, handler risks are not of concern provided engineering controls are employed; that is, water soluble bags for wettable powder formulations and closed mixing/loading systems for liquid formulations. Postapplication risks are not of concern at the current 24 hour REI.				
Rationale for Ecological Risk Mitigation: Reduced environmental exposure from phosmet use will result from the limited number of applications.				
Fire Ant Control (0.009 lb a.i./A rate)	NA	Mixer/loader MOEs on day of treatment range from 115 - 158	Public health use.	Retain this use on agricultural label, limited to use by a pest control operator
Voluntary Use Cancellation				
Household Ornamental	NA	Mixing/loading/applying wettable powders with a low pressure handwand: MOEs = 42 - 83	Not assessed	Accept cancellation
Household Fruit Tree	NA	Mixing/loading/applying wettable powders with a low pressure handwand: MOEs = 42 - 83	Not assessed	Accept cancellation
Domestic Pet		Post application risk to children is high.	Not assessed	Accept cancellation

(2) Animal Use Risk Mitigation

All products used on dogs will be voluntarily canceled. The high pressure hose application to cattle and swine will be removed from labels.

(3) Homeowner Use Risk Mitigation

All products used in home garden (except fire ant treatments) and all products used on dogs will be voluntarily canceled. Fire ant treatment products in a residential setting will be permitted only when applied by a pest control operator.

(4) Handler Risk Mitigation

To reduce exposure to handlers, application rates will be reduced, where feasible; and a time-limited registration will be implemented for nine crops, see Table 16 for details, and the high pressure hose application to cattle and swine will be removed from labels. In addition, all products used in home garden and all products used on dogs will be voluntarily canceled. Fire ant treatment products in a residential setting will be permitted only when applied by a pest control operator.

(5) Post-Application Risk Mitigation

All products used in home garden and all products used on dogs will be voluntarily canceled. Re-entry intervals for workers entering treated orchards, fields or vineyards will be increased; application rates will be reduced, where feasible; and a time-limited registration will be implemented for nine crops, see Table 16 for details.

2. Environmental Risk Mitigation

The number of Applications per season will be reduced to three, unless specified in this document or current labels specify fewer. Registrants will also be required to add a precautionary statement on all labels indicating that phosmet is highly toxic to bees.

The following statements need to be added to end use product labels:

“This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.”

“This product is highly toxic to bees exposed directly to treatment of residues on crops. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Protective information may be obtained from your cooperative Agricultural Extension Service.”

“This chemical can contaminate surface water through aerial and ground spray applications. Under some conditions, it may also have a high potential for runoff into surface water after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlying tile drainage systems that drain to surface water.”

The following statements need to be added to manufacturing use product labels:

“This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless the action is in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.”

E. Other Labeling Requirements

In order to remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing phosmet. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at this time. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the

specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the Federal Register before the end of 2001.

2. Spray Drift Management

The Agency is in the process of developing more appropriate label statements for spray, and dust drift control to ensure that public health, and the environment is protected from unreasonable adverse effects. In August 2001, EPA published draft guidance for label statements in a pesticide registration (PR) notice ("Draft PR Notice 2001-X" http://www.epa.gov/PR_Notices/#2001). A Federal Register notice was published on August 22, 2001 (<http://www.epa.gov/fedrgstr>) announcing the availability of this draft guidance for a 90-day public comment period. After receipt, and review of the comments, the Agency will publish final guidance in a PR notice for registrants to use when labeling their products.

Until EPA decides upon, and publishes the final label guidance for spray, and dust drift, registrants (and applicants) may choose to use the statements proposed in the draft PR notice. Registrants should refer to, and read the draft PR notice to obtain a full understanding of the proposed guidance, and its intended applicability, exemptions for certain products, and the Agency's willingness to consider other versions of the statements.

For purposes of complying with the deadlines for label submission outlined in this document, registrants (and applicants) may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling.

For products applied outdoors as liquids (except mosquito adulticides):

"Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals."

"For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles."

