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
Special Review and Reregistration Division
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	IRED	IRED completed 9/2001
Azinphos-methyl (AZM)	IRED	IRED completed 10/2001
Bensulide	IRED	IRED completed 9/2000
Cadusafos	TRED	TRED completed 9/2000
Chlorethoxyphos	TRED	TRED completed 9/2000
Chlorpyrifos	IRED	IRED completed 9/2001
Coumaphos	TRED	TRED completed 2/2000
DDVP (Dichlorvos)	IRED	IRED completed 6/2006
Diazinon	IRED	IRED completed 7/2002
Dicrotophos	IRED	IRED completed 4/2002
Dimethoate	IRED	IRED completed 6/2006
Disulfoton	IRED	IRED completed 3/2002
Ethoprop	IRED	IRED completed 9/2001 IRED addendum completed 2/2006
Fenitrothion	TRED	TRED completed 10/2000
Malathion	RED	RED completed 8/2006
Methamidophos	IRED	IRED completed 4/2002
Methidathion	IRED	IRED completed 4/2002
Methyl Parathion	IRED	IRED completed 5/2003
Naled	IRED	IRED completed 1/2002
Oxydemeton-methyl	IRED	IRED completed 8/2002
Phorate	IRED	IRED completed 3/2001
Phosalone	TRED	TRED completed 1/2001
Phosmet	IRED	IRED completed 10/2001
Phostebupirim	TRED	TRED completed 12/2000
Pirimiphos-methyl	IRED	IRED completed 6/2001
Profenofos	IRED	IRED completed 9/2000
Propetamphos	IRED	IRED completed 12/2000
Terbufos	IRED	IRED completed 9/2001
Tetrachlorvinphos	TRED	TRED completed 12/2002
Tribufos	IRED	IRED completed 12/2000
Trichlorfon	TRED	TRED completed 9/2001

October 30, 2001

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

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 azinphos-methyl. The public comment period on the revised risk assessment phase of the reregistration process is closed.

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.

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 May 19, 1999. Additionally, the Agency held a Technical Briefing on May 19, 1999, where the results of the revised human health and environmental effects risk assessments were presented to the general public. 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 May 19, 1999, and closed on July 19, 1999.

Based on its review of all relevant information and comments, EPA identified interim risk mitigation measures, largely focused on dietary risks, that were implemented in 1999. This document identifies additional mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of azinphos-

methyl. The EPA is now publishing its interim reregistration eligibility and risk management decision for the current uses of azinphos-methyl and its associated human health and environmental risks. The tolerance reassessment decision for azinphos-methyl will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete. The Agency's decision on the individual chemical azinphos-methyl can be found in the attached document entitled, "Interim Reregistration Eligibility Decision for Azinphos-methyl."

A Notice of Availability for this Interim Reregistration Eligibility Decision for Azinphos-methyl is being published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public 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. A 60-day public comment period on the risk management decision will begin with the publication of the Notice of Availability.

The interim RED is based on the updated technical information found in the azinphos-methyl 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 and benefits assessments for azinphos-methyl**,** 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 assessments. The docket also includes comments on the revised risk assessments, and any risk mitigation proposals submitted during Phase 5. Comments on mitigation or mitigation suggestions were submitted by: Bayer Corporation, one of the technical registrants; public interest groups; growers and grower organizations. In addition, the docket includes benefits assessments for azinphos-methyl, as well as comments on those assessments submitted by the general public and stakeholders.

Please note that the azinphos-methyl risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's reregistration decision except for the decision on tolerance reassessment. 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 azinphos-methyl. The Agency will issue the final tolerance reassessment decision for azinphos-methyl once the cumulative assessment for all of the organophosphates is complete.

Taking into account both the risks and benefits of azinphos-methyl use, the Agency has determined that all uses of azinphos-methyl are ineligible for reregistration based on their currently approved labeling. Although EPA is unable to find these uses eligible under their currently approved labeling, EPA has identified conditions under which a limited number of uses of azinphos-methyl could be eligible for a time-limited reregistration of four years, if specific mitigation measures are adopted. The registrations for these uses will, in effect, expire on October 30, 2005, unless the registrant requests and EPA grants an extension of the registration. The eight uses that could be eligible for a time-limited registration provided mitigation is implemented are: apples and crabapples; pears; sweet cherries; highbush and lowbush blueberries; caneberries (application to canes and soils only); Brussels sprouts (application to soil at transplant only); nursery stock (quarantine use only); and southern pine seed orchards.

Although the Agency has determined that none of the other uses of azinphos-methyl are eligible for reregistration, the Agency believes that it would be appropriate to allow a phase-out period for certain of these uses with comparatively high benefits in order to provide growers with an orderly transition to the use of alternative pest control tools and practices, provided that the mitigation measures specified in this IRED are implemented during the phase-out period. The seven uses that could be phased out are: almonds, tart cherries, cotton, cranberries, peaches, pistachios, and walnuts.

The remaining 28 uses have little use and/or low benefits and will be proposed for immediate cancellation.

Sections IV and V of this interim RED describe the risk mitigation measures and the product labeling amendments necessary to implement them for the phase out and time-limited registrations. Section V also outlines the data requirements necessary to support the continued use of azinphos-methyl on these sites. **Registrants must submit amended labeling reflecting the use deletions and mitigation measures contained in this IRED within 90 days of receipt of this letter and the attached document.**

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by azinphos-methyl. If these measures outlined in this document are not implemented within the specified time period, the Agency will proceed with further regulatory action.

This document outlines both generic and product-specific data requirements for this chemical. Note that complete DCIs, with all pertinent instructions, are being sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of required responses to 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.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager for azinphos-methyl, Véronique LaCapra, at (703) 605-1525. For questions about product reregistration and/or the Product DCI, please contact Jane Mitchell, at (703) 308-8061.

Sincerely,

Lois A. Rossi, Director
Special Review and Reregistration Division

Attachment

Interim Reregistration Eligibility Decision
for
Azinphos-Methyl

Case No. 0235

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Glossary of Terms and Abbreviations

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to

	municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
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.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
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
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline

PAM	Pesticide Analytical Method
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
PRN	Pesticide Registration Notice
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
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
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)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization

WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decision for azinphos-methyl. The decisions outlined in this document do not include the final tolerance reassessment decision for azinphos-methyl; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. Twenty-eight tolerances will be proposed for revocation to coincide with cancellation of these uses. Nine others will be proposed for revocation effective after 2005 to coincide with the phase out of use on those crops. The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for the seven remaining azinphos-methyl tolerances once cumulative risks are considered.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and the 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 azinphos-methyl. After considering the revised risks, as well as mitigation proposed by Bayer Corporation, one of the technical registrants, and extensive input from grower organizations, university researchers, and other interested stakeholders, EPA developed its risk management decision for uses of azinphos-methyl that pose risks of concern. This decision is discussed fully in this document.

Azinphos-methyl is an organophosphate insecticide used on a variety of pests, first registered in the US in 1959. It is used on a number of fruit and nut crops and a variety of vegetables. There are no residential or public health uses. Currently less than 2 million pounds of active ingredient are used annually.

Risks Summary

Dietary risk from food, both acute and chronic, is not of concern for the general population or for any population subgroup. EPA has obtained new single serving apple monitoring data from USDA's Pesticide Data Program indicating that residues in single apples are less than had been previously estimated based on pear data. No further mitigation is needed to address dietary risk at this time. Taking into account the mitigation outlined in this document aggregate risk from food and drinking water combined is not of concern.

There are, however, concerns for workers who mix, load and apply azinphos-methyl to agricultural sites. Even after factoring in exposure reductions provided by closed mixing and loading systems, closed cab application equipment, and all feasible personal protective equipment, safety margins (margins of exposure or MOEs) still fall well below the target of 100 for the majority of pesticide handler exposure scenarios considered.

Risk to field workers who reenter azinphos-methyl treated sites to harvest, thin, prune

and perform other post-application activities is of particular concern. MOEs for many of these workers are less than 10 for critical activities. Even taking into account the additional margin of safety afforded by using a very protective endpoint, MOEs for many reentry workers are less than 30, where the target MOE is 100. EPA used a NOAEL (0.56 mg/kg/day) from a dermal rat study for the reentry assessment. The LOAEL in this study was 10-fold higher, 5.6 mg/kg/day, based on minimal cholinesterase inhibition (15-17%).

EPA has also identified ecological risks associated with azinphos-methyl use. There is a potential for spray drift and runoff into water bodies with the most drift being associated with aerial applications. Azinphos-methyl is very highly toxic to freshwater and marine fish and to invertebrates, and if it enters a water body in sufficient quantities, it can result in death and reproductive effects in aquatic organisms. There is also potential exposure and risk to birds, mammals, and bees from direct spray, drift, and surface residues.

Benefits Summary

Because the concerns for azinphos-methyl are risks to workers and the environment, under FIFRA, EPA must consider whether or not these risk are unreasonable taking into account the benefits of the pesticide's use. The Agency's assessment of the benefits of azinphos-methyl shows that the benefits differ dramatically across the range of uses. For some crops, azinphos-methyl does not appear to be an important pest-control tool and current users would not likely be adversely affected if the chemical were no longer available for those uses. For other crops, azinphos-methyl provides moderately high economic benefits to users. For these uses, alternative controls are available but may not be as effective or may be more expensive. For a small group of uses, azinphos-methyl provides very significant economic benefits to users and in certain situations is essential to the continued production of the crop. In these cases few if any alternative controls are currently available. For complete crop-specific benefits assessments see: www.epa.gov/pesticides/op/azinphosmethyl.

Risk Management Summary

Taking into account both the risks and benefits of azinphos-methyl use, EPA has determined to place the uses of azinphos-methyl into three categories. Uses with minimal benefits are ineligible and will be canceled without a phase out period. These include alfalfa, beans, birdsfoot trefoil, broccoli, cabbage, caneberries (foliar applications only), cauliflower, citrus, celery, clover, cucumbers, eggplant, filberts, grapes, melons, nectarines, nursery stock (other than quarantine uses), onions (green and dry bulb), parsley, pecans, peppers, plums and dried plums, potatoes, quince, spinach, strawberries, and tomatoes.

For uses with moderately high economic benefits, the Agency has determined that the benefits do not outweigh the risks and finds these uses ineligible for reregistration. However, for these uses, the Agency believes that the benefits make it appropriate to allow a 4-year phase-out period that would allow growers to make an orderly transition to alternative pest control products

or practices, provided certain mitigation measures are implemented during the phase out period. Seven uses fall into this category: almonds, tart cherries, cotton, cranberries, peaches, pistachios, and walnuts.

For the eight remaining uses, there are significant economic benefits associated with the use of azinphos-methyl, and EPA believes that other pesticides or agricultural practices cannot substitute for azinphos-methyl in providing adequate control of key target pests at the present time. The Agency believes that the benefits associated with these uses outweigh the risks, provided that the interim mitigation outlined in this IRED is implemented, and finds these uses to be eligible for reregistration. However, because of continuing concern for the remaining risks posed by these uses, the Agency is conditioning the registration of these uses by establishing an expiration date of four years. Uses with a 4-year time limited registration are: apples (and crabapples), blueberries (lowbush and highbush), Brussels sprouts (application to soil at transplant only), caneberries (application to canes and soil only), sweet cherries, quarantine use on nursery stock, pears and southern pine seed orchards.

For the seven phased-out uses and the eight time-limited ones, interim mitigation is needed to address both ecological and worker risks. This mitigation includes eliminating aerial application on many sites, reducing the amount of azinphos-methyl that can be applied per season, extending restricted entry intervals, and establishing no-spray buffer zones around permanent water bodies.

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, which was August 3, 1996. 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. Azinphos-methyl 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 azinphos-methyl. It is intended to be only the first phase in the reregistration process for azinphos-methyl. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for azinphos-methyl.

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
- 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 Sept. 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 baseline 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 risk 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 potential risks of the chemical. The measures included in this interim RED are consistent with the Worker Pesticide Registration Notice.

This document consists of six sections. Section I 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 provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices lists 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.

II. Chemical Overview

A. Regulatory History

Azinphos-methyl was first registered in the United States in 1959 by the United States Department of Agriculture (USDA) for use as an insecticide. A Registration Standard was issued on September 11, 1986, to require the submission of numerous studies to support its continued registration.

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act provided a schedule for the reregistration process to be completed. In order to meet these requirements the Agency issued a Data Call-In (DCI) on June 16, 1993, to require the submission of numerous studies in the areas of residue chemistry, environmental fate, toxicology, ecological effects, usage data, pest management data, comparative product performance data and pest resistance data.

The Agency initiated the Acute Worker Risk Strategy in 1992. This was a process which looked at over 80 chemicals that had any reported worker incidents in California; the state which has what is generally considered the highest quality human incident data base. Using information on toxicity and frequency of incidents, the Agency determined that collection of additional incident data was needed for 28 of these chemicals, including azinphos-methyl. In 1993, the Agency issued a DCI, calling in Poison Control Center incident data from throughout the US. The Agency's review of that data ranked azinphos-methyl as 5th among registered pesticides. As a result of this effort, industry established its Best Management Practices Workgroup to look at approaches that the entire industry could adopt for acutely toxic chemicals.

Based on some large fish kill incidents in Louisiana, in 1993, the Agency negotiated an agreement with the State of Louisiana, and the producers of azinphos-methyl (both technical and end-use formulators). The agreement limited the use of azinphos-methyl on sugarcane in Louisiana to prescriptive use only; that is, all applications required the prior approval of the State. The purpose of the agreement was to further reduce the potential for adverse aquatic effects, and to develop a mechanism whereby the use of azinphos-methyl would be immediately suspended should fish kill incidents occur in the future. In 1999, this use was voluntarily canceled by all azinphos-methyl registrants.

In June 1998, the California Department of Pesticide Regulation (CDPR) issued 120-day emergency regulations to protect agricultural workers exposed to azinphos-methyl used on most tree crops and grapes. In coordination with CDPR, EPA worked with the registrants to establish interim mitigation on a national level. This effort lead to extending REIs for stone and pome fruit, reducing some maximum application rates, requiring additional PPE, requiring closed mixing-loading systems, and deleting some uses. To have these measure fully implemented for the 1999 growing season, CDPR issued emergency regulations in April 1999 requiring that most of these

measures be immediately adopted.

Most recently, on August 2,1999, EPA entered into an agreement with all registrants producing azinphos-methyl to extend REIs for all uses that weren't covered by the 1998 label amendments, to further reduce the maximum application and/or seasonal rates for pome and stone fruit, to prohibit the use on cotton in Louisiana and states east of the Mississippi River, to reduce the maximum application and seasonal rates on cotton for the rest of the country, to prohibit the use of some application equipment, to reduce the application and seasonal rates for Southern pine seed orchards, and to prohibit use on sugarcane. These label changes were on all product sold by the registrants in 2000.

A. Chemical Identification

!	**Common Name:**	Azinphos-methyl
!	**Azinphos-methyl**:	O,O-dimethyl-S-((4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl) phosphordithioate
!	**Chemical family:**	Organophosphate
!	**Case number:**	0235
!	**CAS registry number:**	86-50-0
!	**OPP chemical code:**	058001
!	**Empirical formula:**	$C_{10}H_{12}N_3PS_2$
!	**Molecular weight:**	317.1
!	**Trade and other names:**	metiltrizotion, carfene, cotion-methyl, gusathion, gusathion-M, guthion, Bay 9027, Bay 17147, R-1582 and chrysthyon
!	**Basic manufacturers:**	Bayer Corporation; Makhteshim Agan; & Gowan Company.

Pure azinphos-methyl is a colorless to white odorless crystalline solid with a melting point of 72-74° C. Technical azinphos-methyl is a cream to yellow-brown granular solid with a melting point of 67-70° C. Azinphos-methyl is readily soluble in most organic solvents (acetone, toluene, chloroform, acetonitrile, benzene, xylene, carbon tetrachloride, and chlorobenzene), slightly soluble in methanol, ethanol, and 1-propanol, and nearly insoluble in water (28 ppm at 20° C). Azinphos-methyl is subject to hydrolysis and decomposes with gas evolution at elevated

temperatures.

A. Use Profile

The following information is based on the currently registered uses of azinphos-methyl:

Type of Pesticide: Insecticide

Summary of Use Sites:

Food: Pome Fruits (Apples, Crabapples, Pears & Quinces), Stone Fruits (Peaches, Cherries, Nectarines, Plums & Dried Plums (Prunes)), Tree Nuts (Almonds, Hazelnuts (Filberts), Pecans, Pistachios & Walnuts), Fruiting Vegetables (Tomatoes, Eggplants & Peppers), Cucurbits (Cucumbers), Leafy Vegetables (Celery, Spinach & Parsley), Brassica Vegetables (Broccoli, Brussels Sprouts, Cabbage & Cauliflower), Vegetables (Snap Beans), Forage Crops (Alfalfa, Birdsfoot Trefoil & Clover), Bulb Vegetables (Onions), Melons (Watermelons, Cantaloupes & Other Melons), Roots & Tubers (Potatoes), Berries (Blackberries, Blueberries, Boysenberries, Cranberries, Loganberries, Raspberries & Strawberries), Citrus Fruits (Oranges, Grapefruits, Lemons, etc.), Miscellaneous Crops (Cotton & Grapes).

Residential: There are no residential uses of azinphos-methyl.

Public Health: None.

Other Nonfood: Nursery Plants, Southern Pine Seed Orchards.

Target Pests: Azinphos-methyl controls a wide variety of insects. Major pests include codling moth, plum curculio, apple maggot, aphids, leafrollers, mites, mealybug, moths, boll weevil, etc.

Formulation Types Registered: Formulated as a liquid emulsifiable concentrate (22% EC) and wettable powder in water soluble bags (35% & 50% WP).

Method and Rates of Application: Applied by airblast sprayers, chemigation, groundboom sprayers, and aerially by fixed-wing & helicopter aircraft.

Equipment - Airblast sprayers, groundboom sprayers, sprinkler irrigation (chemigation), aircraft.

Method and Rate - Maximum use rates (lbs a.i./acre) and the maximum number of applications allowed yearly vary with crop types, as follows (lbs a.i./acre; # of applications): Pome Fruits (1.0-1.5; 4-5), Stone Fruits (0.75-2.0; 4), Tree Nuts (2.0-2.5; 3), Fruiting Vegetables (0.5-1.5; 3), Cucurbits (0.5; 3), Leafy Vegetables (0.5; 3), Brassica

Vegetables (0.75; 3); Forage Crops (0.5-0.75; 1-2), Bulb Vegetables (0.75; 3), Melons (0.5; 3); Root & Tuber Vegetables (0.75; 3), Caneberries (0.5-.75; 4), Citrus Fruits (2.0; 2); Strawberries (0.5, 4), Cranberries(0.5-1.0, 3), Grapes(0.75-1.0, 3), Cotton (0.5; 4); and Ornamentals and Trees (1.0-2.0; 4).

Timing - Applied throughout the growing season. Most early season applications to tree fruits occur shortly after petal fall. Late season applications may be necessary closer to harvest because pests may directly affect the marketability of commodities.

Use Classification: Azinphos-methyl is classified as toxicity category one, and therefore, must have restricted use language on all end use labels.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for the currently registered pesticide uses of azinphos-methyl, based on available pesticide usage information for 1987 through 1997. A full listing of all uses of azinphos-methyl, 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. Additional information on usage is contained in EPA's benefits assessments that are available in the azinphos-methyl docket and on the OPP web site.

Table 1. Azinphos-methyl Estimated Usage for Representative Sites

Crop	Lbs. Active Ingredient Applied (000) (Wt. Avg.)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Blackberries	0	18%	9%
Blueberries	17	51%	34%
Cranberries	9	69%	41%
Raspberries	<0.5	14%	9%
Strawberries	2	12%	7%
Grapefruit	14	17%	7%
Lemons	<0.5	<0.5%	<0.5%
Oranges	11	3%	1%
Tangelos	<0.5	3%	1%
Apples	890	88%	71%
Apricots	2	15%	10%

Cherries, Sweet	27	58%	44%
Cherries, Tart	40	80%	71%
Nectarines	2	6%	4%
Peaches	120	30%	21%
Pears	130	91%	70%
Plums & Prunes	13	12%	6%
Grapes	9	2%	1%
Almonds	160	39%	21%
Pecans	7	3%	1%
Pistachios	41	48%	43%
Walnuts	67	30%	17%
Onions	2	2%	2%
Eggplant	<0.5	24%	9%
Peppers, Sweet	1	13%	4%
Celery	1	13%	7%
Lettuce	<0.5	<0.5%	<0.5%
Spinach	<0.5	1%	<0.5%
Broccoli	<0.5	<0.5%	<0.5%
Brussels Sprouts	<0.5	2%	1%
Cabbage	3	13%	6%
Cantaloupes	2	5%	3%
Cauliflower	<0.5	2%	1%
Cucumbers	1	3%	<0.5%
Melons	2	2%	1%
Squash	<0.5	1%	1%
Potatoes	65	10%	6%
Tomatoes, Fresh	6	10%	6%
Tomatoes, Proc.	9	11%	7%
Peas, Green	1	<0.5%	<0.5%

Alfalfa	3	<0.5%	<0.5%
Cotton	470	11%	6%

[1] Weighted Average is based on data for 1987 through 1997; the most recent years and more reliable data are weighted more heavily.

III. Summary of Azinphos-Methyl Risk Assessment

The following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide azinphos-methyl, as fully presented in the documents, "Human Health Risk Assessment, Azinphos-Methyl" dated May 19, 1999, "Environmental Fate and Effects Risk Assessment, Azinphos-Methyl," dated July 15, 1999, and subsequent addenda which are cited below. 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 azinphos-methyl were presented at a May 19, 1999, Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management decision for azinphos-methyl only; the Agency must complete a 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 human health risk assessment for azinphos-methyl in August 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessment was updated and refined. This revised assessment was made available for public comment following the Technical Briefing on May 19,1999. Additional revisions to the risk assessment have been made during Phase 6 as a result of label changes agreed to by the registrants in an August 1999 Memorandum of Agreement, additional data submissions, further internal review by the Agency, and changes in Agency policy. These revisions are summarized below.

Reductions in application rates: As part of a Memorandum of Agreement signed by azinphos-methyl registrants in August 1999, maximum application rates were reduced for a subset of use sites:

1. For apples, crab apples, pears, and other pome fruits, the maximum seasonal rate was set at 4.5 lbs ai/A with a maximum of 1.5 lbs ai/A per application;
2. For peaches and nectarines, the maximum seasonal rate was set at 3.375 lbs ai/A;
3. For cotton, the maximum seasonal rate was set at 2 lbs ai/A with a maximum of 0.5 lbs ai/A per application;
4. For southern pine seed orchards, the maximum seasonal rate was reduced to 4.5 lbs ai/A with a maximum of 1.5 lbs ai/A per application.(and a maximum of 3 applications per season).

These interim label changes are reflected in current handler and re-entry risk calculations.

Biomonitoring study: In August 2001, the registrant submitted a 1999 biomonitoring study assessing exposure to workers applying azinphos-methyl to orchard crops (apples, peaches, pears) using an airblast sprayer. The Agency has determined this study does not support reducing the

dermal absorption rate for azinphos-methyl. A dermal absorption rate of 42% was set in the May 1999 Human Health Risk assessment, based on data from a dermal absorption study in rats (MRID 4245701). Details of this review can be found in the memorandum "HED review of MRID 454761-02 in response to Bayer's request to lower the dermal absorption rate from 42% to 21.9%," dated October 11, 2001.

Revised acute dietary risk assessment: In April 2001 the Agency revised the acute dietary exposure assessment to include apple single serving Pesticide Data Program (PDP) residue data, as described in the memorandum, "Azinphos-methyl: Revised Monte Carlo Assessment to Include PDP Apple Single Serving Data," dated April 26, 2001. The inclusion of these data is the only change that has been made to the acute dietary assessment since the May 19, 1999 risk assessment. The Agency did not revise the chronic dietary exposure assessment to include these data because these risks were already below the Agency's level of concern based on the May 1999 assessment.

Revised acute drinking water risk assessment: Based on the revised acute dietary assessment, the Agency has revised its calculations of acute drinking water risk and calculated DWLOCs for all population subgroups. In addition, estimated environmental concentrations of azinphos-methyl in ground water under highly vulnerable conditions have been generated with the SCI-GROW model using current label application rates. These estimates are presented in the memorandum, "SCI-GROW Estimates of Concentrations in Ground water for Azinphos-methyl," dated October 24, 2001.

Revised handler risk assessment: The occupational handler exposure risk assessment was revised to address the changes in application rates listed above, and to incorporate changes in the default values for daily acres treated adopted by the Agency in April 1999. These revisions are described in the memorandum, "Revised Occupational Handler Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Azinphos-Methyl," dated July 10, 2001.

Revised re-entry worker risk assessment: The occupational re-entry worker risk assessment was revised to incorporate changes in application rates and updated transfer coefficients and crop groupings outlined in EPA's revised *Agricultural Transfer Coefficient* policy, which reflects data collected by the Agricultural Re-entry Task Force. These revisions are described in the memorandum, "Azinphos-Methyl: Third Version of the Revised Occupational Postapplication Exposure and Risk Calculations [Chemical Code 058001]," dated October 10, 2001.

The toxicology database for azinphos-methyl includes three studies using human volunteers: a single-dose oral study (1998); a single-dose dermal absorption study (1999); and a 28-day repeated-dose oral study (1999). The following observations can be made on the potential impact of these data on the azinphos-methyl risk assessment. Assuming that these studies were conducted according to appropriate ethical standards, they could be used in a weight-of evidence approach to inform the selection of the inter-species uncertainty factors for human health risk

assessment. For example, the single-dose (acute) oral 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 azinphos-methyl and could provide a basis for reduction of the uncertainty factor for acute dietary risk. Similarly, the repeated-dose oral human study could be compared to existing animal data to determine if it could provide a basis for reduction of the uncertainty factor for chronic dietary risk, or in short-term or intermediate-term assessments, such as those used to estimate worker risk from azinphos-methyl use. The dermal absorption study could be used to calculate a dermal absorption factor, which could be compared to the dermal absorption factor calculated using existing animal data.

1. Dietary Risk from Food

a. Toxicity

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 azinphos-methyl can be found in the May 19, 1999 Human Health Risk Assessment.

Acute (1-day) dietary risk was estimated using an acute RfD of 0.003 mg/kg/day, based on a LOAEL of 1 mg/kg/day from an acute neurotoxicity study in rats (MRID 43360301). This LOAEL was selected based on inhibition of plasma, red blood cell, and brain cholinesterase observed following a single dose. No NOAEL was observed in this study. Consequently, an additional safety factor of 3x was applied in addition to the existing uncertainty factors for inter-species extrapolation (10x) and intra-species variability (10x), resulting in a total uncertainty factor of 300x for the acute dietary risk assessment.

Data from a 1998 single-dose oral study in human volunteers suggest that humans are no more sensitive than rats to a 1-day oral exposure to azinphos-methyl. If these data were included in the acute dietary risk assessment, they could support the removal of the 10x interspecies uncertainty factor, resulting in a total uncertainty factor of 30x for the acute dietary risk assessment.

Chronic dietary risk was estimated using a chronic RfD of 0.00149 mg/kg/day, based on a NOAEL of 0.149 mg/kg/day established in a 1-year chronic toxicity study in dogs (MRID 41804801). The LOAEL in this study was 0.688 mg/kg/day for males and 0.775 mg/kg/day for females, based on the above noted significant decreases in red blood cell cholinesterase activity in both sexes as well as an increased incidence of diarrhea in males. A total uncertainty factor 100x was used for the chronic dietary risk assessment to account for inter-species extrapolation (10x) and intra-species variability (10x).

The Agency has determined that data from the 1999 28-day repeated-dose oral study in human volunteers would not support removal of the 10x inter-species uncertainty factor. This

determination was based on concerns for offspring effects (pup mortality) observed at the same dose level as cholinesterase inhibition in adult rats (dams) in one and two generation reproduction studies in rats. Since only cholinesterase inhibition was measured in the human study, the 10x inter-species uncertainty factor would need to be retained in order to be protective for other effects that could occur in humans following chronic dietary exposure to azinphos-methyl.

Azinphos-methyl is classified as a "not likely" human carcinogen. This classification was based on the lack of evidence of carcinogenicity in male and female mice (MRID 00147895) and in male and female rats (MRID 41119901).

b. FQPA Safety Factor

The Agency has determined that the 10x FQPA safety factor for azinphos-methyl can be removed. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. Developmental and reproductive studies in animals showed no increased susceptibility in fetuses or pups, and there was no evidence of abnormalities in the development of fetal nervous systems. Specifically:

(i) Developmental toxicity studies showed no evidence of additional sensitivity in fetuses as compared to maternal animals following *in utero* exposure in rats and rabbits.

(ii) Both a one- and a two-generation reproductive toxicity study in rats showed no increased susceptibility in pups when compared to adults.

(iii) There was no evidence of abnormalities in the development of the fetal nervous system in the pre/postnatal studies. Neither brain weight nor histopathology (nonperfused) of the nervous system was affected in the subchronic and chronic toxicity studies.

(iv) The toxicology database is complete based on current requirements.

Available data on exposure to infants and children were also considered. The available residue data used for dietary exposure provides the most highly-refined assessment possible at this time. Limited data were available for use in assessing drinking water exposure. However, the models used to assess drinking water exposure provide upper-bound concentration estimates of azinphos-methyl in ground water and surface water, and are based on conservative assumptions regarding pesticide transport from the point of application to water sources. The assumptions and models used in the assessments are considered health-protective and do not underestimate the potential risk for infants and children.

c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes 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 ainphos-methyl, the FQPA safety factor is 1; therefore, the acute or chronic RfD = 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.

A brief overview of the studies and uncertainty factors used to calculate the acute (aPAD) and chronic (cPAD) population adjusted doses for the dietary risk assessment is outlined in Table 2:

Table 2. Toxicological endpoints and other factors used in the dietary risk assessment of azinphos-methyl.

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	PAD
Acute Dietary	No NOAEL; LOAEL = 1.0 mg/kg/day	Plasma, red blood cell, and brain ChE inhibition	Acute rat neurotoxicity (MRID 43360301)	300[1]	1X	0.0033 mg/kg/day
Chronic Dietary	NOAEL = 0.149 mg/kg/day;	Red blood cell ChE inhibition at LOAEL of 0.688 mg/kg/day	1-yr Chronic dog toxicity (MRID 41804801)	100	1X	0.00149 mg/kg/day

d. Exposure Assumptions

The Agency uses a tiered approach to assess acute dietary risk. Revised acute dietary risk analyses for azinphos-methyl were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91. The acute dietary risk assessment has been extensively refined using USDA Pesticide Data Program (PDP) data, which reflect actual uses. The most refined analysis conducted for azinphos-methyl included: (1) PDP monitoring data for blended commodities; (2) PDP composite data adjusted for single servings (available for peaches and translated to other stone fruit); (3) PDP single serving monitoring data (available for apples

[1]Data from the 1998 single-dose oral study in human volunteers would support the removal of the 10x inter-species uncertainty factor, resulting in a total uncertainty factor of 30x for the acute dietary risk assessment.

and pears and translated to quince and crabapples); (4) FDA (Market Basket Survey) monitoring data; (5) field trial data for other commodities; and (6) percent crop treated data.

The chronic dietary exposure estimate is used to calculate the lifetime risk of consuming an average amount of azinphos-methyl residues in the diet. The chronic dietary exposure assessment does not generate a "worst case" estimate of chronic dietary exposure. This highly refined assessment calculates anticipated residues using FDA monitoring data and field trial data adjusted for percent crop treated.

a. 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 azinphos-methyl acute dietary risk from food is below the Agency's level of concern, 43% of the acute PAD for the U.S. general population. For the most exposed subgroups, all infants (<1 year) and children (1-6 years), the percent acute PAD values are 83% and 80% at the 99.9th percentile of exposure.

These results are based on a revised probabilistic analysis incorporating apple single serving PDP residue data. The details of this analysis can be found in the memorandum "Azinphos-methyl: Revised Monte Carlo Assessment to Include PDP Apple Single Serving Data," dated April 26, 2001, which is available in the azinphos-methyl docket. The May 1999 analysis had indicated that acute dietary exposure to azinphos-methyl was of concern for children (1-6 years old). The current assessment demonstrates that acute dietary exposure is no longer of concern for children (1-6 years old) or any other population subgroup.

Data from the 1998 single-dose oral study in human volunteers could support the removal of the 10x inter-species uncertainty factor. However, reducing the uncertainty factor would not affect the substantive results of the acute dietary assessment, since exposure is below the Agency's level of concern for all population subgroups based on animal data alone.

The chronic dietary risk from food is well below the Agency's level of concern, 13% of the chronic PAD for the U.S. general population. For the most exposed subgroups, non-nursing infants (<1 year) and children (1-6 years), the % chronic PAD values are 54% and 33%, respectively.

The results of the current revised acute and chronic dietary assessments are summarized in Tables 3:

Table 3. Results of the acute and chronic dietary risk assessments for azinphos-methyl at the 99.9th percentile of exposure

Population subgroup	Acute PAD (mg/kg/d)	Chronic PAD (mg/kg/d)	Acute Exposure (mg/kg/d)	Chronic Exposure (mg/kg/d)	% Acute PAD	% Chronic PAD
U.S. Population	0.003	0.0015	0.001285	0.000195	43	13
Infants (<1 year): All	0.003	--	0.002504	--[2]	83	--
Nursing	--	0.0015	--	0.000194	--	13
Non-nursing	--	0.0015	--	0.000803	--	54
Children (1-6 years)	0.003	0.0015	0.002403	0.000495	80	33
Children (7-12 years)	0.003	0.0015	0.001595	0.000329	53	22
Females (13-19 years)	--	0.0015	–[2]	0.000172	--	11
Females (20+ years)	0.003	0.0015	0.000866[3]	0.000114	29[2]	8
Males (13-19 years)	0.003	0.0015	0.000798	0.000205	27	14
Males (20+ years)	0.003	0.0015	0.000814	0.000121	27	8
Seniors 55+	0.003	0.0015	0.000999	NC[4]	33	NC[3]

1. Dietary Risk from Drinking Water

[2]The preliminary dietary exposure assessments for azinphos-methyl were conducted using DRES (Dietary Risk Evaluation System) software and consumption data from the USDA Continuing Surveys of Food Intake by Individuals (CSFII), 1977-1978. The preliminary acute dietary exposure assessment indicated there were concerns for acute dietary exposure to AZM, and further refinements to the assessment were made using new exposure modeling software and consumption data, i.e. DEEM™ (Dietary Exposure Evaluation Model) and CSFII data from surveys conducted in 1989-1991. However, since the preliminary assessments indicated that chronic dietary exposure and risk were below the Agency's level of concern, no further refinements were necessary. Because two different models were used for the acute and chronic assessments, the population subgroups identified in the model outputs may differ. For example, due to the limited number of infants in the consumption surveys, EPA currently does not report separate estimates for nursing vs. non-nursing infants. However, the previous DRES system did not provide an estimate for all infants, and so separate estimates for nursing and non-nursing infants have been provided for chronic dietary risk.

[3]Acute exposure and %aPAD were grouped for females 13-50 years of age (see footnote no.2).

[4]Chronic exposure and %cPAD were not calculated for seniors 55+.

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. Modeling is considered to be an unrefined assessment and usually provides a high-end estimate of risk. In the case of azinphos-methyl, drinking water concentrations were estimated using limited surface and ground water monitoring data, and model estimates generated by the Tier II PRZM-EXAMS surface water model and the Tier I SCI-GROW ground water model. These are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than the SCI-GROW model. The true drinking water concentration is expected to fall between monitoring concentrations (lower bound) and estimated model concentrations (upper bound).

Environmental fate data indicate that azinphos-methyl is mobile and has the potential to reach surface water dissolved in runoff. Since azinphos-methyl is only moderately mobile to leaching and degrades by hydrolysis, it is not likely to leach to ground water in most situations. Limited monitoring data suggest that azinphos-methyl may reach ground water in areas with rapid ground water recharge, such as karst terrain.

Azinphos-methyl is moderately persistent in soil under aerobic conditions (DT_{50} of 27 days, DT_{90} of 146 days), degrading rapidly by aqueous photolysis (DT_{50} of 77 hours), but rather slowly by soil photolysis (½ life of 180 days). Hydrolysis is alkaline catalyzed and is fairly rapid at high pH, on the order of days. Azinphos-methyl is moderately persistent at acid and neutral pH.

The only environmental degradate of human toxicological concern is the oxygen analog, which was found at a maximum of about 5% of the total amount of pesticide that was applied in a soil aerobic metabolism study.

a. Surface Water

The surface water assessment has been primarily based on Tier II modeling (PRZM-EXAMS). PRZM-EXAMS is used to estimate the upper-bound concentrations 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. Modeling has been done for the high use crops and a limited subset of lower use crops. These crops are almonds, apples (and crab apples), cherries, cotton, peaches, pears, plums and dried plums (prunes), potatoes, and walnuts. Additionally, for azinphos-methyl, monitoring data from STORET, two studies from the United States Geological Survey and the state of Florida have been reviewed and summarized.

The lower bound was estimated from monitoring data, and the upper bound from PRZM-EXAMS modeling of the maximum use pattern labeled for eastern peaches, 1.125 lbs ai/A per application for a maximum of 4.5 lbs ai/A per year. This rate reflects the maximum label rate in July 1999; the August 1999 MOA reduced the maximum label rate for eastern peaches to 3.375 lbs ai/A per year. Because rainfall in the east is generally higher than in the west, and more

rainfall falls during the growing season, estimated environmental concentrations (EECs) for eastern regions are generally higher than for western regions for the same crop. In order to provide an upper bound for surface water concentrations, only eastern scenarios were considered for those crops grown in both regions. In addition to the maximum label rate, the model was also run using the typical application rate for peaches, 3 applications of 0.6 lbs ai/A (1.8 lbs ai/A per year). This is similar to the current typical application rate on eastern peaches, 2 applications of 0.75 lbs (1.5 lbs ai/A per year). Using the typical application rate, the EEC was 16 ppb.

The version of PRZM-EXAMS used to estimate surface water concentrations for azinphos-methyl asumed a 1-hectare pond with no outlet, surrounded by a 10-hectare field planted entirely to the crop being modeled. The model was run assuming aerial application.

b. Ground Water

Since azinphos-methyl is only moderately mobile to leaching and degrades by hydrolysis, it is not expected to reach ground water under most conditions. The exception to this may be in areas of rapid ground water recharge such as karst terrain or areas where preferential flow is the dominant transport mechanism. When azinphos-methyl does reach ground water, it is not expected to persist. There are a limited number of detections of azinphos-methyl in ground water. A Tier I screening model, SCI-GROW, was used to estimate drinking water concentrations derived from ground water.

The Agency has determined that the maximum concentration of azinphos-methyl in ground water to be 0.40 ppb. This value was estimated from SCI-GROW modeling of the maximum use pattern on walnuts, 2.0 lbs/ai/A per application for a maximum of 6.0 lbs ai/A per year, reflecting the current label rate (for details, see the memorandum "SCI-GROW Estimates of Concentrations in Ground water for Azinphos-methyl," dated October 24, 2001). EPA also looked at monitoring data collected in the Potomac Basin of Virginia in 1987. Of 60 collected samples of ground water, 16 contained azinphos-methyl. These samples were collected in an area of karst topography, suggesting that these areas many be particularly vulnerable to contamination. Karst terrain occurs throughout the U.S., including areas of Florida, Kentucky, Pennsylvania, Missouri, Iowa, New Mexico and Virginia. However, there were a number of problems with these data. The Agency was unable to obtain the raw data including actual measurements, use sites, and locations sampled. In addition, there were no descriptions of sampling methods or analytical methods. Because of the lack of information to confidently conclude that the monitoring data are valid, the Agency relied on the modeling data for the ground water assessment.

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 monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern. DWLOCs for each population subgroup are then compared to estimated concentrations in surface water and ground water. Estimated environmental concentrations that are less than the DWLOCs for all subgroups do not exceed the Agency's level of concern for drinking water risk.

The results of the Agency's drinking water analysis are summarized here. Details of this analysis can be found in the HED Human Health Risk Assessment, dated May 19, 1999. Acute DWLOCs were recently revised to reflect changes in the acute PAD following the incorporation of apple single serving PDP residue data into the acute dietary probabilistic analysis. The details of this analysis can be found in the memorandum "Azinphos-methyl: Revised Monte Carlo Assessment to Include PDP Apple Single Serving Data."dated April 26, 2001.

Acute dietary risk from drinking water

The following is a table that compares the DWLOC calculated for acute risk from drinking water with the EECs for both surface and ground water based on the assumptions provided above.

Table 4. Summary of DWLOC Calculations for Acute Risk

Population subgroup	Acute PAD (mkd)	Food exposure (mkd)	Allowable water exposure (mkd)	Max.[5] ground water conc. (ppb)	Typical[6] surface water EEC (ppb)	DWLOC (ppb)
U.S. Population	0.003	0.001285	0.001715	0.40	16	60
Infants (<1 year)	0.003	0.002504	0.000496	0.40	16	5
Children (1-6 years)	0.003	0.002403	0.000597	0.40	16	6

[5]Based on modeling (SCI-GROW) the maximum labeled application rate for walnuts, 2.0 lbs ai/A per application for a maximum of 6.0 lbs ai/A per year.

[6]Based on modeling (PRZM-EXAMS) the typical application rate for peaches, 3 applications of 0.6 lbs ai/A.