"For orchard and vineyard airblast applications, do not direct spray above trees and vines, and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 -10 mph at the application site as measured by an anemometer outside of the orchard or vineyard on the upwind side."

“For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.”

For overhead chemigation:

“Apply only when wind speed is 10 mph or less.”

On all product labels:

“The applicator also must use all other measures necessary to control drift.”

For products applied as dusts—all affected products, except home and garden products:

“Do not allow dust to drift from the application site, and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.

“For ground rig applications, apply product no more than 4 feet above the ground or the crop canopy, and only when wind speed is 10 mph or less at the application site as measured by an anemometer.”

“For orchard and vineyard ground applications, do not direct dust above trees and vines, and shut off application at row ends, and toward outer rows. Apply only when wind speed is 3 - 10 mph at the application site as measured by an anemometer outside of the orchard or vineyard on the upwind side.”

“For aerial applications, use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. If application includes a no-spray zone, do not release dust at a height greater than 10 feet above the ground or the crop canopy.”

On all product labels:

“The applicator also must use all other measures necessary to control drift.”

For hand-applied products, including home and garden products, to be applied as sprays or dusts:

“Do not allow spray or dust to drift from the application site, and contact people, structures people occupy at any time, and the associated property, parks and recreation areas,

nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. Apply only when wind speed is not more than 10 mph. For sprays, apply largest size droplets possible.”

Alternatively, registrants may elect to use the following language, which is the current Agency policy on drift labeling:

For products that are applied outdoors in liquid sprays, regardless of application method, the following must be added to the labels:

“Do not allow this product to drift.”

The Agency recognizes that the above option does not address other application types. Registrants may therefore wish to adapt some variation of the old, and proposed new language for their particular products, depending on their application methods.

V. What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV and V, which include, among other things, submission of the following:

For products containing phosmet, registrants need to submit the following items for each product within eight months of the date of the PDCI:

(1) an application for reregistration (EPA Form 8570-1, filled in, with a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document);

(2) responses to the generic and/or product specific Data Call-Ins (DCIs) as instructed in the enclosed DCIs;

(3) two copies of the Confidential Statement of Formula (CSF); and

(4) a certification with respect to data compensation requirements. Note that the first set of required responses for the product-specific DCI is due 90 days from the receipt of the DCI. The second set of required responses is due eight months from the date of the DCI. For questions about product reregistration and/or the product-specific DCI, please contact Barbara Briscoe at (703) 308-8177.

Labels: For each product containing phosmet, registrants need to submit five copies of the draft label incorporating all label amendments outlined in Table 17 of this document, within 120 days of the date of this interim RED.

For the generic DCI, the following items are due:

- (1) DCI response form, due 90 days from the receipt of the DCI;
- (2) Registrant response form, due 90 days from the receipt of the DCI;
- (3) the actual generic data in response to the DCI.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of phosmet for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

- 21-Day Dermal Toxicity. The submitted 21-day dermal toxicity study [MRID 44795801] is considered to be acceptable, and satisfies the guideline requirement [870.3200] for a 21-day dermal toxicity study; however, the use of a control group run specifically to obtain cholinesterase data for comparison with the phosmet-treated groups in the study is inappropriate. In order to verify the NOAEL, historical control data for cholinesterase activity [plasma and brain] must be submitted; in addition, the registrant should conduct a statistical analysis of the combined control cholinesterase data.
- Subchronic Neurotoxicity. To confirm the lack of neuropathology for phosmet, additional data are required to fully characterize the severity of the digestion chambers (lesions) in the sciatic and peroneal nerves observed in high-dose male rats. Specifically, the registrant should provide data concerning the number of fibers affected in each case, compared with the same information for historical controls. Incidence of these and similar lesions in historical controls should be fully described.
- Residue Chemistry. Representative storage stability studies for phosmet oxon in an oil seed or nut matrix.
- Residue Chemistry. Geographically representative field trial residue data for blueberries.
- Residue Chemistry. Residue data for cotton gin byproducts (a new requirement under OPPTS 860.1550).
- Environmental Fate. To better understand the persistence and mobility of phosmet in the environment, an Aerobic Soil Metabolism study, [835.4100] and Leaching-Adsorption/Desorption studies [835.1230 and 835.1240] on the toxic degradate phosmet oxon are required.

- Spray Drift. The following guideline studies are required because phosmet is applied aerially:
A. Background for Pesticide Aerial Drift Evaluation, [840.1000];
B. Spray Droplet Size Spectrum, [840.1100]; and
C. Spray Drift Field Deposition, [840.1200].

Gowan Company has agreed to submit the following studies under an agreement reached with the Agency:

- Biomonitoring of workers;
- Study of the feasibility of gloves suitable for field workers; and
- Updated benefits information.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. Registrant responses are under review.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies.

The MUP labeling should bear the labeling contained in Table 17 at the end of this section.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, accompanies this interim RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 17 at the end of this section.

C. Existing Stocks

The Agency has determined that all phosmet products sold or distributed after June 30, 2002, must bear labeling that is approved by the EPA and is consistent with the risk mitigation measures identified in this interim RED.

In addition, EPA has reached an agreement with Gowan Company that provides for the re-evaluation of phosmet in five years. Gowan Company has committed to develop certain data during this time. All products produced after October 30, 2006, will bear labeling with extended REIs, as specified in the agreement, for nine crops unless data are submitted in a timely fashion and EPA decides to extend the existing REIs or establish a lesser one. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 17: Summary of Labeling Changes for Phosmet		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	“Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”	Directions for Use
	“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”	Directions for Use
	“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”	Directions for Use
Formulation Restriction	This product may only be used to formulate wettable powder end-use products that are packaged in water soluble packaging.	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.	Precautionary Statements
End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
Handler PPE requirements (all formulations)	<p>Note the following information when preparing labeling for all end use products:</p> <p>For sole-active-ingredient end-use products that contain Phosmet, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.</p> <p>For multiple-active-ingredient end-use products that contain Phosmet, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label,</p>	

Description	Amended Labeling Language	Placement on Label
	<p>and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.</p> <p>PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity testing for the end-use product. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p>	
<p>PPE Requirements Established by the IRED For Liquid Products</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical resistant material</i>). “If you want more options, follow the instructions for category” [registrant inserts A, B, C, D, E, F, G, H] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants; - Shoes plus socks; - Chemical-resistant gloves for mixers and loaders, applicators using hand held equipment and persons exposed to the concentrate; and - Chemical resistant apron for mixers and loaders, and persons exposed to the concentrate. <p>See Engineering Controls for additional requirements.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the IRED for wettable powder products</p> <p>The registrant has agreed that only wettable powder products packaged in water soluble packaging will be eligible for reregistration.</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical resistant material</i>). “If you want more options, follow the instructions for category” [registrant inserts A, B, C, D, E, F, G, H] “on an EPA chemical-resistance category selection chart.”</p> <p>“Applicators performing pine seedling dipping must wear:</p> <ul style="list-style-type: none"> - Coveralls over long-sleeved shirt and long pants; - Chemical-resistant gloves; - Chemical-resistant footwear plus socks; - Chemical-resistant apron; and - A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or He prefilter.” <p>“Mixers, loaders, all other applicators and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants; - Socks and shoes; - Chemical-resistant gloves for mixers and loaders, applicators using hand held equipment; - Chemical resistant apron for mixers and loaders. <p>See Engineering Controls for further requirements.”</p> <p>Note: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation in the above respirator statement must be dropped.</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the IRED for Formulations Applied as Dust	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical resistant material</i>). “If you want more options, follow the instructions for category” [registrant inserts A, B, C, D, E, F, G, H] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - Coveralls over long-sleeved shirt and long pants; - Chemical-resistant gloves; - Chemical-resistant footwear plus socks; - Chemical-resistant apron; - Chemical-resistant headgear if overhead exposure; and - A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or He prefilter.” <p>Note: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation in the above respirator statement must be dropped.</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>Add the following statement for liquid, dust and wettable powder formulations:</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE Requirements)