Children (7-12 years)	0.003	0.001595	0.001405	0.40	16	14
Females (13-50 years)	0.003	0.000866	0.002134	0.40	16	64
Males (13-19 years)	0.003	0.000798	0.002202	0.40	16	77
Males (20+ years)	0.003	0.000814	0.002186	0.40	16	77
Seniors 55+	0.003	0.000999	0.002001	0.40	16	70
For infants and children, assumes 10 kg body weight and 1 liter water consumption per day. For females, assumes 60 kg body weight and 2 liter water consumption per day. For U.S. population, males, and seniors 55+, assumes 70 kg body weight and 2 liter water consumption per day.						

The surface water EEC from typical application practice on peaches is 16. The EEC represents a level that would be found once every ten years in a site that is more vulnerable than 90% of all use sites. Even with typical application practice this exceeds the DWLOC by a factor of approximately 3. This assessment is based on the peach use which the Agency has determined to be ineligible for reregistration for reasons including worker and ecological risk. For uses that may be retained , the highest EECs base on typical application practice are for cherries and apples, which are 5.1 and 4.6 micrograms per liter respectively, only slightly above the DWLOC. With the additional mitigation that is to be implemented for these crops, including the elimination of aerial application, we expect the concentrations in surface water to fall below the DWLOC. Thus, drinking water derived from surface water for these and other retained uses would not be of concern.

As described in section 1e, data from the 1998 single-dose oral study in human volunteers would support the reduction of the 10x inter-species uncertainty factor, which in turn could reduce the acute PAD. This consideration supports the conclusion that the acute dietary risk from drinking water would be well below the Agency's level of concern for both surface water for all population subgroups.

Chronic dietary risk from drinking water

The highest annual mean concentrations of azinphos-methyl in surface water ranged from 0.027 ppb to 7.2 ppb. As in the assessment of acute drinking water risk, the lower bound was estimated from monitoring data, and the upper bound from PRZM-EXAMS modeling of the maximum use pattern labeled for eastern peaches, 1.125 lbs ai/A per application for a maximum of 4.5 lbs ai/A per year (see above for comments on this rate).

Chronic drinking water exposure from ground water was estimated at 0.064 ppb to 0.40 ppb. The lower bound was based on 1998 USGS ground water monitoring, which found four detections of azinphos-methyl ranging from 0.003 to 0.064 ppb. An estimate of the concentration that might be found in ground water under highly vulnerable conditions[7] was made using SCI-GROW. This modeling resulted in a maximum annual mean EEC of 0.40 ppb, based on the maximum annual application rate for walnuts of 6 lbs per acre.

For chronic risk, limited monitoring data and July 1999 model estimates of the maximum yearly mean concentration of azinphos-methyl in water indicate that potential exposure to drinking water derived from ground water is not of concern for all populations. Model estimates suggest that potential exposure to drinking water derived from surface water may be of concern for non-nursing infants (DWLOC = 7; maximum mean annual surface water EEC = 7). However, based on its physico-chemical properties, residues of azinphos-methyl are not expected to persist long enough in either surface or ground water to pose a chronic exposure.

Table 6. Summary of DWLOC Calculations for Chronic Risk

Population subgroup	Chronic PAD (mkd)	Food exposure (mkd)	Allowable water exposure (mkd)	Max. mean annual[8] ground water EEC (ppb)	Max. mean annual[9] surface water EEC (ppb)	DWLOC (ppb)
U.S. Population	0.0015	0.000195	0.001305	0.40	7	46
Nursing infants (<1 year)	0.0015	0.000194	0.001306	0.40	7	13
Non-nursing infants (<1 year)	0.0015	0.000803	0.000697	0.40	7	7
Children (1-6 years)	0.0015	0.000495	0.001005	0.40	7	10

[7]Modeling was conducted for shallow ground water under sandy soils, and not ground water in karst terrain.

[8]Based on modeling (SCI-GROW) the maximum labeled application rate for walnuts, 6.0 lb ai/A per year.

[9]Based on modeling (PRZM-EXAMS) the maximum labeled application rate for eastern peaches, 4.5 lbs ai/A per year.

Children (7-12 years)	0.0015	0.000329	0.001171	0.40	7	12
Females (13-19 years)	0.0015	0.000172	0.001328	0.40	7	40
Females (20+ years)	0.0015	0.000114	0.001386	0.40	7	42
Males (13-19 years)	0.0015	0.000205	0.001295	0.40	7	45
Males (20+ years)	0.0015	0.000121	0.001379	0.40	7	48
For infants and children, assumes 10 kg body weight and 1 liter water consumption per day. For females, assumes 60 kg body weight and 2 liter water consumption per day. For U.S. population, males, and seniors 55+, assumes 70 kg body weight and 2 liter water consumption per day.						

3. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and if appropriate residential and incidental exposure. 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 discussed in the Revised Human Health Risk Assessment chapter, dated May 19,1999, and are updated here to reflect the results of the revised acute dietary assessment incorporating apple single serving PDP residue data (see the memorandum "Azinphos-methyl: Revised Monte Carlo Assessment to Include PDP Apple Single Serving Data," for details).

For azinphos-methyl, the aggregate risk assessment does not include residential exposure, because there are no residential uses. Also, secondary exposures, such as spray drift are not included in the assessment. However, the Agency is currently developing a method to address secondary exposure.

Aggregate acute risk (food and water) is not of concern for any population subgroups. Although calculated EECs result in approximately three fold exceedances of the DWLOC, current mitigation will reduce environmental concentrations below the level of concern.

Aggregate chronic risk (food and water) is not of concern. Chronic dietary exposure is less than 50% of the cPAD for all population subgroups except non-nursing infants (54% cPAD). The resultant DWLOC for non-nursing infants is 7 ppb. Although conservative modeling

estimates suggest that maximum mean annual surface water concentrations (7.2 ppb) may slightly exceed this DWLOC, the fate data for azinphos-methyl indicate that residues would not persist long enough in either surface or ground water to pose a chronic exposure in drinking water.

4. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of azinphos-methyl include: individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators. 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. This MOE is based on a 10x uncertainty factor for interspecies variability, and a 10x uncertainty factor for intraspecies variability.

Data from a 1999 28-day repeated-dose oral study in human volunteers suggest that humans are no more sensitive than rats to repeated oral exposure to azinphos-methyl, if only cholinesterase inhibition is considered as an endpoint. However, pup mortality was observed at the same doses as substantial maternal cholinesterase inhibition in both 1-generation and 2-generation reproductive studies in rats. In order to be protective of effects that may not be related to cholinesterase inhibition that could potentially result from short or intermediate term exposures to azinphos-methyl, the Agency has determined that the 10x interspecies uncertainty factor should not be removed for the occupational risk assessment.

a. Toxicity

Azinphos-methyl is acutely toxic at relatively low oral or dermal doses when tested in rats, but was found to be less toxic to dermally exposed rabbits because it is detoxified in the rabbit's skin. Azinphos-methyl is moderately toxic via inhalation and only slightly irritating to the eye. It is non-irritating to the skin but did produce dermal sensitization in guinea pigs. The acute toxicity profile for azinphos-methyl is summarized in Table 5a.

Table 5a. Acute toxicity profile for occupational exposure for azinphos-methyl

Guideline No.	Study Type	MRID No.	Results	Toxicity Category
81-1	Acute Oral (Rat)	00155002	LD_{50} =4.6 mg/kg% 4.4 mg/kg&	I
81-2	Acute Dermal (Rat)	00155003	LD_{50} =200-250 mg/kg% 155 mg/kg&	I

Guideline No.	Study Type	MRID No.	Results	Toxicity Category
81-2	Acute Dermal (Rabbit)	40280102	LD_{50} =>2000 mg/kg	III
81-3	Acute Inhalation (Rat)	40280103	LC_{50} = >0.21mg/L	II
81-4	Primary Eye Irritation (Rabbit)	43337501	No ocular effects at 48 hrs.	III
81-5	Primary Skin Irritation (Rabbit)	43337101	Non-irritating	IV
81-6	Dermal Sensitization (Guinea Pig)	41064401	Sensitizer	N/A

The toxicity of azinphos-methyl is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for azinphos-methyl, including a 7-day dermal toxicity study in rats.

Selection of toxicological endpoints and uncertainty factors

The toxicological endpoints and other factors used in the occupational risk assessment for azinphos-methyl are listed below in Table 5a. Short-term exposure risk estimates (used to assess short-term handler risk and all post-application worker risks) are based on a 1-week rat dermal absorption study (MRID 42452701) that included cholinesterase inhibition measurements. The NOAEL was 0.56 mg/kg/d, based on 15 to 16% RBC cholinesterase inhibition seen at the LOAEL of 5.6 mg/kg/d. Because this study used dermal exposure (the test material was on the skin of rats for 10 to 24 hours), a dermal absorption factor is not required when calculating MOEs. The difference between the NOAEL and LOAEL is 10 fold. Using this study also assumes that rat skin and human skin have equal permeability.

The only other dermal study available is a 21-day dermal toxicity study in rabbits. EPA did not choose the endpoint from this study because the rabbit has unique physiological and biochemical characteristics that tend to lead to underestimation of the dermal toxicity of organophosphate chemicals, like azinphos-methyl, which require biological activation to the oxone. The rabbit posses a high concentration of blood arylesterases which detoxify such compounds before they can be activated in the liver making the rabbit uniquely insensitive to their toxicity.

Because the endpoint selected for the intermediate-term exposure risk assessment (used to assess intermediate-term handler risk, only) was based on a 1-year chronic oral study in dogs, a dermal absorption factor of 42% was applied to the oral NOAEL. This value is based on the

same rat dermal absorption study discussed above (MRID 42452701). The dermal absorption rate varied with the amount of test substance applied to the rat skin. At the lowest tested rate, (0.056 mg/kg/d), the highest dermal absorption (42%) was noted. At higher rates (0.56 and 5.6 mg/kg/d) dermal absorption was 22 and 18%, respectively. In the 1999 single dose dermal absorption study in human volunteers, dermal absorption ranged from 5% to 45% of the amount applied, with an average of 22%. A dermal absorption factor of 42% approaches the upper limit of dermal absorption observed in the human study and thus is consistent with both the animal and human data for azinphos-methyl.

Table 5b. Summary of toxicological endpoints and other factors used in the human occupational risk assessment for azinphos-methyl.

Assessment	Dose	Endpoint	Study	Absorption factor
Dermal (short-term)	NOAEL = 0.56 mg/kg/day	Red blood cell ChE inhibition (16-17%) at LOAEL of 5.6 mg/kg/day	1-week dermal rat (MRID 42452701)	N/A
Dermal (intermediate-term)	NOAEL = 0.36 mg/kg/day (equivalent dermal dose = 0.149 mg/kg/day)	Red blood cell ChE inhibition (27-43%) at LOAEL of 0.688 mg/kg/day	1-year oral dog (MRID 41804801)	42%
Inhalation (any time period)	NOAEL = 0.0012 mg/L	Plasma and red blood cell ChE inhibition at LOAEL of 0.0047 mg/L	90-day inhalation rat (MRID 00155011)	N/A

Endpoint characterization for occupational risk

In formulating the risk management decision for azinphos-methyl, the estimates of worker risk should be examined in light of the entire available toxicological database and not just the study that was used to obtain the NOAEL used in risk calculations. It is important to note that in the 1-week dermal rat study (MRID 42452701) used to establish the NOAEL for short-term risk estimates, adverse effects were noted at a dose 10 times higher (i.e. the LOAEL was 10 times higher than the NOAEL) and further that these effects, although statistically significant, were not of a great magnitude (15 to 16% red blood cell cholinesterase inhibition). This level of inhibition

is below that at which there is a regulatory trigger for NIOSH and CalEPA. NIOSH recommends that a worker should be removed from exposure if his or her red blood cell cholinesterase level drops to or below 40% of the pre-exposure baseline level. CalEPA states that a decrease of 30% of baseline in the RBC or to 40% of baseline in plasma cholinesterase level indicates the need for removal of the individual from all exposure to cholinesterase inhibitors.

CalEPA has conducted their own independent assessment of worker risk. For acute and short-term dermal exposure to post-application workers such as harvesters, CalEPA used the 1998 single-dose oral study in human volunteers (see earlier section on acute dietary risk). Seven males and seven females received a single oral dose of azinphos-methyl at up to 0.75 mg/kg/day. No effects were observed on plasma or RBC cholinesterase at this dosing level.

For evaluating seasonal exposure, CalEPA used a 90-day subchronic oral neurotoxicity study in rats. In this study there was reduced plasma, RBC and brain cholinesterase activity, ranging from 8% ChE inhibition in the brain to 38% inhibition in red blood cells (62-92% of controls) at a dose of 0.9 mg/kg/day (LOAEL). This dose level was divided by a 10 fold uncertainty factor to calculate a NOAEL of 0.09 mg/kg/day.

For estimating dermal absorption, CalEPA used the results of two human toxicity studies. The first was an older study using six male volunteers (Feldman and Maibach, 1974). The second was the 1999 single dose dermal absorption study mentioned above, which used 18 human volunteers. CalEPA calculated an average dermal absorption of 19% based on both of these studies.

The toxicological database for azinphos-methyl also includes one and two generation rat reproductive toxicity studies. At a dose level of 2.5 mg/kg/day, clinical toxicity signs were observed (poor conditioning and convulsions), along with plasma, RBC and brain cholinesterase inhibition. If this effect level is adjusted by the dermal absorption factors of 40% or 19%, the dermal equivalent dose (LOAEL) would be 6.3 or 13 mg/kg/d respectively. Note that this value is 10 to 20 fold higher than the dermal NOAEL used in the Agency's risk assessment. The NOAEL identified in these studies was 0.25 mg/kg/day. Adjusting this value by the dermal absorption factors of 40% or 19%, the dermal equivalent dose (NOAEL) would be 0.63 or 1.3 mg/kg/day respectively. The lower bounding estimate is approximately equal to the value used in the Agency's assessment, while the upper bound value is two-fold higher.

In the recently submitted 1999 28-day repeated-dose oral study in human volunteers, a group of 8 male volunteers were dosed with 0.25 mg/kg/day for 28 consecutive days. There were no effects on either clinical symptomology or inhibition of either plasma or RBC cholinesterase in this study. As for the rat reproductive studies described above, adjusting this dose level by the dermal absorption factors of 40% or 19% would yield a dermal equivalent dose (NOAEL) of 0.63 or 1.3 mg/kg/day respectively. Again, the lower bounding estimate is approximately equal to the dermal NOAEL value used in the Agency's assessment, while the upper bound value is two fold higher.

Cholinesterase inhibition

Acetylcholinesterase (AchE) is an enzyme found in cholinegic neurons. It is the enzyme that breaks down acetylcholine and terminates its action in the synapses between neurons and between neurons and muscle fibers or glands. Inhibition of AchE leads to an accumulation of acetylcholine and a prolongation of its action. The accumulation of acetylcholine can result in cholinegic responses such as smooth muscle contractions (for example abdominal cramps), glandular secretions (such as sweating), skeletal muscle twitching, and at higher concentrations, paralysis. Blood cholinesterase (plasma or red blood cell) measurements are used as surrogate measures of neuronal cholinesterase activity. The Agency policy on cholinesterase is explained in detail in the document entitled "Office of Pesticide Programs Science Policy on the Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides, August 18, 2000", available at http://www.epa.gov/oppfead1/trac/science/cholinhib.pdf.

Adverse effects acute and chronic exposure to high levels of organophosphate pesticides include headache, nausea and dizziness. Anxiety and restlessness are prominent. Worsening may result in muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps, diarrhea. Often prominent are sweating, salivation, tearing, and rhinorrhea.

The United States Department Of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH) has published an "Occupational Safety and Health Guideline for Azinphos-Methyl". This guideline is intended for workers, physicians, industrial hygenists, and other occupational safety and health professionals who need information to conduct effective occupational safety and health programs for azinphos-methyl workers. This information is available on the internet at http://www.cdc.gov/niosh/pdfs/0044-rev.pdf. In this document, NIOSH cites the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of 0.2 mg/m^3 in air as an 8-hour time weighted average. The OSHA PEL also bears a "Skin" notation , which indicates the cutaneous route of exposure contributes to the overall exposure (29 CFR 19190.1000, Table Z-1-A).

NIOSH recommends that before workers are placed in a job with potential for azinphos-methyl exposure, a licensed health care professional should evaluate and document the workers baseline health status. They recommend that a baseline red blood cell acetylcholinesterase level should be established for each potentially exposed worker. Further, periodic medical examinations and biological monitoring are recommended, focusing on identifying the adverse effects of azinphos-methyl on blood cholinesterase activity. NIOSH states that a worker should be removed from exposure if his or her red blood cell cholinesterase level drops to or below 40% of the pre-exposure baseline level for that individual; he or she should not be allowed to return to work until this level has again reached 80% of the pre-exposure baseline.

The California Environmental Protection Agency (Cal EPA) has issued "Guidelines for Physicians Who Supervise Workers Exposed to Cholinesterase-Inhibiting Pesticides, Third

Edition, 1995". California regulation require employers to arrange with a licensed physician for medical supervision of agricultural workers who are applying Toxicity Category I and II oragnophosphate and carbamate pesticides. This guideline stresses the importance of establishing an individuals baseline for both plasma and reb blood cell cholinesterase activity. A drop in plasma or RBC cholinesterase levels to 80% of a worker's baseline of lower indicates the need for retesting. Regulations state that a decrease to 70% of baseline or lower in the RBC cholinesterase level (i.e. 30% inhibition) or to 60% of baseline or lower in plasma cholinesterase level (i.e., 40% inhibition) indicates the need for immediate removal of the individual from all exposure to cholinesterase inhibitors until both parameters return to within 80% of the pre-exposure baseline or higher.

b. Exposure

Exposure to mixer/loader/applicators

Chemical-specific handler exposure data were not available for azinphos-methyl, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from the revised 1999 azinphos-methyl labels. 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 represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the May 19, 1999 Human Health Risk Assessment for azinphos-methyl, 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. Application rates specified on azinphos-methyl labels range from 0.125 to 2.5 pounds of active ingredient per acre in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent eight solid hours of application work for specific types of application equipment.

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 suite of PPE is baseline PPE. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) are applied. If MOEs are still less than 100, engineering controls (EC) are applied.

The current labels for azinphos-methyl require handlers to wear the following PPE:

1) Airblast applicators must be in fully enclosed cabs or if not in fully enclosed cabs, applicators must wear:

- Chemical resistant suit over long-sleeved shirt and long-legged pants
- Chemical resistent hood
- Full-face respirator or half-faced respirator with a face shield
- Chemical resistant footwear plus socks

2) Applicators (other than airblast) and other handlers (other than mixers and loaders) must wear:

- Coveralls over long-sleeved shirt and long-legged pants
- Chemical resistant gloves, such as barrier laminate or viton
- Chemical resistant footwear plus socks
- Protective eyewear
- Chemical resistant headgear for overhead exposure
- For exposures in enclosed areas, a respirator with either 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-23C)
- For exposures outdoors, dust/mist filtering respirator (MSHA/NIOSH) approval number prefix TC-21C)

3) Mixers and loaders must wear:

- All items in (2) above, plus chemical resistant apron

The levels of protection that formed the basis for calculations of exposure from azinphos-methyl activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical resistant gloves and a dust/mist respirator.
- Maximum PPE: Baseline + coveralls, chemical resistant gloves, and an organic vapor respirator.
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a farm closed mechanical transfer system for liquids or a packaged based system (e.g., water soluble packaging for wettable powders).

For handlers, both short-term and intermediate-term assessments were conducted for azinphos-methyl, to reflect exposures of 1-7 days, or one week to several months durations, respectively. For azinphos-methyl, short-term exposures are typically associated with private or individual growers who treat their own fields or orchards. Intermediate-term exposures would be

representative of commercial agricultural applicators who would have multiple exposures through treatment of agricultural areas over the course of one week of more. MOEs for all short-term and intermediate-term scenarios may be found in the memorandum, "Revised Occupational Handler Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Azinphos-Methyl," dated July 10, 2001, which is available in the public docket.

Exposure to post-application (re-entry) workers

Chemical-specific studies were available for estimating post-application worker exposure. In the preliminary assessment (August 1998), none of the dislodgeable foliar residue (DFR) studies met all of the requirements to qualify as totally acceptable. However, the Agency used the most reliable data to perform the post-application exposure assessments. These data, when viewed in the context of other data available in the literature and the data conducted by the CDPR, were deemed adequate to estimate reentry exposure. The data from the various studies are consistent and reveal the slow dissipation rate for which azinphos-methyl is known.

In response to the agricultural reentry data call-in and to the preliminary risk assessment, new DFR studies were submitted for apples and cotton. These studies were performed in more strict compliance with the Agency's requirements and can be considered more reliable. However, when compared to the results from the older studies, the recent studies present a corroborating picture of post-application risk, and did not significantly affect the risk estimates. Including old and new studies, DFR study data were available for tomatoes, potatoes, apples, grapes, and cotton.