Description	Amended Labeling Language	Placement on Label
Engineering Controls for Liquid Formulations	<p>“Engineering Controls”</p> <p>“Mixers and loaders supporting aerial or chemigation applications must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], and must:</p> <ul style="list-style-type: none"> - wear the personal protective equipment required above for mixers/loaders; - wear protective eyewear if the system operates under pressure; and - be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls and chemical-resistant footwear.” <p>"Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."</p> <p>“Applicators using airblast equipment and flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators and flaggers must:</p> <ul style="list-style-type: none"> - wear the personal protective equipment required above for applicators using motorized ground equipment and flaggers; - be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure; - take off any PPE that was worn in the treated area before reentering the cab; and - store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” 	

Description	Amended Labeling Language	Placement on Label
Engineering Controls Wettable Powder Formulations	<p>“Engineering Controls”</p> <p>“Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must:</p> <ul style="list-style-type: none"> - wear the personal protective equipment required above for mixers/ loaders; and - be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, chemical-resistant footwear, and a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R or P or He prefilter.” <p>“Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].”</p> <p>“Applicators using airblast equipment and flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators and flaggers must:</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required above for airblast applicators and flaggers; -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear if overhead exposure; -- take off any PPE that was worn in the treated area before reentering the cab; and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” 	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.)
User Safety Recommendations	<p>“User Safety Recommendations.</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	Precautionary Statements. Hazards to Humans and Domestic Animals (immediately following Engineering Controls) (Must be placed in a box.)

Description	Amended Labeling Language	Placement on Label
Environmental Hazards	<p>“This chemical can contaminate surface water through aerial and ground spray applications. Under some conditions, it may also have a high potential for runoff into surface water after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlaying tile drainage systems that drain to surface water. Limit spray drift.</p> <p>This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.</p> <p>This product is highly toxic to bees exposed directly to treatment of residues on crops. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Protective information may be obtained from your cooperative Agricultural Extension Service.”</p>	Precautionary Statements (immediately following the User Safety Recommendations)
Restricted Entry Interval	“Do not enter or allow entry into treated areas during the restricted entry interval (REI). The REI for each crop is listed in the directions for use associated with each crop.”	Directions for Use, Agricultural Use Requirements Box

Description	Amended Labeling Language	Placement on Label
Restricted-Entry Interval Liquid and Wettable Powder Formulations	<p>The following crops have an REI of 3 days:</p> <p>Apples, Crabapples, Peaches, Pears, Apricots, Plums/Prunes, Nectarines, Sweet Cherries, Tart Cherries, Almonds, Pecans, Pistachios, Lowbush Blueberries, Highbush Blueberries, and Cranberries.</p> <p>The following crops have an REI of 5 days:</p> <p>Sweet Potatoes, Potatoes, Alfalfa, Clover, Cotton, Dry Peas, and Green Peas.</p> <p>The following crops have an REI of 7 days:</p> <p>Walnuts, Beechnut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filberts, Hickory Nuts or Macadamia Nuts, and Kiwifruit.</p> <p>The following crops have an REI of 13 days:</p> <p>Christmas Trees, Evergreen Trees, and Pine Seed Orchards.</p> <p>Grapes: REI=14 days.</p>	Directions for Use, Application Instructions

Description	Amended Labeling Language	Placement on Label
Early Re-entry Personal Protective Equipment Established by the IRED.	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> - coveralls; - shoes plus socks; and - chemical-resistant gloves made of any waterproof material.” 	Directions for Use, Agricultural Use Requirements Box
Double Notification	“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area.”	Directions for Use, Agricultural Use Requirements Box
Entry Restrictions for Dust Formulations	“Do not enter or allow entry until dusts have settled.”	Directions for Use, under Application Restrictions
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Directions for Use, directly above the Agricultural Use Box.