The transfer coefficients used to assess post application exposure were derived from updated transfer coefficients and crop groupings outlined in EPA's revised *Agricultural Transfer Coefficient* policy, which reflects data collected by the Agricultural Re-entry Task Force.

c. Occupational Handler Risk Summary

1) Agricultural Handler Risk

The following is a summary of the occupational handler exposure assessment for agricultural uses of azinphos-methyl, as presented in detail in the memorandum, "Revised Occupational Handler Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Azinphos-Methyl," dated July 10, 2001. There are no registered uses of azinphos-methyl for recreational, residential, or other public (non-occupational) settings.

Azinphos-methyl is applied to 17 major crop groups. Ten major agricultural exposure scenarios were identified and assessed for one or more of these crop groups. Although the risks associated with flagging during aerial applications were assessed, this scenario is not allowed on current labels and is not presented here. The remaining nine scenarios are listed below:

- mixing/loading liquids for aerial/chemigation application
- mixing/loading liquids for groundboom application
- mixing/loading liquids for airblast sprayer application
- mixing/loading wettable powders for aerial application/chemigation irrigation
- mixing/loading wettable powders for groundboom application
- mixing/loading wettable powders for airblast sprayer application
- applying sprays with fixed-wing aircraft
- applying sprays using a groundboom sprayer
- applying sprays using an airblast sprayer

For each crop group, the risks associated with aerial/chemigation, groundboom, and airblast applications were assessed, if applicable. Within each combination of crop group and exposure scenario, a range of application rates was assessed, based on the range of recommended application rates on current labels. All sites registered for both emulsifiable concentrate (EC) and wettable powder (WP) formulations, except parsley (WP only), pistachios (WP only) and nursery stock (WP only). The registered use sites represented by each crop group, the range of application rates, the associated application methods, and the acres treated used in calculating exposure are summarized in Table 6.

Table 6. Use patterns and application rates for occupational exposure for azinphos-methyl

Use site		**Application rate range (lb ai/acre)**	**Application method (acres treated)**
Crop grouping	**Specific crop**		
Roots and Tuber Vegetable	Potato	0.375-0.75	Aerial/chemigation (350), groundboom (80)
Legume Vegetable	Bean Succulent, Bean Snap	0.25-0.5	Aerial/chemigation (350), groundboom (80)
Citrus Fruits	Grapefruit, Lemon, Lime, Orange, Tangerine, Kumquat, Tangelo	1.25-2.0	Aerial/chemigation (350), airblast (20&40)
Pome Fruits	Apple, Pear, Crabapple, Quince	1.0-1.5	Aerial/chemigation (350), airblast (20&40)
Stone Fruits	Cherry	0.75	Aerial/chemigation (350), airblast (20&40)
	Nectarine, Peach, Plum, Prune (low rates)	0.875-1.125	
	Nectarine, Peach, Plum, Prune (high rates)	1.5-2.0	

Use site		Application rate range (lb ai/acre)	Application method (acres treated)
Crop grouping	**Specific crop**		
Berries	Boysenberry, Raspberry, Blackberry, Loganberry, Strawberry	0.25-0.5	Aerial/chemigation (350), groundboom (80)
	Blueberry	0.5-0.75	
	Cranberry	0.5-1.0	
Small Fruits	Grapes	075-1.0	Aerial/chemigation (350), airblast (20&40)
Tree Nuts	Almond, Filbert, Pecan, Walnut	1.5-2.0	Aerial/chemigation (350), airblast (20&40)
	Pistachios	2.5	
Non -Grass Animal Feed	Alfalfa, Clover, Birdsfoot trefoil	0.25-0.75	Aerial/chemigation (1200[10]& 350), groundboom (200[10]& 80)
Oil Seed	Cotton	0.125-0.5	Aerial/chemigation (1200), groundboom (200)
Brassica Leafy Vegetables	Broccoli, Brussels Sprouts, Cabbage, Cauliflower	0.125-0.75	Aerial/chemigation (350), groundboom (80)
Fruiting Vegetables	Pepper, Eggplant	0.375-0.5	Aerial/chemigation (350), groundboom (80)
	Tomato	0.375-1.5	
Cucurbit Vegetables	Cucumber, Cantaloupe, Honeydew melon, Watermelon	0.375-0.5	Aerial/chemigation (350), groundboom (80)
Bulb Vegetables	Dry bulb Onion, Green Onion	0.5-0.75	Aerial/chemigation (350), groundboom (80)
Leafy Vegetables	Celery, Spinach, Parsley	0.375-0.5	Aerial/chemigation (350), groundboom (80)

[10]Higher acreage assumptions apply to alfalfa, only.

Use site		Application rate range (lb ai/acre)	Application method (acres treated)
Crop grouping	**Specific crop**		
Ornamental Plants	Nursery Stock	0.375-2.0	Aerial/chemigation (350), groundboom (80), airblast (20&40)
Micellaneous	Southern Pine Seed Orchards	1.5	Aerial/chemigation (350&1200)

The risks to pesticide handlers are estimated by first calculating the potential daily exposure to handlers (daily exp.), then using that exposure to calculate the daily dose:

(i) Daily exp. (mg ai/day) =

unit exp. (mg ai/lb ai) x max app. rate (lb ai/acre) x max. area treated (acres/day)

(ii) Daily dose (mg ai/kg/day) = daily exp. (mg ai/day) / body weight (kg)

In equation (i), the unit exposure for a given activitiy (e.g., mixing and loading for aerial application) is derived from data in the PHED database (see section 4b above). The margin of exposure (MOE) is calculated as the NOAEL (mg/kg/day) divided by the daily dose (mg/kg/day). The combined risk to handlers from both dermal and inhalation exposures is calculated as follows:

(iii) Combined risk = $1/ [(1/MOE_{dermal} + 1/MOE_{inhalation})$

The Agency has concerns regarding occupational exposure and risk estimates for most exposure scenarios for pesticide handlers. The combined dermal and inhalation risk estimates for handlers using maximum engineering controls are summarized in Table 7. In all cases, risks are driven by dermal exposure. These risk estimates were calculated for the wettable powder (WP) formulation using current maximum label rates and the appropriate default acreage values. Risk estimates also were calculated for the emulsifiable concentrate (EC) formulation; MOEs for mixing and loading the EC formulation were somewhat higher than those calculated for the WP formulation and are shown for every scenario in the revised occupational handler exposure assessment. Risks for both short-term (1 to 7 days) and intermediate-term (1 week to several months) handler exposures to the WP formulation are shown in Table 7 for each crop.

Table 7. Short-term and intermediate-term handler risks for application of the wettable powder formulation of azinphos-methyl at maximum label rates using engineering controls.

Crop	App. rate (lb ai/acre)	Application method (acres treated)	Short-term MOE		Intermediate-term MOE	
			Mixer/ loaders	App.	Mixer/ loaders	App.
Potatoes	0.75	aerial/chemigation (350)	15	29	9.5	19
		groundboom (80)	64	130	42	83
Beans	0.5	aerial/chemigation (350)	10	44	14	28
		groundboom (80)	96	190	63	120
Citrus	2.0	aerial/chemigation (350)	5.5	11	3.6	7.1
		airblast (40)	48	25	31	16
Apples, Pears, Crabapples, Quince, Eastern Plum/Prunes	1.5	aerial/chemigation (350)	7.3	15	4.8	9.4
		airblast (40)	64	33	42	22
Cherries	0.75	aerial/chemigation (350)	15	29	9.5	19
		airblast (40)	130	66	83	43
Eastern Nectarines/ Peaches	1.125	aerial/chemigation (350)	9.7	19	6.4	13
		airblast (40)	85	44	56	29
Western Nectarines/Peaches, Western Plum/ Prunes	2.0	aerial/chemigation (350)	5.5	11	3.6	7.1
		airblast (40)	48	25	31	16

Crop	App. rate (lb ai/acre)	Application method (acres treated)	Short-term MOE		Intermediate-term MOE	
			Mixer/ loaders	App.	Mixer/ loaders	App.
Caneberries, Strawberries	0.5	aerial/chemigation (350)	22	44	14	28
		groundboom (80)	96	200	63	120
Blueberries	0.75	aerial/chemigation (350)	15	29	9.5	19
		airblast (40)	130	66	83	43
		groundboom (80)	64	130	42	83
Cranberries	1.0	aerial/chemigation (350)	11	22	7.1	14
		groundboom (80)	48	97	31	62
Grapes	1.0	aerial/chemigation (350)	11	22	7.1	14
		airblast (40)	96	50	63	32
Almonds, Filberts, Pecans, Walnuts	2.0	aerial/chemigation (350)	5.5	11	3.6	7.1
		airblast (40)	48	25	31	16
Pistachios	2.5	aerial/chemigation (350)	4.4	8.8	2.9	5.7
		airblast (40)	38	40	25	26
Alfalfa	0.75	aerial/chem. (1200)	4.3	8.5	2.8	5.5

Crop	App. rate (lb ai/acre)	Application method (acres treated)	Short-term MOE		Intermediate-term MOE	
			Mixer/ loaders	App.	Mixer/ loaders	App.
		groundboom (200)	26	51	17	33
Clover, Birdsfoot trefoil	0.75	aerial/chemigation (350)	15	29	9.5	19
		groundboom (80)	64	130	42	83
Cotton	0.5	aerial/chem. (1200)	6.4	13	4.2	8.3
		groundboom (200)	38	77	25	50
Broccoli, Brussels Sprouts, Cabbage, Cauliflower	0.75	aerial/chemigation (350)	15	29	9.5	19
		groundboom (80)	64	130	42	83
Peppers, Eggplants	0.5	aerial/chemigation (350)	22	44	14	28
		groundboom (80)	96	190	63	120
Tomatoes	1.5	aerial/chemigation (350)	7.3	15	4.8	9.4
		groundboom (80)	32	64	21	42
Cucumbers, Cantaloupes, Honeydew melons, Watermelons	0.5	aerial/chemigation (350)	22	44	14	28
		groundboom (80)	96	190	63	120
Dry bulb Onions, Green Onions	0.75	aerial/chemigation (350)	15	29	9.5	19

Crop	App. rate (lb ai/acre)	Application method (acres treated)	Short-term MOE		Intermediate-term MOE	
			Mixer/ loaders	App.	Mixer/ loaders	App.
		groundboom (80)	64	130	42	83
Celery, Spinach, Parsley	0.5	aerial/chemigation (350)	22	44	14	28
		groundboom (80)	96	190	63	120
Nursery Stock	2.0	aerial/chemigation (350)	5.5	11	3.6	7.1
		groundboom (80)	24	48	16	31
		airblast (40)	48	25	31	16
Southern Pine Seed Orchards	1.5	aerial/chemigation (350)	7.3	15	4.8	9.4

The only exposure scenarios listed above that are **not** of concern are the following:

Short-term exposures:

(i) groundboom applicators for potatoes, beans, caneberries, strawberries, blueberries, clover, birdsfoot trefoil, cole crops, peppers, eggplant, cucurbits, onions, celery, spinach, and parsley
(ii) airblast mixer/loaders for cherries

Intermediate-term exposures:

(i) groundboom applicators for beans, caneberries, strawberries, peppers, eggplant, cucurbits, celery, spinach, and parsley

All other exposure scenarios are of concern. Although not included in the above scenarios, it is likely that in many cases the same person may mix, load and apply azinphos-methyl for application by groundboom or airblast. In such cases, the risk estimates would be higher than the risks calculated for either mixer/loaders or applicators alone. The highest occupational risks are associated with mixing, loading and applying azinphos-methyl by air: MOEs range from 4.3 to

44 for short-term exposures, and from 2.8 to 28 for intermediate-term exposures.

1) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites to perform agricultural tasks such as harvesting**.** The post-application risk calculations completed in this assessment are described in detail in the memorandum "Azinphos-Methyl: Third Version of the Revised Occupational Postapplication Exposure and Risk Calculations [Chemical Code 058001]," dated October 10, 2001.

The post-application risks for workers entering treated sites were calculated the agricultural activities associated with each crop. The agricultural activities performed by workers vary in exposure, from low exposure activities such as irrigating and scouting, to high exposure tasks such as hand harvesting and hand thinning. The risks to post-application (re-entry) workers are estimated by first calculating the potential daily exposure to workers (daily exp.), then using that exposure to calculate the daily dose:

(i) Daily exp. (mg/day) =

DFR (μg/cm^2) x TC (cm^2/hr) x 8 (hrs/workday) / 1000 (μg/mg conversion)

(ii) Daily dose (mg/kg/day) = daily exp. (mg/day) / 70 (body weight in kg)

In equation (i), the DFR is the dislodgeable foliar residue, or the amount of azinphos that is readily dislodged from the foliage of a given crop. For azinphos-methyl, DFR study data were available for tomatoes, potatoes, apples, grapes, and cotton, and these data were applied to all other crops (see section 4b above). The TC is the transfer coefficient, or the amount of residue that is readily transferred from crop foliage to the skin of a worker. Transfer coefficients are specific to a particular agricultural activity (e.g. harvesting) and crop, rather than to a particular chemical, and are derived from data collected by the Agricultural Re-entry Task Force (see section 4b above). The margin of exposure (MOE) is calculated as the NOAEL (mg/kg/day) divided by the daily dose (mg/kg/day).

The MOEs at current label re-entry intervals are summarized below for applications of the wettable powder formulation at maximum label rates to the critical use sites for azinphos-methyl. The remaining use sites on current labels (alfalfa, beans (succulent and snap), birdsfoot trefoil, broccoli, cabbage (including Chinese), cauliflower, citrus, celery, clover, cucumbers, eggplant, filberts, melons (honeydew melons, muskmelon/canteloupe, watermelons, other melons), nectarines, onions (green and dry bulb), parsley, pecans, peppers, quince, spinach, strawberries, and tomatoes) have little or no use of azinphos-methyl. The MOEs for these use sites are available in the revised memorandum on postapplication risk.

The revised postapplication assessment calculates MOEs for all possible activities for each

crop. Based on information from growers and other stakeholders in the course of the public process, EPA has been able to focus its analysis on the critical hand labor activities for each crop. For example, EPA's reenty assessment calculated MOEs for hand harvesting almonds and other nut crops. However, because nut crops are largely mechanically harvested, and harvesters have little direct contact with treated foliage, the critical activities for setting REIs become scouting, poling, and pruning. Table 8 below reflects only those critical hand labor activities for each crop. Additionally, it should be noted that the MOEs in Table 8 have been calculated using a very protective endpoint. As discussed previously, this assessment is based on a NOAEL of 0.56 mg/kg/day in a dermal rat study with a LOAEL of 5.6 mg/kg/day showing only 15-16% ChE inhibition in red blood cells. Because of the 10-fold difference between the LOAEL and NOAEL, the MOEs could be up to10 times greater than those shown in the table.

Table 8. Margins of exposure (MOEs) for post-application agricultural re-entry activities at current label restricted entry intervals (REIs) using maximum label application rates for the wettable powder formulation.

Crop (max. label rate per app.)	MOEs
Almonds[11] (2.0 lbs ai/A)	2 day REI: MOE = 3 for irrigating and scouting 14 day REI: N/A (no hand thinning) 28 day PHI: MOE = 3 for poling mummy nuts & pruning; risks of activities associated with mechanical harvesting (removing nuts from trees with a mechanical shaker, sweeping or blowing nuts into windrows, gathering nuts with a mechanical harvester) are not known but may be high for open cabs. Some hand harvesting is done for young trees, but these are usually not treated with azinphos-methyl. **REI** where the **MOE reaches 100**: 71 days for irrigating, scouting & hand weeding (TC = 400 cm^2/hr), 104 days for poling & pruning (TC = 2500 cm^2/hr)
Apples, crabapples (1.5 lbs ai/A)	2 day REI: MOE = 23 for propping; 2 for irrigation and scouting; 1 for pruning, tying & training 14 day REI: MOE = 1 for hand thinning 14/21 day PHI: MOE = 2 for hand harvesting **REI** where the **MOE reaches 100**: 32 days for propping (TC = 100 cm^2/hr); 79 days for irrigating, scouting & weeding (TC = 1000 cm^2/hr); 102 days for hand harvesting, hand thinning, pruning, tying & training (TC = 3000 cm^2/hr)

[11]MOE calculations for almonds, apples and crabapples, sweet and tart cherries, peaches, pears, pistachios, plums and prunes, southern pine seed orchards, and walnuts are based on data from four DFR studies in apples.

Blueberries, lowbush[12] (0.75 lbs ai/A)	2 day REI: MOE = 19 for irrigating, scouting 4 day REI: N/A (no applicable activities were identified) 7 day PHI: MOE = 8 for hand harvesting **REI** where the **MOE reaches 100**: 23 days for irrigating, scouting, hand weeding & mulching (TC = 400 cm^2/hr); 38 days for hand harvesting & hand pruning (TC = 1500 cm^2/hr).
Blueberries, highbush[13] (0.75 lbs ai/A)	2 day REI: MOE = 3 for mowing, irrigating, scouting 4 day REI: MOE = 3 for hand weeding & mulching; <1 for hand pruning (only done in off-season) 7 day PHI: MOE = <1 for hand harvesting **REI** where the **MOE reaches 100**: 100 days for irrigating, scouting, hand weeding & mulching (TC = 500 cm^2/hr); 161 days for hand harvesting and hand pruning (TC = 5000 cm^2/hr).
Brussels sprouts (0.75 lbs ai/A)	2 day REI: MOE = 3 for irrigating and scouting immature plants; 1 for irrigating & scouting mature plants 4 day REI: MOE = 3 for thinning and weeding immature plants; 1 for pruning & topping mature plants 7 day PHI: MOE = 2 for hand harvesting **REI** where the **MOE reaches 100**: 45 days for irrigating, scouting, thinning & weeding immature plants (TC = 2000 cm^2/hr); 54 days for scouting mature plants (TC = 4000 cm^2/hr); 56 days for hand harvesting, irrigating, pruning, topping, & tying mature plants (TC = 5000 cm^2/hr).
Caneberries (blackberries, raspberries, loganberries, boysenberries) (0.5 lbs ai/A)	***NOTE:*** re-entry risks assessed for foliar application; risks of application to canes and soil are not known. 2 day REI: MOE = 3.9 for mowing, irrigating, & scouting immature plants; 2.0 for scouting mature plants 4 day REI: MOE = 4.2 for hand weeding; 2.1 for training immature plants; 0.4 for pruning & training mature plants 14 day PHI: MOE = 0.6 for hand harvesting The **REI** where the **MOE reaches 100**: 89 days for irrigating, hand weeding & scouting immature plants (TC = 500 cm^2/hr); 108 days for scouting mature plants & training immature plants (TC = 1000 cm^2/hr); 154 days for pruning, hand harvesting & training mature plants (TC = 5000 cm^2/hr).

[12]MOE calculations for lowbush blueberries, Brussels sprouts, cranberries, nursery stock, and potatoes are based on data from a DFR study in potatoes.

[13]MOE calculations for highbush blueberries, caneberries, and grapes are based on data from a DFR study in grapes.

Cherries, sweet (0.75 lbs ai/A)	2 day REI: MOE = 4.6 for irrigating & scouting 14 day REI: MOE = N/A (no hand thinning) 15 day PHI: MOE = 2.9 for hand harvesting The **REI** where the **MOE reaches100**: 65 days for irrigating & scouting (TC = 1000 cm^2/hr); 87 days for hand harvesting (TC = 3000 cm^2/hr)
Cherries, tart (0.75 lbs ai/A)	2 day REI: MOE = 4.6 for irrigating & scouting 14 day REI: N/A (no hand thinning) 15 day PHI: N/A (no contact mechanical harvesting) The **REI** where the **MOE reaches100**: 65 days for irrigating & scouting (TC = 1000 cm^2/hr)
Cotton[14] (0.5 lbs ai/A)	2 day REI: MOE >100 for irrigating and scouting immature plants; 17 for irrigating and scouting mature plants. 4 day REI: MOE >100 for thinning and weeding immature plants, 23 for thinning and weeding mature plants 7 day PHI: N/A (no contact mechanical harvesting) The **REI** where the **MOE reaches 100**: 0 days for irrigating, scouting, thinning & weeding immature plants (TC = 100 cm^2/hr), 14 days for irrigating, scouting, thinning & weeding mature plants (TC = 1500 cm^2/hr).
Cranberries (1.0 lbs ai/A)	2 day REI: MOE = 14 for irrigating and scouting 4 day REI: MOE = 17 for hand weeding 21 day PHI: MOE = 68 for rake harvesting The **REI** where the **MOE reaches 100**: 26 days for irrigating, scouting, hand weeding & rake harvesting (TC = 400 cm^2/hr)
Grapes (1.0 lb ai/A)	2 day REI: MOE = 4.2 for hedging, irrigating & hand weeding; 2.1-4.2 for scouting 21 day REI: MOE = 0.8 for leaf pulling, cane cutting & bunch thinning; 0.4 for girdling & cane turning 21 day REI/PHI: MOE = 0.8 for hand harvesting The **REI** where the **MOE reaches 100**:108 days for hedging, scouting, irrigating & hand weeding (TC = 500 cm^2/hr); 126 days for scouting (TC = 1000 cm^2/hr); 169 days for leaf pulling, cane cutting, bunch thinning & hand harvesting (TC = 5000 cm^2/hr); 188 days for girdling & cane turning (TC = 10000 cm^2/hr)
Peaches (Eastern region, 1.125 lb ai/A rate)	2 day REI: MOE = 31 for propping; 3.1 for irrigation & scouting; 1.0 for pruning & training 14 day REI: MOE = 1.8 for hand thinning 21 day PHI: MOE = 2.6 for harvesting **REI** where the **MOE reaches 100**: 27 days for propping (TC = 100 cm^2/hr); 73 days for irrigation, scouting & weeding (TC = 1000 cm^2/hr); 96 days for hand thinning, harvesting, pruning & training (TC = 3000 cm^2/hr)

[14]MOE calculations for cotton are based on data from a DFR study in cotton.

Peaches (Western region, 2.0 lb ai/A rate)	2 day REI: MOE = 17.2 for propping; 1.7 for irrigation, scouting & weeding; 0.6 for pruning & training 14 day REI: MOE = 1.0 for hand thinning 21 day PHI: MOE = 1.5 for harvesting **REI** where the **MOE reaches 100**: 38 days for propping (TC = 100 cm^2/hr); 85 days for irrigation, scouting & weeding (TC = 1000 cm^2/hr); 107 days for hand thinning, harvesting, pruning & training (TC = 3000 cm^2/hr)
Pears (1.5 lbs ai/A)	2 day REI: MOE = 2.3 for mowing, irrigating & scouting; 0.8 for pruning & training 14/21 day REI/PHI: MOE = 2.1/1.9 for hand harvesting and hand thinning **REI** where the **MOE reaches 100**: 32 days for propping (TC = 100 cm^2/hr); 79 days for irrigating, scouting & weeding (TC = 1000 cm^2/hr); 102 days for hand harvesting, hand thinning, pruning, tying & training (TC = 3000 cm^2/hr)
Pistachios (2.5 lbs ai/A)	2 day REI: MOE = 2.8 for irrigating, scouting and hand weeding 14 day REI: N/A (no hand thinning) 21 day PHI: 1.4 for poling mummy nuts & pruning; risks of activities associated with mechanical harvesting not known. Some hand harvesting is done for young trees, but these are usually not treated with azinphos-methyl. **REI** where the **MOE reaches 100**: 76 days for irrigating, scouting & hand weeding (TC = 500 cm^2/hr), 108 days for poling & pruning (TC = 2500 cm^2/hr)
Plums & Prunes (Eastern region, 1.5 lb ai/A rate)	2 day REI: MOE = 23 for propping; 2.3 for irrigation, scouting & weeding; 0.8 for pruning & training 14 day REI: MOE = 1.4 for hand thinning 15 day PHI: MOE = 1.4 for harvesting **REI** where the **MOE reaches 100**: 32 days for propping (TC = 100 cm^2/hr); 79 days for irrigating, scouting & weeding (TC = 1000 cm^2/hr); 102 days for hand harvesting, hand thinning, pruning, tying & training (TC = 3000 cm^2/hr)
Plums & Prunes (Western region, 2.0 lb ai/A rate)	2 day REI: MOE = 17 for propping; 1.7 for irrigation, scouting & weeding; 0.6 for pruning & training 14 day REI: MOE = 1.0 for hand thinning 15 day PHI: MOE = 1.1 for harvesting **REI** where the **MOE reaches 100**: 38 days for propping (TC = 100 cm^2/hr); 85 days for irrigation, scouting & weeding (TC = 1000 cm^2/hr); 107 days for hand thinning, harvesting, pruning & training (TC = 3000 cm^2/hr)
Potatoes (0.75 lbs ai/A)	2 day REI: MOE = 19 for irrigating & scouting immature plants; 3.7 for irrigating & scouting mature plants 4 day REI: MOE = 22 for thinning and weeding immature plants 7 day PHI: N/A (no contact mechanical harvesting) **REI** where the **MOE reaches 100**: 23 days for irrigating, scouting, thinning & weeding immature plants (TC = 300 cm^2/hr); 42 days for irrigating & scouting mature plants (TC = 1500 cm^2/hr).

Nursery stock (ornamentals) (2.0 lbs ai/A)	***NOTE:*** re-entry risks assessed based on application to cut flowers. 2 day REI: MOE = 0.8 for irrigating & scouting immature/low foliage plants; 0.5 for irrigating & scouting mature/high foliage plants 4 day REI: MOE = 1.0 for thinning & hand weeding immature/low foliage plants; 0.4 for thinning mature/high foliage plants and for hand harvesting, pruning, & pinching all plants **REI** where the **MOE reaches 100**: 60 days for irrigating, scouting, thinning & weeding immature/low foliage plants (TC = 2500 cm^2/hr); 66 days for irrigating & scouting mature/high foliage plants (TC = 4000 cm^2/hr); 72 days for thinning mature/high foliage plants and for hand harvesting, pruning, & pinching all plants (TC = 7000 cm^2/hr).
Southern Pine Seed Orchards (1.5 lbs ai/A)	2 day REI: MOE = 2.3 for mowing, irrigating and scouting 4 day REI: MOE = 1.4 hand harvesting of cones, cone pruning, pruning, training, tying, thinning, staking and topping **REI** where the **MOE reaches 100**: 79 days for irrigating & scouting (TC = 1000 cm^2/hr); 102 days for hand harvesting of cones, hand pollination, cone pruning, pruning, training, tying, thinning, staking & topping (TC = 3000 cm^2/hr).
Walnuts (2.0 lbs ai/A)	2 day REI: MOE = 3.4 for irrigating and scouting 14 day REI: N/A (no hand thinning) 28 day PHI: MOE = 2.5 for poling mummy nuts & pruning; risks of activities associated with mechanical harvesting (removing nuts from trees with a mechanical shaker, sweeping or blowing nuts into windrows, gathering nuts with a mechanical harvester) are not known but may be high for open cabs. **REI** where the **MOE reaches 100**: 71 days for irrigating, scouting & weeding (TC = 500 cm^2/hr), 104 days for poling & pruning (TC = 2500 cm^2/hr).

As shown above, the risks to re-entry workers are above the level of concern for all assessed activities in all the crops where azinphos-methyl is used. For example, the MOE for hand harvesting in apples (21 day PHI, 1.5 lbs ai/A) is 2. The MOE for hand harvesting apples does not reach 100 until 102 days after application.

1. Incident Data

Since the review of azinphos-methyl incident reports dated August 21, 1997 and described in the Human Health Risk Assessment dated May 19, 1999, additional pertinent on Poison Control Center information and cholinesterase monitoring data have been found (see the memorandum "Update to Review of Azinphos-Methyl Incident Reports," dated May 18, 1999 and available in the docket). The earlier review reported 39 occupational and 76 non-occupational symptomatic cases due to exposure to azinphos-methyl (as a single exposure rather than exposure to multiple products) between 1985 and 1992. An additional four years of data covering 1993-1996 found another 14 occupational and 49 non-occupational symptomatic cases due to azinphos-methyl. Overall there does not appear to be any trend from the earlier years to the 1993-1996 time period, though a decline in occupational cases and an increase in non-

occupational cases is suggested. However, trends in Poison Control Center data can be affected by the changes in participation by individual centers over the years. Typically, non-occupational exposures occur when bystanders are exposed to field residue or spray drift.

Additional information has been obtained concerning exposures to azinphos methyl that included measurements of blood cholinesterase levels. This information is summarized below.

California accessed medical monitoring records for 542 agricultural pesticide applicators under medical supervision in 1985 for exposure to the more toxic cholinesterase-inhibiting organophosphate and carbamate pesticides (Ames et al. 1987, 1989). In California, cholinesterase monitoring is required for all pesticide applicators who handle Toxicity Category I or II organophosphate or carbamate pesticides for 30 hours or more in any 30- day period. To be included in the survey, the worker had to have at least one pre-exposure (baseline) cholinesterase measurement and at least one exposure value (mid-season). A data-call-in was issued by the California Department of Food and Agriculture and local Agricultural Commissioners through pesticide application firms to their medical supervisors. Follow up letters were sent and phone calls made to employers, physicians, and laboratories performing tests, but significant under reporting is likely to have occurred. Therefore, these workers may not be representative of all workers undergoing medical monitoring in California. However, they do represent exposure effects verified by medical laboratories. Cholinesterase activity depression of 20 percent or more below baseline was observed in 127 or 23 percent of the 542 workers. Depression of 20 percent or more below baseline represents strong evidence of exposure (Gallo and Lawryk 1991).

Specific pesticide exposure was available for 94 of the 127 cases, based on usage records for the previous two weeks. Of these, 31 percent had been exposed to mevinphos, 21 percent to methomyl, and 21 percent to parathion, the three leading pesticides responsible for cholinesterase inhibition. Of the 94 cases with inhibition, 11% had exposure in the past two weeks to azinphos-methyl. Note that many of the workers were exposed to two or more pesticides during the two weeks before they had cholinesterase depression of 20% or more. Twelve of the workers in this study were reported to have pesticide-related illnesses by their physicians. These data demonstrate that agricultural workers, who mix, load and apply the more toxic pesticides are subject to significant levels of exposure despite the considerable restrictions in place to prevent exposure.

California has maintained a Pesticide Illness Surveillance Program with consistent data collection procedures since 1982 (data tabulations provide by Louise Mehler, M.D., California EPA). From 1982 through 1996 there were 63 illnesses (with a possible, probable or definite relationship). In 12 of these cases, azinphos-methyl was considered the primary pesticide responsible for poisoning. Of the 63 cases with some exposure to azinphos-methyl, 22 (35%) had below normal levels of cholinesterase or evidence of a marked increase in cholinesterase (20% or more) subsequent to their exposure. Of the 12 cases where azinphos-methyl was determined to be the primary cause of poisoning, five (42%) had evidence of cholinesterase depression. The evidence consisted of cholinesterase depression below laboratory normal values in three of the

five cases and subsequent increases in cholinesterase of 40% or more reported in two of the five.

A study of 20 California peach harvest workers was conducted to test different biomarkers of exposure (McCurdy et al. 1994). Cholinesterase measurements were taken 6 days prior to exposure, on the third day of exposure, and 44 days after initial exposure. Thirty days prior to exposure, azinphos-methyl had been applied to study orchards at a rate of 1.5 pounds per acre. The re-entry period for azinphos-methyl in California is 14 days. In comparison with baseline median values, red blood cell cholinesterase values decreased 7% after 3 days of exposure and 19% over the 6-week harvesting season. The higher reduction in cholinesterase at the end of the study rather than on day 3 of exposure was unexpected and thought to be due to an improper handling of samples collected on day 3. This study did not examine health outcomes in the workers.

A similar study of peach harvesters in California was reported by Schneider et al. 1994. In this study 23 harvesters (exposed) and 10 sorters (considered to have minimal exposure) had baseline cholinesterase levels taken and then entered an orchard 51 days after an application of 1.5 pound per acre of azinphos methyl. The reduction in plasma cholinesterase was not significant when harvesters were compared to sorters. However, red blood cell cholinesterase values for harvesters were significantly below those of sorters for two post-exposure blood draws as measured by three testing methods. Compared to their baseline levels exposed harvesters experienced a 10-20% decline in red blood cell cholinesterase. No symptoms of organophosphate poisoning were reported by any of the workers.

Two studies reported in the late 1970s also examined field workers exposed to azinphos-methyl in California. In a study reported by Kraus et al. (1977) 21 peach thinners were monitored who entered the orchard 12-18 hours after spraying. A 15% decline of whole blood cholinesterase was reported over the five days of the study. There were no clinical signs of organophosphate poisoning. Richards et al. (1978) reported on a similar study of peach thinners. In this study eight workers were exposed thinning peaches in a field treated with azinphos-methyl and experienced a 8% decline in red blood cell cholinesterase. No workers reported signs of organophosphate poisoning.

Based on these incident data reports and biomonitoring studies, field workers exposed to azinphos-methyl may experience declines in red blood cell cholinesterase. In the studies examined for this review, none of the workers reported ill effects that could be directly attributed to cholinesterase inhibition. Poison Control Centers continue to report symptomatic cases due to azinphos-methyl at a rate of about 16 cases per year.

A. 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 July 15, 1999, and the memoranda "Azinphos-methyl:

EFED's Data Requests, Risk Characterization, and Risk Reduction Options," dated October 19, 2001, and "SCI-GROW Estimates of Concentrations in Ground water for Azinphos-methyl," dated October 24, 2001. All of these documents areavailable in the public docket.

Data reviewed since the 1999 technical briefing.

Since the 1999 technical briefing, the Agency has received a number of documents including additional data for consideration in the assessment of environmental risk for azinphos-methyl. The most substantive of these was a review of historical monitoring data "Historical Occurrence of Acephate, Azinphos-methyl, Chlorpyrifos, Diazinon, and Malathion in Waters of the United States 1990-1997," submitted by the primary registrant, Bayer. The review of this document (D256900) found that the vast majority of the data for azinphos-methyl had been already considered in the July 15, 1999 Environmental Fate and Effects Division chapter. Of the data that had not been previously reviewed, most were collected in places where there was minimal or unknown usage of azinphos-methyl. The registrant did not provide any ancillary data to support the review or interpretation of the data. The Agency obtained the original studies and these were reviewed directly. Of particular concern were the data collected in the state of Washington. Detectable concentrations of azinphos-methyl were found at thirteen of the thirty-four sites sampled. Ten sites had more than five samples with detectable concentrations, and eight sites had sample concentrations greater than 0.1 ：g/L. Azinphos-methyl was detected in all 26 samples collected at a site in Pacific County. Water contamination at this site was probably the result of application of azinphos-methyl to cranberries. Other studies in Mississippi Valley and Arkansas did not find measurable concentrations, even though cotton and other crops on which azinphos-methyl is used were grown in at least some of the basins at the Arkansas site. However, the amount of azinphos-methyl used in the watersheds above the sampling sites was not known.

An analytical method for measuring concentrations of azinphos-methyl and its oxygen analog in water also was submitted for review. However, the method did not include an Independent Laboratory Validation (ILV), which is required in order to review the analytical method. Review of the analytical method (including the ILV) is necessary to provide assurance that monitoring data is of an acceptable quality for regulatory and legal purposes. Given the potential for aquatic incidents associated with azinphos-methyl and its high aquatic toxicity, a well validated analytical method for water should be available for state, regional, and tribal agencies for enforcement purposes and for documentation of aquatic incidents. Thus the Agency recommends that an ILV for azinphos-methyl in water should be submitted.

1. Environmental Fate and Transport

The environmental fate data base for azinphos-methyl is mostly complete. However, additional data are needed for areas of concern and uncertainty.

Azinphos-methyl is mobile and has a high potential to reach surface water through both spray drift and runoff, and moves in the dissolved phase of runoff. Azinphos-methyl is not likely

to leach to ground water in most situations. However, based on suggestive evidence in the open literature azinphos-methy may reach gorund water in areas of high recharge, such as karst terrain. Of the major organophosphates applied to foliage , azinphos-methyl is one of the most persistent. It is moderately persistent at acid and neutral pH, while it is hydrolyzed fairly rapidly at high pH, i.e. on the order of several days. It degrades rapidly by direct aqueous photolysis (half-life = 77 hours), but rather slowly by soil photolysis (half-life = 180 days).

A major route of dissipation for azinphos-methyl is foliar degradation and wash off. Environmental degradates, identified in terrestrial field dissipation studies, are substantially less toxic than parent azinphos-methyl.

2. Ecological Incidents

Historically, azinphos-methyl has more aquatic incidents in the Agency's ecological incident database than any other pesticide. However, no major incidents associated with normal azinphos-methyl use were reported in the year 2000. Minor incidents may have been reported in aggregate reports with other pesticides, but not enough time was available to determine the extent of these potential occurrences. Major incidents are reported by the registrant in individual reports, whereas minor incidents are reported in aggregate with other pesticides, but the criteria distinguishing major and minor incidents (e.g., number of fish killed) have not been specified.

Azinphos-methyl has 143 incidents reported prior to 2000, only including incidents that are probable or highly probable to be associated with the routine use of azinphos-methyl, and excluding those associated with pesticide misuse. This number of incidents is more than twice the number of incidents associated with chlorpyrifos, which has the next highest number of pesticide associated incidents (63 incidents). Azinphos-methyl is responsible for over 21% of all reported aquatic incidents.

A large majority of the incidents were associated with the use of azinphos-methyl on cotton and sugar cane. Seventy-seven of these incidents were associated with cotton and 37 were associated with sugar cane. In addition, there were 15 incidents in Louisiana that were unclassifed or classifed as "agricultural," that are highly likely to have been associated with one of these two use patterns. Taken together, these incidents account for 129 of the 143 incidents reported for azinphos-methyl. As part of the August 1999 Memorandum of Agreement, the use on sugarcane was prohibited and the use on cotton was restricted to west of the Mississippi River, excluding the state of Louisiana; application rates on cotton were also reduced.

Of the remaining incidents, 1 is associated with apples (MO), 1 with citrus (FL), 3 with potatoes (ME), and 1 with peaches (MO). There are also 7 incidents that are unclassifed or classifed as "orchard" in New York (2), Washington (1), Wisconsin (1), North Carolina (1), Maine (1), and Michigan (1).

Including pesticide misuses and incidents that are less certain to have resulted from the use

of azinphos-methyl, there are a total of 256 incidents associated with the use of this pesticide. These include an almond incident (CA), a second apple incident (NC), 1 blueberry incident (ME), 1 forestry incident (AR), and one nursery incident (GA). The balance are associate with use on sugar cane and cotton.

Aside from the number of incidents, the size of the incidents and kinds of species killed for azinphos-methyl stand in contrast to other currently registered pesticides. Some of the incidents associate with sugarcane are listed as "6 miles long" and "2 miles long". Ten others have over 10,000 fish killed. Some of the fish included are those not otherwise found in the incident database including, gar, catfish, buffalo, and bowfin, and carp. These "aquatic incidents" also included some otherwise terrestrial or semiaquatic species including turtles, an alligator, a dog, and a pig.

In addition to the aquatic incidents, there were 12 terrestrial incidents reported in the database for azinphos-methyl. Two of these were concurrent with an aquatic incident. Of these 12, five were misuses. In contrast, phosmet, the primary alternative to azinphos-methyl, has 4 terrestrial incidents and 1 aquatic incident. All the terrestrial incidents involved bees. There is little additional information on the aquatic incident other than that it occurred in North Carolina from use on an orchard.

3. Risk to Birds and Mammals

The Agency compares risk quotients (RQs) to levels of concern (LOCs) to assess the potential for adverse effects. An RQ is determined by comparing potential exposure values (i.e. estimated exposure concentrations (EECs)), with ecotoxicity values (e.g., Median Lethal Concentration (LC_{50}) and Median Lethal Dose (LD_{50}) values). Table 11 summarizes the acute and chronic risk quotients (RQs) for birds and mammals for the critical use sites of azinphos-methyl. Although RQs were calculated for the use on sugarcane, this use has since been cancelled and is not shown here. RQs were not calculated for application to southern pine seed orchards or nursery stock. In addition, RQs are based on label application rates in July 1999, which in some cases were reduced as part of the August 1999 Memorandum of Agreement. The label rates used in the assessment are shown in parentheses below each crop (number of applications per season x lbs ai/A per application).

Table 11. Summary of RQs for birds and mammals for critical use sites of azinphos-methyl.