Description	Amended Labeling Language	Placement on Label
Additional Restrictions	<p>Registrants amend labels of all products to reflect the following:</p> <p>All formulations: “Use in residential, park or recreational areas is prohibited.</p> <p>Liquid Products:</p> <p>These products are limited to use on the following crops: alfalfa, cotton, blueberries, and potatoes. Fire Ant treatment is limited to use by a pest control operator only. Potatoes must be harvested mechanically. Sweet potatoes must be harvested mechanically.</p> <p>Alfalfa: Do not apply more than once per cutting.</p> <p>Blueberries, low bush: PHI=7 days Limit phosmet applications to 2.8 lb a.i./A per year.</p> <p>Blueberries, highbush: Limit phosmet applications to 2.8 lb a.i./A per year.</p>	Directions for Use

Description	Amended Labeling Language	Placement on Label
Additional Restrictions	<p>Wettable Powder Products:</p> <p>“Potatoes must be harvested mechanically.”</p> <p>“Sweet potatoes must be harvested mechanically.”</p> <p>Kiwifruit: PHI=28 days</p> <p>Peas (green): PHI= 18 days</p> <p>Apricots, Plums/Prunes and Nectarines: Limit phosmet applications to 9.1 lb a.i./A per year.</p> <p>Pears: Use rate for pears reduced from 5 lb a.i./A to 4 lb a.i./A. Limit phosmet applications to 11.2 lb a.i./A per year.</p> <p>Grapes: Limit phosmet applications to 4.55 lb a.i./A per year.</p> <p>Blueberries, low bush: PHI=7 days Limit phosmet applications to 2.8 lb a.i./A per year.</p> <p>Blueberries, highbush: Limit phosmet applications to 2.8 lb a.i./A per year.</p> <p>Cherries, sweet: PHI=19 days Limit phosmet applications to 5.25 lb a.i./A per year.</p> <p>Cherries, tart: Limit phosmet applications to 5.25 lb a.i./A per year.</p>	

Description	Amended Labeling Language	Placement on Label
Additional Restrictions	<p>For all nut crops:</p> <p>“Nuts must be harvested mechanically.”</p> <p>“Pruning in nut crops must occur before dormant applications of phosmet.”</p> <p>Pistachios:</p> <p>Limit phosmet applications to 12 lb a.i./A per year.</p> <p>Pecans:</p> <p>Limit phosmet applications to 7 lb a.i./A per year.</p> <p>Walnuts:</p> <p>Limit phosmet applications to 12 lb a.i./A per year.</p> <p>Beechnut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filberts, Hickory Nuts or Macadamia Nuts:</p> <p>PHI=28</p> <p>Limit phosmet applications to 12 lb a.i./A per year.</p> <p>Christmas trees and evergreen trees:</p> <p>Limit phosmet applications to 3 per year.</p> <p>Cattle, Swine:</p> <p>"Do not apply to the point of runoff."</p> <p>No high pressure hose application method allowed.</p> <p>Limit phosmet applications to 3 per year for the following crops:</p> <p>Ornamental (nursery), Christmas Trees, Evergreen Trees,</p> <p>Dust Products: Do not apply to grapes.</p>	

Description	Amended Labeling Language	Placement on Label
<p>Spray Drift Restrictions for Outdoor Products Applied as a Liquid</p>	<p>For purposes of complying with the deadlines for label submission outlined in this document, registrants (and applicants) may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling.</p> <p><u>For products applied outdoors as sprays:</u></p> <p>“Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.”</p> <p>“For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.”</p> <p>“For orchard and vineyard airblast applications, do not direct spray above trees and vines, and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 -10 mph at the application site as measured by an anemometer outside of the orchard or vineyard on the upwind side.”</p> <p>“For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.”</p> <p>“The applicator also must use all other measures necessary to control drift.”</p> <p>For overhead chemigation:</p> <p>“Apply only when wind speed is 10 mph or less.”</p>	<p>Directions for Use in General Precautions and Restrictions</p>

Description	Amended Labeling Language	Placement on Label
Spray Drift Restrictions for Outdoor Products Applied as a Dust	<u>For products applied as dusts:</u> “Do not allow dust to drift from the application site, and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.” “The applicator also must use all other measures necessary to control drift.”	Directions for Use

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.

Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Related Documents and How to Access Them

This interim Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of January 15, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on March 20, 2000.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: "<http://www.epa.gov/pesticides/op>."

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT		USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>			
New Guideline Number	Old Guideline Number		
830.1550	61-1	Product Identity and Composition	All 40510801, 40274801, 43868002
830.1600	61-2A	Start. Mat. & Mnfg. Process	All 00075996, 00112317
830.1620		Description of Production Process	All 40510802, 43868002
830.1670	61-2B	Formation of Impurities	All 40510802, 43868002
830.1700	62-1	Preliminary Analysis	All 40510801, 43868001
830.1750	62-2	Certification of limits	All 40510801, 43868001
830.1800	62-3	Analytical Method	All 00112263, 00112314, 00112317, 00126567, 40510801, 43868001
830.6302	63-2	Color	40274801
830.6303	63-3	Physical State	40274801
830.6304	63-4	Odor	40274801
830.6313		Stability	All 40274801
830.7200	63-5	Melting Point	40274801
830.7300	63-7	Density	All 40274801
830.7840 830.7860	63-8	Solubility	All 40344401, 40274801
830.7950	63-9	Vapor Pressure	All 40344401
830.7550	63-11	Octanol/Water Partition Coefficient	All 40344401
830.7000	63-12	pH	All 40274801

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT			USE PATTERN	CITATION(S)
830.6313	63-13	Stability	All	40274801
830.6314	63-14	Oxidizing/Reducing Action	All	41909901
830.6316	63-16	Explodability	All	41909901
830.6317	63-17	Storage Stability	All	41909901
830.7100	63-18	Viscosity	All	41909901
830.6320	63-20	Corrosion characteristics	All	41909901
<u>ECOLOGICAL EFFECTS</u>				
850.2100	71-1	Avian Acute Oral Toxicity	A, B	00084460
850.2200	71-2A	Avian Dietary Toxicity - Quail	A, B	00022923, 0013707
850.2200	71-2B	Avian Dietary Toxicity - Duck	A, B	00022923, 00109135
850.2400	71-3	Wild Mammal Toxicity	A, B	0046189
850.2300	71-4A	Avian Reproduction - Quail	A, B	00125786
850.2300	71-4B	Avian Reproduction - Duck	A, B	00105999
850.1075	72-1A	Fish Toxicity Bluegill	A, B	00063194, 112306
850.1075	72-1C	Fish Toxicity Rainbow Trout, Fathead Minnow, Channel Catfish	A, B	00109135, 00063194
850.1010	72-2A	Invertebrate Toxicity	A, B	00063194, 00085219, 43752603
850.1010	72-2B	Invertebrate Toxicity - TEP	A, B	40612701, 43752603
None	72-3A	Estuarine/Marine Toxicity - Fish	A, B	40612702
None	72-3B	Estuarine/Marine Toxicity - Mollusk	A, B	40098001
None	72-3C	Estuarine/Marine Toxicity - Shrimp	A, B	40098001 40094602, 40657201
None	72-4A	Fish- Early Life Stage	A, B	40938701, 40652801

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT			USE PATTERN	CITATION(S)
None	72-4B	Estuarine/Marine Invertebrate Life Cycle	A, B	42724901
850.3020	141-1	Non-target Insect Acute Contact Toxicity	A, B	00132710, 05000837, 00060625
<u>TOXICOLOGY</u>				
870.1100	81-1	Acute Oral Toxicity-Rat	A, B	00046189
870.1200	81-2	Acute Dermal Toxicity-Rabbit	A, B	00046190
870.1300	81-3	Acute Inhalation Toxicity-Rat	A, B	00063197
870.2400	81-4	Primary Eye Irritation-Rabbit	A, B	00046192
870.2500	81-5	Primary Skin Irritation	A, B	00046191
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	A, B	44587601
870.6200	81-8	Acute Neurotoxicity Screen	A, B	Data Gap, 44673301, 44811801, 41916401
870.3100	82-1A	90-Day Feeding - Rodent	A, B	44811801
870.3200	82-2	21-Day Dermal - Rat	A, B	Data Gap (confirmatory), 44795801
870.4100	83-1B	Chronic Feeding Toxicity - Dog	A, B	00076436
870.4200	83-2B	Oncogenicity - Mouse	A, B	00141659
870.3700	83-3A	Developmental Toxicity - Rat	A, B	41962902
870.3700	83-3B	Developmental Toxicity - Rabbit	A, B	41962901
870.3800	83-4	2-Generation Reproduction - Rat	A, B	41520001
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	A, B	41916401, 00141659, 00160114
870.5140	84-2A	Mutagenicity	A, B	00164884, 00164885, 00164886, 00164887, 00164888, 40199401
870.7485	85-1	General Metabolism	A, B	41296001, 41425701

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT			USE PATTERN	CITATION(S)
870.7600	85-2	Dermal Absorption	A, B	40122201
		Human Data	A, B	44851001
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>				
875.2100	132-1A	Foliar Residue Dissipation	Food and Ornamental Uses	40425 301, 40 12230 1, Agricultural Reentry Task Force Data
875.2400	133-3	Dermal Passive Dosimetry Exposure	Food and Ornamental Uses	40425 301, 42 59580 1, 4012 2301, Agricultural Reentry Task Force Data
875.2500	133-4	Inhalation Passive Dosimetry Exposure	Food and Ornamental Uses	40122 301, Agricultural Reentry Task Force Data
<u>ENVIRONMENTAL FATE</u>				
None	160-5	Chemical Identity		40510801, 40274801, 43868002
835.2120	161-1	Hydrolysis	A, B	40394301, 40510801, 40274801, 43868002
835.2240	161-2	Photodegradation - Water	A, B	42607901
835.2410	161-3	Photodegradation - Soil	A, B	40759801
835.4100	162-1	Aerobic Soil Metabolism	A, B	00112304, Data Gap (phosmet oxon)
835.4200	162-2	Anaerobic Soil Metabolism	A, B	41497801
835.1230	163-1	Soil/Sediment Absorption/Desorption	A,B	40599002, 41 142701, Data Gap (phosmet oxon)
835.1240	163-1	Leaching/Absorption/Desorption	A, B	40599002, 41 142701, Data Gap (phosmet oxon)
835.6100	164-1	Terrestrial Field Dissipation	A, B	41464902, 40599003
835.1850	165-1	Confined Rotational Crop	A, B	42837901, 44356201
<u>RESIDUE CHEMISTRY</u>				
None	171-2	Chemical Identity	A, B	40510801, 40274801, 43868002
860.1300	171-4A	Nature of Residue - Plants	A, B	00037167, 00112312, 41257801, 41990101, 42617601, 42617701, 42621401, 44356001, 44356101, 44404801

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT			USE PATTERN	CITATION(S)
860.1300	171-4B	Nature of Residue - Livestock	A, B	00112241, 42640201, 42646801, 44061301, 44061302
860.1340	171-4C	Residue Analytical Method - Plants	A, B	00037165, 00037166, 00037167, 00037168, 00056849, 00056852, 00056862, 00067069, 00078567, 00084808, 00087762, 00095485, 00112241, 00112262, 00112265, 00112274, 00112296, 00112313
860.1340	171-4D	Residue Analytical Method - Animals	A, B	00112241, 44244401, 44281101
860.1380	171-4E	Storage Stability	A, B	00056850, 00056851, 00084815, 00097846, 00112279, 41100701, 41211401, 43556301, 43556302, Data Gap
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		
		Fat, Meat and Meat Byproducts of Cattle Goats Hogs Horses and Sheep	A, B	00037155, 00037161, 00037162, 00056860, 00078568, 00078569, 00078570, 00112249, 00112316, 00112325, 05012698, 44244401, 44281101
		Milk	A, B	05012698
		Eggs and the Fat Meat and Meat Byproducts of Poultry	A, B	00112310
860.1500	171-4K	Crop Field Trials (Berries Group - Blueberry)	A, B	00084809, 41971301, Data Gap
860.1500	171-4K	Crop Field Trials (Cereal Grains Group - Corn, grain)	A, B	00084811, 00112283
860.1500	171-4K	Crop Field Trials (Cereal Grains Group - Corn, sweet)	A, B	00084811, 00112283
860.1500	171-4K	Crop Field Trials (Forage Fodder and Straw of Cereal Grains)	A, B	00037157, 00084811
860.1500	171-4K	Crop Field Trials (Citrus Fruits Group)	A, B	00084810, 00112283, Data Gap
860.1500	171-4K	Crop Field Trials (Non-grass Animal Feeds - Alfalfa)	A, B	00056858, 00095485