Site	Food group	Acute RQs		Chronic RQs	
		Birds	Mammals	Birds	Mammals
Almonds (2 x 2 lbs ai/A)	grazers insectivores granivores	1.1 0.6 <0.1	1.3 0.8 <0.1	21 11 2	43 23 4

Apples, Crabapples & Pears (4 x 1.5 lbs ai/A)	grazers insectivores granivores	1.6 0.9 0.1	2.0 1.1 0.1	47 25 4	99 52 8
Blueberries (3 x 0.75 lbs ai/A)	grazers insectivores granivores	0.6 0.4 <0.1	0.8 0.4 0.1	18 9 1	37 20 3
Brussels sprouts (3 x 0.75 lbs ai/A)	grazers insectivores granivores	0.7 0.4 0.1	0.9 0.5 0.1	21 11 2	45 24 4
Caneberries (2 x 0.5 lbs ai/A)	grazers insectivores granivores	0.4 0.2 <0.1	0.5 0.3 <0.1	12 7 <1	25 14 2
Cherries (4 x 0.75 lbs ai/A)	grazers insectivores granivores	0.6 0.3 <0.1	0.7 0.4 <0.1	15 8 <1	31 17 2
Cotton (8 x 0.75 lbs ai/A)	grazers insectivores granivores	0.9 0.5 <0.1	1.1 0.6 <0.1	29 16 2	61 34 4
Cranberries (3 x 1.0 lbs ai/A)	grazers insectivores granivores	0.7 0.4 <0.1	0.9 0.5 0.1	19 11 1	41 23 3
Peaches (3 x 1.125 lbs ai/A)	grazers insectivores granivores	0.8 0.5 <0.1	1.0 0.6 0.1	20 10 2	41 22 3
Pistachios (1 x 2.5 lbs ai/A)	grazers insectivores granivores	1.2 0.7 0.1	1.5 0.8 0.1	N/A	N/A
Walnuts (3 x 2 lbs ai/A)	grazers insectivores granivores	1.5 0.8 0.1	1.8 1.0 0.1	38 20 3	79 42 6

Although the acute risk quotients (RQs), which range from <0.1 to 2.0, do not indicate a large concern for terrestrial organisms, field and pen studies showed that applications of azinphos-methyl at maximum labeled use rates in apple orchards in Michigan and Washington resulted in documented mortality of a variety of birds and small mammals. Approximately 40% of all azinphos-methyl used is applied in apple orchards. According to USDA/NASS (preliminary summary for 2000), approximately 464,500 acres of apples were grown in the U.S, and azinphos-

methyl was applied to 78% of the acreage. As indicated by the field studies in Washington and Michigan, apple orchards are inhabited by a variety of birds and mammals. Forty-one species of birds and 11 wild mammal species were observed in the eight treated apple orchards (11-54 acres each) in Washington, and 36 bird species and 17 mammal species were observed in the eight treated orchards in Michigan. Based on this information, the Agency presumes that use of azinphos-methyl in apple and other orchards poses a high acute risk to birds and mammals.

Pen studies in treated alfalfa enclosures demonstrated short-term population effects on survival of voles, deer mice, and northern bobwhite chicks following single applications of azinphos-methyl. Multiple applications also had short-term but additive effects on vole survival. Although vole populations tended to recover to control levels within one to several weeks after exposure to azinphos-methyl, the researchers speculated that effects could be more pronounced and prolonged for species with less recovery potential than the highly fecund gray-tailed vole.

Chronic risk quotients (RQs) range from <1 to 47 for birds and from 2 to 99 for mammals. Uncertainty exists in extrapolating results of reproductive studies from the laboratory to the field, and no reproductive field studies are available for azinphos-methyl. However, the high exceedances of the level of concern strongly suggest that adverse reproductive effects are likely from chronic exposure. Because multiple applications are made at all azinphos-methyl use sites, chronic exposure is likely for those birds and mammals that survive repeated acute exposure. Although exceedances were higher for mammals than birds for all uses, chronic risk in orchards is likely to be higher for birds than for mammals. Orchard application, which accounted for >75% of the total poundage of azinphos-methyl in 1996, is predominately by air blast directed into the trees. Many species of birds are known to feed and nest in orchard trees. During the field study in Washington apple orchards, 41 bird species were recorded within the orchards, and nine species were observed nesting. As indicated in the laboratory reproductive studies, azinphos-methyl may adversely effect egg production, embryo viability, and chick survival at low concentrations. Reproduction might also be impacted due to behavioral effects (e.g., nest desertion) on adults and subsequent starvation or predation of unattended eggs and nestlings.

The Agency also is concerned that routes of exposure other than ingestion of contaminated food sources could be important in orchards. Dermal exposure may occur if birds contact wet residues remaining on tree foliage after air-blast application. In the Michigan field study, 14 species of birds were observed in treated orchards within 30 minutes of the azinphos-methyl application, indicating a likelihood for dermal exposure. Both dermal and inhalation exposure of brooding adults and their young might occur if application is made when birds are nesting. Although adults may leave orchards as the application equipment approaches, nestlings and fledglings are unable to leave to avoid the spray; some adults also may not leave if attending nests at the time of application. Insufficient information exists to assess the significance of these exposure routes for azinphos-methyl, but a laboratory study demonstrated that multiple pathways may be important. Secondary exposure and toxicity to predators and scavengers feeding on dead or dying birds, mammals, or aquatic organisms also may be important in some situations, but more information is needed to assess impacts to individuals and local populations of secondary

consumers such as raptors and mammalian carnivores.

4. Risk to Aquatic Species

The aquatic levels of concern are exceeded for marine/estuarine and freshwater fish and aquatic invertebrates, as shown in Table 12 below.

Table 12. Summary of risk quotients (RQs) for aquatic species for major use sites of azinphos-methyl.

Site	Species group	Species	Acute RQs	Chronic RQs
Apples, Crabapples & Pears	Freshwater Fish	Rainbow trout Brook trout Bluegill sunfish	3.1 - 4.8 7.4 - 11.6 2.2 - 3.4	21 - 39 N/A N/A
	Freshwater Invertebrates	Dapnia magna Gammarus fasciatus	7.9 - 12.3 55.6 - 86.9	27 - 44 N/A
	Estuarine & Marine Animals	Sheepshead minnow Mysid shrimp	3.3 - 5.2 42.4 - 66.2	24 - 39 N/A
Almonds, Filberts & Walnuts	Freshwater Fish	Rainbow trout Brook trout Bluegill sunfish	2.8 - 4.1 6.8 - 10.0 2.0 - 2.9	20 - 32 N/A N/A
	Freshwater Invertebrates	Dapnia magna Gammarus fasciatus	7.1 - 10.6 50 - 75	24 - 36 N/A
	Estuarine & Marine Animals	Sheepshead minnow Mysid shrimp	3.0 - 4.4 38.1 - 57.1	19 - 31 N/A
Cotton	Freshwater Fish	Rainbow trout Brook trout Bluegill sunfish	16.8 - 30.1 40.7 - 73.2 11.9 - 21.4	120 - 215 N/A N/A
	Freshwater Invertebrates	Dapnia magna Gammarus fasciatus	43.2 - 77.7 305 - 549	162 - 277 N/A
	Estuarine & Marine Animals	Sheepshead minnow Mysid shrimp	18.1 - 32.5 232 - 418	109 - 202 N/A
Potatoes	Freshwater Fish	Rainbow trout Brook trout Bluegill sunfish	4.7 11.3 3.3	33 N/A N/A
	Freshwater Invertebrates	Dapnia magna Gammarus fasciatus	12 85	41.6 N/A

	Estuarine & Marine Animals	Sheepshead minnow Mysid shrimp	5 65	31 N/A
Cherries & Plums	Freshwater Fish	Rainbow trout Brook trout Bluegill sunfish	2.8 - 3.7 6.7 - 8.9 2.0 - 2.6	20.0 - 29.1 N/A N/A
	Freshwater Invertebrates	Dapnia magna Gammarus fasciatus	7.1 - 9.5 50 - 67	33.2 - 34.4 N/A
	Estuarine & Marine Animals	Sheepshead minnow Mysid shrimp	3 -4 38 -51	19 - 28 N/A
Peaches	Freshwater Fish	Rainbow trout Brook trout Bluegill sunfish	14.0 33.8 9.9	110.9 N/A N/A
	Freshwater Invertebrates	Dapnia magna Gammarus fasciatus	36 254	134 N/A
	Estuarine & Marine Animals	Sheepshead minnow Mysid shrimp	15 193	106 N/A

The toxicity of azinphos-methyl to a wide variety of fish has been measured including salmonids, minnows, and perch. The most sensitive species in a core study was the brook trout with an LC_{50} at 1.2 ：g L^{-1} (ppb). However, all salmonids had an LC_{50} less than 10 ：g L^{-1}. Catfish appeared to be the least sensitive with LC_{50}'s greater than 1 mg L^{-1}(ppm). Of 16 species tested 9 had LC_{50}'s of less than 10 ：g L^{-1}, indicating that many species are susceptible to azinphos-methyl near the level of the most sensitive species. For crops that are still registered, the maximum label application practice produces 1 in 10 year EEC's above 10 ：g L^{-1} for apples, walnuts, potatoes, cherries, and peaches. This is consistent with the number and magnitude of the aquatic incidents that have occurred from azinphos-methyl use.

As described in section 1 above, there have been a large number of incidents associated with the use of azinphos-methyl on major crops. When azinphos-methyl usage covers a large proportion of a watershed, catastrophic fish kills have sometimes occurred. The majority of the fish kill incidents were related to the use of azinphos-methyl on sugarcane and cotton, which has been prohibited (sugarcane) or restricted (cotton) since August 1999. The preponderance of incidents associated with the use on sugarcane and cotton was probably due to the proximity of these crops to water and to the intense and frequent rainfalls in the use areas.

Historically, there also have been incidents associated with the use of azinphos-methyl in orchard crops. However, there are fewer incidents for these sites than for cotton and sugarcane, even though more azinphos-methyl is used on orchards. Several factors are responsible for this.

First, the climate in the Southeast where sugarcane and cotton are grown has more frequent and intense rainfall resulting in greater runoff loading of azinphos-methyl. This difference in total rainfall also causes eastern orchards to have higher associated risks than western orchards. The seasonality of rainfall also is a factor. Precipitation in the West tends to fall in the winter when the crops are not actively growing and pesticide applications usually do not take place. The exception to this would be dormant applications to orchard crops such as almonds. These applications are made during the rainy season on the west coast and are therefore associated with greater runoff potential. Second, row crops tend to receive aerial applications while orchards receive spray blast applications. Spray blast tends to have reduced drift because of large droplet sizes and better canopy interception. Again, dormant applications are an exception since the trees are without foliage and there is greatly decreased canopy interception. A third factor is that general agronomic practice keeps the floor of most orchards at least partially covered in grass. This greatly reduces runoff compared to that from row crops. Another factor is the proximity of the fields or orchards to water.

Azinphos-methyl has been detected at fish kill incident sites in concentrations in excess of the fish and aquatic invertebrates LC_{50}s and chronic No Observable Adverse Effect Concentrations (NOAECs). The LC_{50}s for aquatic invertebrates and fish are both approximately 1 ppb and the chronic NOAECs are 0.2 ppb. Based on the similar toxicity values, it is also likely that aquatic invertebrates are similarly impacted, even though mortality effects to aquatic invertebrates are rarely detected. Population reduction in aquatic invertebrates may result in food shortages for organisms higher in the food chain. The similarity in the acute and chronic endpoints does not eliminate the possibility of chronic effects. Chronic effects, such as effects on reproduction or growth, also may not be seen initially at an incident site. However, when a large number of fish die the population may have difficulty recovering. In addition, significant secondary effects may be caused by decay of the large number of fish killed.

5. Risk to Endangered Species

OPP has initiated three consultations with the Fish and Wildlife Service (FWS) on the potential effects of azinphos-methyl on endangered and threatened species. To date, the FWS has issued two Biological Opinions. In these Opinions, the FWS found jeopardy for 33 fish species, 31 aquatic invertebrate species, 4 amphibian species, 5 bird species, 4 insect species, and 4 insect pollinated plant species. An additional 7 fish species, 1 amphibian and 1 bird were expected to be affected, but not jeopardized. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment procedures, and an older approach to consultation which is currently being revised through interagency collaboration.

EPA's current assessment of ecological risks uses both more refined methods to define ecological risks of pesticides and new data, such as that for spray drift. Therefore, the Reasonable and Prudent Measures (RPMs) in the Biological Opinion(s) may need to be reassessed and modified based on these new approaches. In addition, a significant amount of monitoring data

have been developed over the past few years in the U. S. Geological Survey's National Water Quality Assessment program. These data, which show aquatic levels of potential concern, need to be incorporated into any new assessments for endangered and threatened species.

The Agency is currently engaged in a Proactive Conservation Review with FWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of azinphos-methyl to federally listed threatened and endangered species. At that time, the Agency will also consider any regulatory changes recommended in the IRED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets described in the risk management chapter which address azinphos-methyl, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to azinphos-methyl at levels of concern.

IV. Interim Risk Management and Reregistration Decision for Azinphos-methyl

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., active ingredient specific) data required to support reregistration of products containing azinphos-methyl active ingredients.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient azinphos-methyl, as well as an azinphos-methyl-specific dietary (food+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 azinphos-methyl, EPA has sufficient information on the human health and ecological effects of azinphos-methyl to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA.

Taking into account both the risks and benefits of azinphos-methyl, the Agency has determined that all uses of azinphos-methyl are ineligible for registration based on their currently approved labeling. Although EPA is unable to find these uses eligible for reregistration under their currently approved labeling, EPA has identified conditions under which a limited number of uses of azinphos-methyl could be eligible for a time-limited reregistration of four years, if certain specific mitigation measures are adopted. These uses are:

- Apples and crab apples
- Pears
- Sweet cherries
- Blueberries (lowbush and highbush)
- Caneberries (blackberries, boysenberries, loganberries, raspberries), application to canes and soil only
- Brussels sprouts, soil injection use at transplant only
- Nursery stock, quarantine use only
- Southern pine seed orchards

After reviewing the available mitigation measures, EPA has determined that these uses could be eligible for a four-year time-limited registration 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) cumulative risks considered for the organophosphates support a final reregistration eligibility decision. Label changes are described in this section. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of azinphos-

methyl, and lists the submitted studies that the Agency found acceptable.

EPA has not been able to identify mitigation measures that would bring the risks of the other azinphos-methyl uses to levels that the Agency considers reasonable, taking into account the economic, social, and environmental costs and benefits of the pesticide use. Although the Agency has determined that none of these other uses are eligible for reregistration, the Agency believes it appropriate to allow a "phase out" period for certain of these uses with comparatively high benefits in order to provide growers with an orderly transition to the use of alternative pest-control tools and/or practices, provided that certain mitigation measures specified in the document are adopted during the "phase out" period. These uses are:

- Almonds
- Cherries, tart
- Cotton
- Cranberries
- Peaches
- Pistachios
- Walnuts

The remaining uses of azinphos-methyl have risk concerns, but little or no use and thus zero to very low benefits. Alternatives for azinphos-methyl also exist for these uses. These uses will be cancelled immediately with provisions for use of existing stocks in the channels of trade. These uses are:

- Alfalfa
- Beans (succulent and snap)
- Birdsfoot trefoil
- Broccoli
- Cabbage (including Chinese)
- Caneberries (blackberries, boysenberries, loganberries, raspberries), *foliar application only*
- Cauliflower
- Citrus
- Celery
- Clover
- Cucumbers
- Eggplant
- Filberts
- Grapes
- Melons (honeydew melons, muskmelon/canteloupe, watermelons, other melons)
- Nectarines
- Nursery stock, *other than quarantine use*
- Onions, green

- Onions, dry bulb
- Parsley
- Pecans
- Peppers
- Plums and dried plums
- Potatoes
- Quince
- Spinach
- Strawberries
- Tomatoes

Although the Agency has not yet considered cumulative risks for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary regardless of the outcome of the cumulative risk assessment. Based on its current evaluation of azinphos-methyl alone, the Agency has determined that azinphos-methyl 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 and other provisions identified in this document, the Agency expects to take regulatory action to address the risk concerns associated with the currently labeled uses of azinphos-methyl.

In light of the margins of exposure for occupational risk described elsewhere in this IRED and the number of uses that are ineligible for reregistration because of occupational risks, EPA has determined that it is appropriate to implement the required changes to azinphos registrations relatively quickly. If registrants elect not to submit applications for amended registrations consistent with this IRED within 90 days, EPA expects to commence preparation of a draft notice of intent to cancel.

At the time that a cumulative assessment is conducted, the Agency would address any risk concerns determined as a result of that assessment. 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 considered cumulative risks for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing azinphos-methyl food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has considered cumulative risks, azinphos-methyl tolerances will be reassessed in that light. At that time, the Agency will reassess azinphos-methyl 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 defining mitigation measures now for the individual chemical azinphos-methyl, 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 considered all comments received during Phase 5 of the OP Pilot Process. Below is a brief summary of the substantive comments and the Agency response. A detailed discussion of the previous comments received on the Human Health Risk Assessment and the Preliminary Environmental Fate and Effects Risk Assessment along with the Agency's responses is in the OPP docket for azinphos-methyl (Docket #34131C) and on the internet.

Comments on the Revised Human Health Risk Assessment

Comment: Bayer Corporation submitted a response to the Agency's phase 5 request for mitigation proposals. They agreed to reductions in use rates, increases in post-harvest intervals (PHIs) and restricted entry intervals (REIs), prohibition of application methods that potentially pose higher risk, deletion of use sites, tolerance reductions, etc. Also, they asserted that additional data would show that the occupational and dietary risk estimates are not of concern. They volunteered to begin collecting more complete and quantitative information on workers activities.

Response: Bayer Corporation's comments and proposals formed the basis of the August 2, 1999 Memorandum of Agreement (MOA) between the Agency and the registrants. Additional data have shown that acute dietary risks for azinphos-methyl for acute dietary are no longer of concern. Bayer Corporation's collection of more complete and quantitative information on worker activities may be useful; however, these data have not yet been provided to the Agency. Bayer has provided acute and repeat-dose oral studies using human volunteers, as well as biomonitoring data. The Agency has reviewed these studies and those reviews are summarized elsewhere in this document.

Comment: Growers, grower group associations and others explained the use pattern and benefits of azinphos-methyl, including its role in Integrated Pest Management (IPM) and resistance management programs, its essential uses (e.g. to control pests that cause an increase in aflatoxins), and the lack of alternatives for this broad spectrum organophosphate pesticide.

Response: The Agency has considered the benefits associated with the use of azinphos-methyl, as

appropriate, in developing the risk management outlined in this document. However, under the provisions of FQPA, EPA can not use benefits as a rationale for exceeding acceptable dietary risk levels (individual, aggregate or cummulative). For other risk concerns, i.e., occupational or ecological, the Agency routinely considers both the risks and benefits. Full benefits assessments for azinphos methyl can be found on EPA's web site at www.epa.gov/pesticides/op/azm.htm.

Comment: Several comments were related to science and policy issues; e.g. use of human data, using cholinesterase as an endpoint of concern, appropriate use of safety factors, etc.

Response: The Agency and the Tolerance Reassessment Advisory Committee (TRAC) have established an open and orderly public participation process for the review of EPA's science policies. Copies of proposed and completed policy papers and the status of each in the process can be found at http://www.epa.gov/oppfead1/trac/science/.

Comment: Commentors expressed concerns about our acute dietary, occupational, and ecological risk estimates. Some commentors believe the risk estimates warrant immediate Agency action, while other commentors question whether the risk estimates reflect actual risks.

Response: The Agency's acute dietary risk assessment (food only) is highly refined, and risk estimates are not of concern for any population group. Drinking water estimates are less refined estimates, but based on the changes to the use pattern are also not of concern. The Agency has yet to factor in cumulative risk posed by all organophosphates, and additional mitigation may be required when those considerations are completed. In evaluating ecological and worker risks, EPA has also considered the benefits of azinphos methyl before proposing regulatory action. As a result of this interim RED, registrants will be required to conduct controlled biomonitoring study of workers and develop other data to support the continued use of azinphos methyl for a limited time period.

Comments on the Environmental Fate and Effects Risk Assessment

Comment: The Almond Hullers and Processors Association commented that during the summer months it does not rain in the Central Valley in CA, especially in the southern end (Kern County), where most of the almond acreage is located.

Response: This information was used in the model simulations for the ecological risk assessment.

Comment: The Washington State Department of Agriculture indicated that research suggests azinphos-methyl is hazardous to honey bees for 4 days when applied to blooming crops or blooming weeds, especially in and around orchards. They recommended that label restrictions be imposed to prohibit applications at blooming.

Response: Bee warning language will be included on revised labels.

Comment: Bayer Corporation questioned why many of their proposed measures to further refine the risk assessment were not taken into account in the ecological risk assessment.

Response: Bayer Corporation's proposed deletion of some minor uses during Phase 5 represented only a small proportion of the total use and would not appreciably reduce the risks posed by azinphos-methyl. However, the elimination of aerial applications on most sites and the use reductions outlined in this document will substantially reduce risk to the environment.

Comment: Bayer Corporation proposed a 25 foot spray buffer (from aquatic sites) for tree crops (apples, pears, peaches, nuts, etc.) be added to the label as a mitigation measure to address the risk of fish kills.

Response: The mitigation specified in this document including no-spray buffer zones the elimination of aerial applications on most crops and label language requiring sprays into the orchard on the outside rows will reduce risk from runoff of orchard crops.

Comment: Bayer Corporation stated that field dissipation studies conducted in California soils are representative of the west coast and accurately depict the dissipation of azinphos-methyl, and therefore, they believe no additional data are required.