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT			USE PATTERN	CITATION(S)
860.1500	171-4K	Crop Field Trials (Fruiting Vegetables - Tomato)	A, B	00081616
860.1500	171-4K	Crop Field Trials (Peas, forage)	A, B	00061721, 00084814, 00112283, 43536601
860.1500	171-4K	Crop Field Trials (Peas, succulent and dried)	A, B	00084814, 43536601
860.1500	171-4K	Crop Field Trials (Pome Fruits - Apple)	A, B	00044198, 00056854, 00056858, 00093486, 00106602, 00112302
860.1500	171-4K	Crop Field Trials (Pome Fruits - Crabapple)	A, B	40557401
860.1500	171-4K	Crop Field Trials (Pome Fruits - Pear)	A, B	00093486
860.1500	171-4K	Crop Field Trials (Potato)	A, B	40557401
860.1500	171-4K	Crop Field Trials (Stone Fruits Group - Apricot)	A, B	00037173
860.1500	171-4K	Crop Field Trials (Stone Fruits Group - Cherry)	A, B	00037174
860.1500	171-4K	Crop Field Trials (Stone Fruits Group - Nectarine)	A, B	00037173, 00093486
860.1500	171-4K	Crop Field Trials (Stone Fruits Group - Peach)	A, B	00037173, 00056854, 00093486, 00106602
860.1500	171-4K	Crop Field Trials (Stone Fruits Group - Plum)	A, B	00037174, 00093486, 43377501, 43377502
860.1500	171-4K	Crop Field Trials (Sweet Potato)	A, B	00093486, 00116602, 45436801
860.1500	171-4K	Crop Field Trials (Tree Nuts Group - Almond, hulls)	A, B	00044198, 00056858, 00084813, 0093486
860.1500	171-4K	Crop Field Trials (Nuts)	A, B	43536901
Miscellaneous Commodities				

Data Supporting Guideline Requirements for the Reregistration of Phosmet

REQUIREMENT			USE PATTERN	CITATION(S)
		Cottonseed	A, B	00067068, 00112245, 00112281, 40111101
		Cotton, gin byproducts	A, B	Data Gap
		Cranberry	A, B	00084812, 00112283
		Grape	A, B	00037175, 00112247
		Kiwifruit	A, B	00112279
		Pistachio	A, B	00160755
860.1520	171-4L	Processed Food (Apple)	A, B	41840401
860.1520	171-4L	Processed Food (Citrus)	A, B	00112283, 00084810, Data Gap
860.1520	171-4L	Processed Food (Cottonseed)	A, B	40111101
860.1520	171-4L	Processed Food (Grape)	A, B	43391801
860.1520	171-4L	Processed Food (Plum/prune)	A, B	43391802
860.1520	171-4L	Processed Food (Potato)	A, B	43401301
860.1850	165-1	Confined Rotational Crops	A, B	42837901, 44356201
<u>OTHER</u>				
810.1000	90-1	Use/Usage Data	A, B	Data Gap
	201-1	Droplet Size Spectrum	A, B	Data Gap
	202-1	Drift Field Evaluation	A, B	Data Gap