Response: The Agency agrees that the two California soils are representative of alfalfa culture in California. However, alfalfa is a relatively minor crop for azinphos-methyl, and these studies are not representative of conditions at major west coast use sites such as apples or almonds, as agricultural practices for orchard culture do not resemble those for a field crop like alfalfa. These studies also have other deficiencies as detailed in the DER and risk assessment; e.g. 40-45% of the applied pesticide is unaccounted for, and the absence of leaching cannot be attributed to an immobility of azinphos-methyl, when there was insufficient rainfall to precipitate any downward movement in the soil. Therefore, the guideline requirement remains open and new field dissipation studies conducted on the west coast (CA and WA) on orchard crops are required. Additionally, a field dissipation study conducted in soils having a low pH is required, preferably in the southeastern US.

Comment: Bayer Corporation commented that considerable information had not been evaluated by the Agency. Bayer listed specific studies; i.e. MRIDs 42516702, 42516701, 43015901, 43649801, 44411804, 44411802, and 44266501.

Response: Of these, the runoff studies, "Field Scale Runoff Study in Georgia" (MRID 42516702) and "Field Scale Runoff Study in Mississippi"(MRID 42516701) have been reviewed and found scientifically sound. A third study "Stream Monitoring Around Sugarcane in Louisiana" (MRID 43015901) was rejected as scientifically unsound (Jones, D198426), because only three samples were actually collected in the study. Five other studies, ("Aquatic Exposure Assessment for Almonds" (MRID 43649801) and "Proximity of Apple Orchards to Aquatic Habitats" (MRID

44411804), "Aquatic Exposure Assessment for Guthion on Apples" (MRID 44411802), "Watershed Assessment of Apple Orchards" (MRID 44411804), and "Aquatic Exposure Assessment Issues for GUTHION on Apples" (MRID 44266501) have not had formal DERs prepared. However, the revised risk assessment contains a discussion of these studies.

Comment: Bayer Corporation had several comments concerning the Agency's water resources, aquatic, and terrestrial risk assessments, i.e. requirements for monitoring data, analytical methods utilized, procedures utilized, and endpoints chosen.

Response: In each instance, the Agency responded by explaining how and why certain standard evaluation procedures or methods were used, why certain data were or were not used, and why certain additional data are still required. Refer to the response to comments document in the public docket.

Comment: Bayer Corporation disagrees with the Agency's requirement for a fish full life cycle study.

Response: These data are still required for the following reasons: a) azinphos-methyl is expected to be transported to water from its intended uses; b) the estimated environmental concentration in water is equal to or greater than one-tenth the NOAEC in the freshwater fish early life stage study conducted with rainbow trout; and c) the studies of other organisms indicate the reproductive physiology of fish may be affected. However, raw data from three previously submitted chronic fish life studies (i.e. MRIDs 00073605, 4057901 and 42021601) may help satisfy this requirement. These raw data must be submitted to the Agency.

Comment Period on this IRED

EPA is providing a 60-day comment period on the risk management proposal contained in this IRED. While all comments are welcome, those with specific data bearing on the risk and benefit assessments are most useful. For example, specific data, such as comparative efficacy data of azinphos-methyl and alternatives, and quantified estimates of cost differences among alternatives are more useful than simple statements that azinphos-methyl is important in IPM programs or is a necessary tool.

EPA does not have appropriate data or methods to provide a quantified estimate of exposure for people who participate in pick-your-own fruit harvesting operations. The Agency is generally aware that the durations of such exposures tend to be short, and that the intensity of activities of people engaging in this voluntary activity would be less than field workers. This IRED proposes label language precluding or limiting (e.g. increasing the pre-harvest interval) the use of azinphos methyl in pick-your-own operations to address these potential exposures. EPA invites comment on this issue.

EPA has recently received comments related to potatoes, cotton, peaches and plums, and

others proposing reduced usage scenarios and alternative mitigation. These comments will be considered during the comment period.

C. Regulatory Position

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 is 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 aggregate exposures to azinphos-methyl from food and drinking water (considered without the effect of its common mechanism with other organophosphates) are acceptable. In other words, if azinphos-methyl did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for azinphos-methyl 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 and drinking water only, since azinphos-methyl has no residential uses. 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 azinphos-methyl "fit" within the individual risk cup. Therefore, the azinphos-methyl tolerances associated with any azinphos-methyl uses found eligible for FIFRA reregistration remain in effect at least for the duration of such registrations unless a full reassessment of the cumulative risk from all organophosphates leads to a requirement to change such tolerances.

b. Tolerance Summary

On June 22, 2000, EPA published a final rule on revocation and lowering of certain tolerances for azinphos-methyl (refer to 65 FR 38748). Some of these changes resulted from the August 2, 1999 MOA that intended to reduce risk to children, workers, and the environment, including revocation of the tolerance on sugarcane, and the lowering of tolerances on apples, crabapples, cranberries, grapes, pears, and quinces. Other revocations included the following: 1) revocation of tolerances for commodities for which there are no registered uses; 2) revocation of tolerances for uses on crops that are no longer significant animal feed items (e.g. sugarcane bagasse); 3) revocation of tolerances for which there are processing studies showing no

concentration in the processed commodity (e.g. dried citrus pulp); 4) revocation of tolerances for which available data show no indication of finite residues (i.e. various meat products and milk); and 5) in addition, tolerances associated with all uses determined ineligible for registration and cancelled (either voluntarily or as a result of EPA regulatory action) or cancelled following a phase-out would also be proposed for revocation in connection with such cancellation. Changes in commodity terminology and definitions were also made for several commodities in order to conform to current Agency practice.

In the individual assessment, tolerances for residues of azinphos-methyl in/on plant commodities [40 CFR §180.154] are presently expressed in terms of azinphos-methyl (O,O-Dimethyl S-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl) methyl] phosphorodithioate. The summary table below presents the current tolerances for azinphos-methyl, as supported by submitted residue data. Sufficient data are available to ascertain the adequacy of the established tolerances for the commodities listed below. Based upon these data, the established tolerances do not need to be amended at this time. Note that tolerances that remain in effect cannot be considered "reassessed", as required by FQPA, until the cumulative risk assessment of all organophosphates is completed.

Table 13. Tolerance reassessment summary for azinphos-methyl.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.154 (a):			
Alfalfa	2	Revoke	
Alfalfa, hay	5	Revoke	
Almonds	0.2	Revoke effective after 2005	The U.S. tolerance could be lowered to 0.2 ppm to harmonize with the corresponding Codex MRL.
Almonds, hulls	5.0	Revoke effective after 2005	The U.S tolerance could be lowered to 5.0 ppm to harmonize with the corresponding Codex MRL.
Apples	1.5	1.5	
Beans, succulent (snap)	2	Revoke	
Birdfoot trefoil	2	Revoke	
Birdfoot trefoil hay	5	Revoke	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment/*Correct Commodity Definition*
Blackberries, boysenberries, loganberries, raspberries	2	8	Residues of 7.6 ppm occurred from registered use on lower part of the cane with a 3-day PHI. *Caneberries*
Blueberries	5	5	
Broccoli	2	Revoke	
Brussels sprout	2	2	
Cabbage	2	Revoke	
Cauliflower	2	Revoke	
Celery	2	Revoke	
Cherries	2	2	Redefine to cherries, sweet
Cherries	2	Revoke effective after 2005	Redefine to cherries, tart
Citrus fruits	2	Revoke	
Clover	2	Revoke	
Clover, hay	5	Revoke	
Cottonseed	0.5	Revoke effective after 2005	
Crabapples	1.5	1.5	
Cranberries	0.5	Revoke effective after 2005	
Cucumbers	2	Revoke	
Eggplants	0.3	Revoke	
Filberts	0.3	Revoke	
Grapes	4.0	Revoke	
Melons	2	Revoke	
Onions	2	Revoke	
Parsley, leaves	5	Revoke	
Parsley, roots	2	Revoke	
Peaches	2	Revoke effective after 2005	The U.S. tolerance could be increased to 4.0 ppm to harmonize with the corresponding Codex MRL.
Pears	1.5	1.5	
Pecans	0.3	Revoke	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment/*Correct Commodity Definition*
Peppers	0.3	Revoke	
Pistachios	0.3	Revoke effective after 2005	
Plums (fresh prunes)	2	Revoke effective after 2005	
Potatoes	0.2	Revoke	
Quinces	1.5	Revoke	
Spinach	2	Revoke	
Strawberries	2	Revoke	
Sugarcane	0.3	Revoke	Expired 6/30/00
Tomatoes (pre- and post-H)	2	Revoke	
Walnuts	0.3	Revoke effective after 2005	Additional data are forthcoming.
Tolerances needed under 40 CFR §180.154			
Cotton gin byproducts	none	TBD	Residue data required.
Apple, wet pomace	none	4	
Cottonseed hulls	none	1	Residue data required.

* 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.

Codex Harmonization. The Codex Alimentarius Commission has established maximum residue limits (MRLs) for azinphos methyl residues in/on various plant and animal commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table 14.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs: The U.S. tolerances for almonds can be decreased and the tolerance for peaches can be increased to harmonize with the Codex MRLs. Both of these uses are being phased out in the US. These tolerances will be revoked effective after 2005.

Table 14. Codex MRLs for azinphos-methyl and applicable U.S. tolerances.

Codex		Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	**MRL (mg/kg)**		
Alfalfa forage (green)	2	Revoke	
Almonds	0.2	0.2	U.S. use is being phased out. Tolerance will be revoked effective after 2005.
Broccoli	1	Revoke	
Brussels sprouts	1	2	
Celery	2	Revoke	
Cotton seed	0.2	0.5	The registered U.S. use pattern precludes lowering the tolerance to harmonize with the Codex MRL.
Fruits (except as otherwise noted)	1	1.5 to 5	The registered U.S. use patterns preclude lowering tolerances to harmonize with Codex MRLs.
Grapes	4	Revoke	
Melons, except watermelon	2	Revoke	
Peach	4	4	U.S. use is being phased out. Tolerance will be revoked effective after 2005.
Potato	0.2	Revoke	
Vegetables (except as otherwise noted)	0.5	Revoke	

As shown in Table 13, the Agency expects to commence proceedings to revoke 27 tolerances, and will revoke an additional 7 effective after 2005. Any raising of tolerance(s) will be deferred, pending the consideration of the cumulative assessment.

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, azinphos-methyl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Labels

The risk mitigation measures described in section D below are necessary to reduce the exposure and risks to workers who handle azinphos-methyl and workers re-entering fields treated with azinphos-methyl, and to reduce exposure and risks to terrestrial and aquatic organisms and environments. Label amendments, in addition to the existing label requirements, are necessary in order to continue registration and/or marketing during phase-out of azinphos-methyl products.

Provided the risk mitigation measures and other provisions described in the following section are incorporated in their entirety into labels for azinphos-methyl-containing products, the Agency finds that only the currently registered uses of azinphos-methyl enumerated in section IV.A. would be eligible for a time-limited registration of four years, pending a cumulative assessment of the organophosphates. The regulatory rationale for time-limited registration and for each of the mitigation measures is discussed below.

D. Regulatory Rationale

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

The primary purpose of reregistration is for EPA to determine whether existing pesticide registrations satisfy the standard for pesticide registration set forth in section 3(c)(5) of FIFRA. In order for a pesticide to meet the standard in section 3(c)(5), the Administrator must determine, among other things, that when it is used in accordance with widespread and commonly recognized practice, the pesticide will not generally result in unreasonable adverse effects on the environment. Unreasonable adverse effects on the environment are defined in section 2(bb) of FIFRA as either (1) any unreasonable risk to man or the environment, taking into account the costs and benefits of the use of any pesticide, or (2) a human dietary risk in excess of the safety standard that must be met in order to issue a pesticide tolerance under section 408 of the FFDCA. The first part of the FIFRA 2(bb) standard is a risk-benefit standard that applies to all uses of a pesticide. The second

part of the standard is a "risk only" standard that applies to dietary risk issues under the FFDCA (in particular, whether the Agency can make a "reasonable certainty of no harm" finding with respect to any tolerances required to support use of azinphos-methyl). As part of this IRED, EPA has considered whether the uses of azinphos-methyl meet the risk-benefit standard called for in FIFRA, and whether the tolerances associated with azinphos-methyl meet the FFDCA standard without consideration of cumulative risk issues with other organophosphate pesticides, which are not being considered in this IRED and instead will be considered after the Agency conducts a cumulative risk assessment for the organophosphates.

As to the dietary risk issue, for the reasons discussed in Chapter III.A., EPA has concluded that, considering all issues other than cumulative risk issues with other organophosphates, there is a reasonable certainty that the tolerances for azinphos-methyl will not result in harm and that the uses of azinphos-methyl will therefore not result in dietary risks in excess of the safety standard in section 408 of the FFDCA.

In assessing the risks and benefits of the uses of azinphos-methyl, the Agency has considered the available data concerning the ecological and occupational risks, and economic benefits, associated with use of azinphos-methyl. Typically when determining whether a pesticide meets the FIFRA risk-benefit standard, the Agency first examines whether occupational and ecological risks fall within an ample prescribed margin of safety. Where they do not, the Agency looks at the possibility of implementing mitigation measures to achieve the desired margins of safety. Where the desired margins can not be reached, the Agency then determines whether the benefits associated with the use of the pesticide outweigh the remaining risks.

In the case of azinphos-methyl, as described in more detail in Chapter III.A. of this IRED, the Agency has concluded that the margins of exposure for handlers of azinphos-methyl and those who work in treated fields and orchards are significantly lower than the margins generally considered acceptable, and that with the general exception of soil-directed applications to caneberries and Brussels sprouts, the imposition of practicable mitigation measures will not result in achievement of the desired margins of safety. The occupational risks associated with azinphos-methyl do not differ dramatically among most uses of the pesticide, and for most of these uses the margins of safety will continue to fall well below the desired level even if mitigation measures are implemented. Ecological risk will be at least partially mitigated by the elimination of aerial application on all but cotton (4-year phase out), cranberries (4-year phase out), lowbush blueberries (4-year time-limited registration), and southern pine seed orchards (4-year time-limited registration), and by the addition of label language requiring inward nozzle spray for airblast application to the outer rows of orchard crops. Nevertheless, there are still concerns for aquatic and terrestrial organisms from run-off and off-site drift.

The Agency's assessment of the benefits of azinphos-methyl shows that the benefits differ dramatically across the range of uses of the pesticide. For some crops, azinphos-methyl does not appear to be an important pest-control tool and current users would not likely be adversely affected if the chemical were no longer available for those uses. For other crops, azinphos-methyl

provides moderately high economic benefits to users. For a small group of uses, azinphos-methyl provides very significant economic benefits to users and in certain situations is essential to continued production of the crops.

In determining whether the risks associated with various uses of azinphos-methyl exceed the benefits associated with such uses, the Agency looked not only at the margins of exposure, but at various qualitative issues related to the risk assessment as well. EPA's assessment of the occupational risk associated with azinphos-methyl is based on an evaluation of a broad range of studies addressing many kinds of potential health effects and a great deal of data on potential human exposure to the pesticide when performing a variety of agricultural occupational tasks. EPA also discussed an occupational risk assessment conducted by the State of California with scientists in the California Department of Pesticide Regulation.

EPA's standard policy is to focus its risk assessment on whatever potential health effect occurs at the lowest amount of exposure. Based on this policy, the risk assessment for azinphos-methyl is based upon cholinesterase inhibition generally, and is specifically predicated upon the results of cholinesterase studies measuring enzyme changes in the blood. Doses that first cause measurable changes in cholinesterase levels in red blood cells tend to be less than doses that begin to show overt symptoms of sickness associated with exposure to cholinesterase-inhibiting compounds. In addition, the levels from which the Agency calculates margins of exposure are based upon levels at which test animals did not show any enzyme change in blood (the margins are based upon the "no observable adverse effect level," or NOAEL, from the animal tests).

The desired margins of safety are selected to provide assurance that adverse health effects will not occur to workers exposed to pesticides. While the margins of safety with use of azinphos-methyl are considerably less than the desired levels, this does not mean that workers will necessarily suffer any measurable change in blood enzyme levels, or will have any symptomatic effects related to occupational exposures to azinphos-methyl. It does, however, mean that the Agency has less assurance that blood enzyme levels will be unaffected.

In balancing these uncertainties associated with worker risks against the economic benefits associated with azinphos-methyl, and in light of the fact that the risks appear relatively similar across most of the uses of the pesticide, the Agency has determined to place the uses of azinphos-methyl into three categories.

For some uses, there are minimal economic benefits associated with the use of azinphos-methyl, because azinphos-methyl is used on only a small percentage of the crop, and/or alternative pesticides are readily available**.** The Agency has determined that the benefits associated with these uses do not outweigh the risks associated with these uses and finds that these uses are ineligible for reregistration and should be cancelled without any phase-out period, but with provisions for the use of stocks already in the channels of trade. The following 28 uses fall into this category:

Uses to be cancelled without phase-out:

1. Alfalfa
2. Beans (succulent and snap)
3. Birdsfoot trefoil
4. Broccoli
5. Cabbage (including Chinese)
6. Caneberries (blackberries, boysenberries, loganberries, raspberries), *foliar application only*
7. Cauliflower
8. Citrus
9. Celery
10. Clover
11. Cucumbers
12. Eggplant
13. Filberts
14. Grapes
15. Melons (honeydew melons, muskmelon/canteloupe, watermelons, other melons)
16. Nectarines
17. Nursery stock, *other than quarantine use*
18. Onions, green
19. Onions, dry bulb
20. Parsley
21. Pecans
22. Peppers
23. Plums and dried plums
24. Potatoes
25. Quince
26. Spinach
27. Strawberries
28. Tomatoes

For some uses, there are moderately high economic benefits associated with the use of azinphos-methyl. The Agency believes the benefits associated with these uses do not outweigh the risks associated with these uses and finds that these uses are ineligible for reregistration. However, for these uses, the Agency also believes that the benefits make it appropriate to allow a 4-year "phase-out" period that would allow growers to make an orderly transition away from azinphos-methyl to alternative pest-control products or practices, provided that certain risk mitigation measures specified in this IRED are adopted to lessen the risk to workers during this "phase-out" period. The following 7 uses fall into this category:

Uses to be cancelled with a four-year phase-out:

1. Almonds
2. Cherries, tart
3. Cotton
4. Cranberries
5. Peaches
6. Pistachios
7. Walnuts

For the eight remaining uses, there are significant economic benefits associated with the use of azinphos-methyl, and EPA believes that other pesticides or agricultural practices cannot substitute for azinphos-methyl in providing adequate control of key target pests at the present time. The Agency believes that the benefits associated with these uses outweigh the risks associated with these uses, provided that the mitigation measures and other provisions specified in this IRED are adopted. However, because of the continuing concern with the margins of exposures for these uses and in anticipation that the benefits picture may well change, the Agency is conditioning the registrations for these uses by establishing an expiration date of four years for the registrations, and also is requiring the generation of additional data to further characterize both the exposure and the benefits associated with the uses. At the end of the four year period, if registrants believe the benefits continue to outweigh the risks, they may apply for amendments to extend the life of the registrations. The Agency will then determine whether the benefits continue to outweigh the risks, and will extend the registrations if they continue to meet the statutory risk-benefit standard. If the Agency determines that it cannot approve any such amendment, registrants will have an opportunity to challenge such a denial pursuant to section 3(c)(6) of FIFRA. The following 8 uses fall into this final category:

Uses with a 4-year time-limited registration:

1. Apples and crab apples
2. Blueberries (lowbush and highbush)
3. Brussels sprouts, *application to soil at transplant only*
4. Caneberries (blackberries, boysenberries, loganberries, raspberries), *application to canes and soil only*
5. Cherries, sweet
6. Nursery stock, quarantine use
7. Pears
8. Southern pine seed orchards

These reregistration eligibility decisions are discussed in detail in section D.3. below.

1. Human Health Risk Characterization

a. Dietary Risk Characterization

1) Acute Dietary (Food)

Taking into account all currently registered uses of azinphos-methyl, acute dietary risk from food is not of concern, and no risk mitigation is necessary.

2) Chronic Dietary (Food)

Taking into account all currently registered uses of azinphos-methyl, chronic dietary risk from food is not of concern, and no risk mitigation is necessary.

3) Drinking Water

The Agency has determined that, when considering the uses of azinphos-methyl eligible for reregistration, acute and chronic dietary risk from drinking water does not affect the determination that the tolerances for azinphos-methyl, without regard to cumulative issues, meet the "reasonable certainty of no harm" standard in the FFDCA. However, in order to confirm that concentrations found in water are do not pose a concern for drinking water, the Agency is requiring an aerobic aquatic metabolism study and ground water monitoring in high-use areas underlain by karst terrain.

b. Occupational Risk Characterization: Agricultural Uses

Of the currently registered uses of azinphos-methyl, the Agency has determined that 35 are not eligible for reregistration based on risk concerns for workers and the environment. Of these, seven have significant or moderate to moderately high benefits to justify continued use during a 4-year phase out period, provided that the risk mitigation measures specified in this IRED are adopted. The remaining eight uses of azinphos-methyl are eligible for a time-limited registration based in part on their very high benefits for crop production. For these eight uses, the Agency has determined that at this time, no other pesticides or agricultural practices can substitute adequately for azinphos-methyl in providing control of key pests.

In order to determine the restricted entry interval (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. For a specific crop/pesticide combination, the duration required to achieve the target MOE can vary depending on the activity assessed.

In general, the Agency prefers to set a simple 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 simple REI is unworkable, the Agency 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 azinphos-methyl, 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 appropriate 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 most of the 15 azinphos-methyl 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, tree shaking for nut crops in 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)).

For the 15 uses which are either being phased out (7) or time-limited (8), the Agency has determined that a number of mitigation measures to reduce risk to handlers and post-application agricultural workers are necessary in order to warrant continued use under a time-limited registration or phase-out. These measures include the following, each of which applies to some or all of the uses:

- reducing the maximum application rate (lbs ai/A per application)
- reducing the number of applications per year (or maximum total pounds applied per year)
- extending the restricted entry interval
- extending the pre-harvest interval
- requiring closed transfer systems or water soluble bags for mixing/loading

- requiring enclosed cabs or maximum PPE for applying
- prohibiting aerial application

In addition to mitigation, confirmatory data will be required including (other data requirements are listed in Section V):

- data comparing exposure to airblast applicators with enclosed cabs, chemical resistant suits, and other PPE (like double layer clothing)
- monitoring (ChEI) studies of agricultural workers performing high exposure tasks

Even with the most stringent feasible mitigation measures, most of the 15 remaining uses of azinphos-methyl (7 phased out, 8 time-limited) have estimated exposures resulting in very low MOEs for post-application agricultural workers. The highest potential risks of concern for handlers are associated with mixing, loading and applying azinphos-methyl aerially. Of the remaining 15 use sites, aerial application will be prohibited on 11. An additional 2 sites with aerial application will be phased out by 2005. Of the 8 time-limited uses, only two (lowbush blueberries and southern pine seed orchards) would continue to be aerially applied.

A detailed description of the Agency's risk/benefit considerations for these 15 uses is provided in section (3) below.

2. Environmental Risk Characterization

The 15 remaining uses of azinphos-methyl also have associated environmental risk. In general terms, the ecological risks associated with the use of azinphos-methyl potentially are significant. There is a potential for spray drift and runoff into water bodies with the most drift being associated with aerial applications. Azinphos-methyl is very highly toxic to freshwater and marine fish and to invertebrates, and if it enters a water body in sufficient quantities, it can result in death and reproductive effects in aquatic organisms. There is also potential exposure to birds, mammals, and bees from direct spray, drift, and surface residues. Azinphos-methyl is highly to very highly toxic to birds and small mammals, and exposure can result in death and reproductive effects. Azinphos-methyl also is highly toxic to honeybees.

For the 16 uses which are either being phased out (7) or time-limited (8), the Agency has determined that implementation of a number of mitigation measures are necessary to reduce environmental risk. These measures include the following, each of which applies to some or all of the uses:

- reducing the maximum application rate (lbs ai/A per application)
- reducing the number of applications per year (or maximum total pounds applied per year)
- prohibiting aerial application
- requiring clear and enforceable label directions on managing spray drift

- requiring inward nozzle spray for airblast application to outside rows of orchards
- prohibiting dormant applications on orchard crops
- adding no-spray buffer zones around permanent water bodies

3. Occupational and Environmental Risk Mitigation

The following tables provide a description of the Agency's regulatory decision for each of the seven uses that are being phased out over four years, and for each of the eight uses that will have time-limited registrations. The tables include the current label rates, restricted entry intervals (REIs), and pre-harvest interval (PHI) for each use site, as well as the interim mitigation measures designed to reduce risk to workers and the environment. A detailed explanation of the Agency's risk and benefit considerations for each use site follows the listed mitigation measures.

For the fifteen commodities that are included in the four-year time limit and the phase-out of azinphos-methyl, 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 the USDA Office of Pest Management Policy on (202) 720-4074.

Uses to be cancelled with a four-year phase-out:

Almonds	
Current label rates	Maximum of 1.5 - 2.0 lbs ai/A per application; maximum of 2 post-bloom applications per season; minimum of 28 days between applications. Also labeled for alternate row sprays and split applications (air+ground), each at an interval of ≤10 days.
Current REI and PHI	REI: almonds are not thinned and are mechanically harvested; 2 days for all other activities PHI: 28 days
Proposed mitigation	• **phase out registration (4 years)** • limit to 1 application of 2.0 lbs ai/A • increase REI to 30 days for all activities • increase PHI to 30 days to match REI • prohibit hand harvesting • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • keep buffer zones for permanent surface water (currently set at 25 ft) • add bee warning statement on label • encourage development of Pest Management Strategic Plans (PMSPs)

Almonds	
Remaining Risks and Rationale	Risk to aerial mixers, loaders and applicators is addressed by eliminating aerial application on almonds. Use of closed mixing systems or water soluble bags results in estimated MOEs of 31 to 48 for airblast mixer/loaders. Use of closed cabs results in estimated MOEs of 16 to 25 for airblast applicators. EPA estimates that approximately 5,000 to 6,000 people perform hand labor activities in AZM treated almond orchards for about 8 weeks. Risks from activities associated with mechanical harvesting (removing nuts from trees with a mechanical shaker, sweeping or blowing nuts into windrows, gathering nuts with a mechanical harvester) are not known but may be high for open cabs. Some hand harvesting is done for young trees, but these are usually not treated with azinphos-methyl, and thus are not of concern. Information provided to the Agency indicates that pruning can occur immediately after harvest while leaves are still present on trees and could result in high exposures. Poling is likely to present much less exposure than pruning, and in some cases may be considered a no contact activity. Increasing the PHI to 30 days would result in an estimated MOE of 3 for pruners based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 30 for pruners. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potentialfor spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Retaining 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is to control navel orange worm (NOW) at hull split (~July). There is also some use in May to control peach twig borer (PTB). NOW and PTB have the potential to cause significant economic damage to almonds and have been linked to aflatoxin contamination. Alternatives include phosmet and chlorpyrifos, but AZM is preferred due to its long residual activity. 10% of the almond crop is treated in California, and nearly all U.S. almonds are grown in California.

Cherries, tart	
Label rate	Maximum of 0.75 lbs ai/A per application; maximum of 3 lbs ai/A per season; minimum of 14 days between applications.
Current REI and PHI	REI: Tart cherries are not thinned or hand harvested; 2 days for all other activities. PHI: 15 days.
Proposed mitigation	• **phase out registration (4 years)** • prohibit "pick your own" operations or restrict to early season application or increase PHI • limit to 2 applications of 0.75 lbs ai/A per year • increase REI to 19 days for all activities • maintain 14 day application interval • increase PHI to 19 days to match REI • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage use PMSPs
Remaining Risks and Rationale	Risk to aerial mixers, loaders, and applicators is addressed by eliminating aerial applications to cherries. Use of closed mixing systems or water soluble bags results in estimated MOEs of 83 to >100 for airblast mixer/loaders; use of closed cabs results in estimated MOEs of 43-66 for airblast applicators. EPA estimates that 10,000 to15,000 people perform hand labor tasks in AZM treated tart cherry orchards. Increasing the REI to 19 days results in an estimated MOE of 11 for low exposure activities like irrigating and scouting. Tart cherries are not hand thinned. Tart cherries are mechanically harvested, and mechanical harvesting is considered to involve no worker contact with treated foliage. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.

Cherries, tart	
Benefits	The critical use of azinphos-methyl is to control fruit flies and plum curculio. Although there are several other alternatives available, only azinphos-methyl and phosmet are efficacious enough to meet the federally mandated zero tolerance requirement for these pests. 77% of the crop is treated with azinphos-methyl, mostly in MI, PA and NY. 88% of tart cherry acreage is in Michigan, and 94% of crop is treated with azinphos-methyl in that state. Without adequate time for an orderly transition away from the use of azinphos-methyl, there could be significant disruptions in regions where there is a heavy reliance on azinphos-methyl.

Cotton	
Label rates	Maximum of 0.125-0.5 lbs ai/A per application; maximum of 2.0 lbs ai/A per season; maximum of 4 applications per season; minimum number of days between applications not specified.
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities. PHI: 7 days.
Proposed mitigation	• **phase out registration (4 years) (cancellation tied to initiation of Boll Weevil Eradication Program, if this occurs sooner than 4 years)** • limit use to the states of Texas and Missouri (currently, use is restricted to states west of the Mississippi River, excluding Louisiana) • limit to 3 applications of 0.5 lbs ai/A per year • increase REI to 7 days for all activities • require a 5 day application interval • maintain PHI at 7 days • maintain prohibition on hand harvesting • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE (ground only) for applicators • prohibit aerial for any applications that are not part of the Boll Weevil Eradication Program • prohibit dormant use • add 50-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs *NOTE:* cannot prohibit aerial application for this use (most acreage treated aerially).

Cotton	
Remaining Risks and Rationale	Aerial is the only feasible application method for mature cotton because of the large acreage. Use of closed mixing systems or water soluble bags results in estimated MOEs of 4 to 6 for aerial mixer/loaders; assuming closed cockpits, estimated MOEs are 8 to 13 for aerial applicators. Use of closed mixing systems or water soluble bags results in estimated MOEs of 25 to 38 for groundboom mixer/loaders. Use of closed cabs results in MOEs of 50 to 77 for groundboom applicators. EPA believes that a small number of people perform hand labor tasks in AZM treated cotton fields. Increasing the REI to 7 days results in an estimated MOE of 38 for scouting and irrigating mature plants in an estimated MOE of >100 for scouting and irrigating immature plants. Cotton is mechanically harvested, and mechanical harvesting is considered to involve no worker contact with treated foliage. Azinphos-methyl is highly toxic to aquatic organisms, and there is a potential for exposure from spray drift associated with aerial application. Fifty foot no-spray zones around permanent water bodies will decrease risk of exposure to fish, aquatic invertebrates, and other wildlife. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is to control the boll weevil in areas of Texas and Missouri where the Boll Weevil Eradication Program has not yet been implemented. Malathion (ULV application) is the preferred alternative for boll weevil control through the Boll Weevil Eradication Program. Less than 1% of U.S. cotton acreage is treated with azinphos-methyl, largely in Texas, where about 1% of the crop is treated. There is also limited use in Missouri.

Cranberries	
Current Label rates	Maximum of 0.5 - 1.0 lb ai/A per application; maximum of 3 applications per season; minimum of 14 days between applications.
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities. PHI: 21 days
Proposed mitigation	• **phase out registration (4 years)** • limit to 2 applications of 1.0 lb ai/A per year • increase REI to 7 days for all activities • maintain 14 day application interval • maintain 21 day PHI • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE (ground only) for applicators • add 50-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs *NOTE:* cannot prohibit aerial application for this use (almost all acreage treated aerially).
Remaining Risks and Rationale	Aerial application is critical to cranberries. Use of closed mixing systems or water soluble bags results in estimated MOEs of 7 to 11 for aerial mixer/loaders. Assuming closed cockpits, estimated MOEs would be 14 to 22 for aerial applicators. Risk to aerial mixers, loaders, and applicators may be lower than those indicated by the estimated MOEs, because the typical field size for cranberry productions is approximately 80 acres, substantially lower than the 350 acres used to calculate handler risk for aerial application. EPA estimates that there are 1500 to 2000 people who perform hand labor tasks in AZM treated cranberry fields. Increasing the REI to 7 days results in an estimated MOE of 21for scouting and hand weeding. With a 21 day PHI, the estimated MOE for hand raking is 68. Azinphos-methyl is highly toxic to aquatic organisms, and there is a potential for exposure from spray drift associated with aerial application. Fifty foot no-spray zones around permanent water bodies will decrease risk of exposure to fish, including endangered salmonids in the Pacific Northwest, aquatic invertebrates, and other wildlife. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.

Cranberries	
Benefits	The critical use of azinphos-methyl is to control cutworms, fireworms, and fruitworms. Chlorpyrifos is the most effective alternative to control cutworms, but resistance to chlorpyrifos has developed in Massachusetts. Alternatives are available to control fireworms and fruitworms (chlorpyrifos, carbaryl, diazinon, and tebufenozide). Use of azinphos-methyl is declining in all states except Wisconsin, but it is still a key component of pest management in some areas. In New Jersey for example, azinphos-methyl is alternated with chlorpyrifos to prevent resistance. Where resistance occurs losses could be 10% of gross revenues per affected acres. Phosmet is a new registration on this crop (2/2000), and its efficacy as an alternative is unknown. 36% of the U.S crop is treated with azinphos-methyl, mostly in NJ, MA, WI, WA and OR. On a national level, the impact from the lose of azinphos-methyl is estimated at 0.2% of gross revenues.

Peaches		
Label rates	**<u>Eastern region</u>:** maximum of 0.875 - 1.125 lbs ai/A per application; maximum of 3.375 lbs ai/A per season; minimum of 14 days between applications	**<u>Western region</u>:** maximum of 1.5 -2.0 lbs ai/A per application; maximum of 3.375 lbs ai/A per season; minimum of 14 days between applications
Current REI and PHI	REI: 14 days hand harvesting and hand thinning; 2 days for all other activities. PHI: 21 days	
Proposed mitigation	• **phase out registration (4 years)** • prohibit "pick your own" operations or restrict to early season application or increase PHI • limit to 2 applications of 1.125 lbs ai/A per season • increase REI to 14 days for all activities • maintain 14 day application interval • maintain PHI at 21 days • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs	

Peaches	
Remaining Risks and Rationale	Risk to aerial mixers, loaders, and applicators is addressed by eliminating aerial applications to peaches. With the maximum application rate reduced to 1.125 lbs ai/A, the use of closed mixing systems or water soluble bags results in estimated MOEs of 56 to 85 for airblast mixer/loaders; use of closed cabs results in estimated MOEs of for 29 to 44 for airblast applicators. EPA estimates that 6,000 to 8,000 people perform hand labor tasks such as thinning and harvesting in AZM treated orchards. With a PHI of 21 days, reducing the maximum application nationwide to 1.125 lbs ai/A would result in an estimated MOE of 3 for hand harvesters based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 30 for harvesters. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. With an REI of 14 days for other high exposure activities such as hand thinning, reducing the maximum application nationwide to 1.125 lbs ai/A would result in an estimated MOE of 2 based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 20 for thinners. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, including endangered salmonids in the Pacific Northwest, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is to control plum curculio, oriental fruit moth, various scales, various borers, and various leafrollers. With the removal of methyl-parathion, the majority of growers in the southeast and California switched to phosmet, while growers in the northeast and northwest switched to azinphos-methyl. Azinphos-methyl provides excellent plum curculio and scale control, but its use has decreased since the REI was increased to 14 days, preventing use during thinning period (phosmet is used during this period). Cost effective alternatives to azinphos-methyl are available. 40% of the U.S. crop is treated with azinphos-methyl, mostly in PA, NJ, NY, and WA, with lesser use in MI, TX, NC, and SC. With a 4 year transition period, no grower nor national level impacts are anticipated. However, without adequate time for an orderly transition away from the use of azinphos-methyl could create significant disruptions in regions where there is a heavy reliance on azinphos-methyl.

Pistachios	
Current Label rates	Maximum of 2.5 lbs ai/A per application; maximum of 1 application per season.
Current REI and PHI	REI: Pistachios are not thinned and are mechanically harvested; 2 days for all other activities. PHI: 21 days.
Proposed mitigation	• **phase out registration (4 years)** • maintain geographic use restriction: use restricted to CA and AZ • limit to 1 application of 2.0 lbs ai/A • increase REI to 30 days for all activities • increase PHI to 30 days to match REI • prohibit hand harvesting • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs

Pistachios	
Remaining Risks and Rationale	Risk to aerial mixers, loaders and applicators is addressed by eliminating aerial application on almonds. With the reduced maximum application rate of 2.0 lbs ai/A, the use of closed mixing systems or water soluble bags results in estimated MOEs of 31 to 48 for airblast mixer/loaders. Use of closed cabs results in estimated MOEs of 16 to 25 for airblast applicators. EPA estimates that 1,500 to 2000 people perform hand labor tasks in AZM treated pistachios orchards for about 8 weeks. Risks from activities associated with mechanical harvesting are not known but may be high for open cabs. Some hand harvesting is done for young trees, but these are usually not treated with azinphos-methyl, and thus are not of concern. Information provided to the Agency indicates that pruning can occur immediately after harvest while leaves are still present on trees and could result in high exposures. Poling is likely to present much less exposure than pruning, and in some cases may be considered a no contact activity. Reducing the maximum application rate to 2.0 lbs ai/A and increasing the PHI to 30 days would result in an estimated MOE of 3 for pruners based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 30 for pruners. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is for control of navel orangeworm. Azinphos-methyl is the preferred alternative to control navel orangeworm, because of its long residual activity. Spinosad and tebufenozide (new registrations) may provide control. 21% of the crop is treated in California (use of azinphos-methyl is restricted to CA and AZ). CA accounts for 97% and AZ for 3% of the U.S. pistachio acreage.

Walnuts	
Current Label rates	Maximum of 1.5 - 2.0 lbs ai/A per application; maximum of 3 applications per season; minimum of 14 days between applications. Also labeled for split applications (1.0 lb ai/A by air and 1.0 lb ai/A by ground), each at an interval of $\leq$10 days.
Current REI and PHI	REI: walnuts are not thinned and are mechanically harvested; 2 days for all other activities. PHI: 21 days.
Proposed Mitigation	• **phase out registration (4 years)** • limit to 1 application of 2.0 lbs ai/A • increase REI to 30 days for all activities • increase PHI to 30 days to match REI • prohibit hand harvesting • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs

Walnuts	
Remaining Risks and Rationale	Risk to aerial mixers, loaders and applicators is addressed by eliminating aerial application on almonds. Use of closed mixing systems or water soluble bags results in estimated MOEs of 31 to 48 for airblast mixer/loaders. Use of closed cabs results in estimated MOEs of 16 to 25 for airblast applicators. EPA estimates that 2,000 to 2,500 people perform hand labor activities in AZM treated walnut orchards for about 8 weeks. Risks from activities associated with mechanical harvesting (removing nuts from trees with a mechanical shaker, sweeping or blowing nuts into windrows, gathering nuts with a mechanical harvester) are not known but may be high for open cabs. Some hand harvesting is done for young trees, but these are usually not treated with azinphos-methyl, and thus not of concern. Information provided to the Agency indicates that pruning can occur immediately after application while leaves are still present on trees and could result in high exposures. Poling is not done in walnuts. Increasing the PHI to 30 days would result in an estimated MOE of 3 for pruners based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 30 for pruners. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is for control of codling moth. Azinphos-methyl is the preferred alternative due to its long residual activity, although some resistance to azinphos-methyl is developing. Methyl parathion (available through a 24C) and chlorpyrifos are negatively cross-resistant to azinphos-methyl. Phosmet is also an available alternative. 10% of the crop is treated in California, and California produces 99% of walnuts grown in the U.S., of which 40% are exported.

Uses with a 4-year time-limited registration:

Apples, crabapples	
Label rates	Maximum of 1.0-1.5 lb ai/A per application; maximum of 4.5 lb ai/A per year; minimum of 7 days between applications.
Current REI and PHI	REI: 14 days hand harvesting and hand thinning; 2 days for all other activities PHI: 14 days (rates ≤ 1.0 lb ai/A); 21 days (rates > 1.0 lb ai/A)
Proposed mitigation	• **time limited registration (4 years)** • prohibit "pick your own" operations OR restrict application to early season OR establish a 30 day PHI for "pick your own" operations • limit to 3.5 lbs ai/A per year east of the Mississippi, 4.0 lbs ai/A per year west of the Mississippi • maintain maximum application rate of 1.0 lb ai/A or 1.5 lbs ai/A in conjunction with an IPM program • increase REI to 14 days for all activities • maintain 7 day application interval • maintain current PHI of 14 days for rates ≤ 1.0 lb ai/A and 21 days for rates > 1.0 lb ai/A • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or maximum PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs

Apples, crabapples	
Remaining Risks and Rationale	Risk to aerial mixers, loaders, and applicators is addressed by eliminating aerial application on apples and crabapples. Use of closed mixing systems or water soluble bags results in estimated MOEs of 42 to 64 for airblast mixer/loaders. Use of closed cabs results in estimated MOEs of 22 to 33 for airblast applicators. EPA estimates that approximately 45,000 hand harvesters work in AZM treated apple orchards. With a PHI of 21 days, the estimated MOE is 2 for hand harvesters based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 20 for harvesters. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. With an REI of 14 days for other high exposure activities such as hand thinning, the estimated MOE is 1 based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 10 for thinners. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, including endangered salmonids in the Pacific Northwest, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is for codling moth, apple maggot, and oriental fruit moth control. There is zero tolerance for apples infested with these pests**.** No non-OP alternative provides adequate control, and most result in outbreaks of secondary pests. With the removal of methyl-parathion and the restriction placed on chlorpyrifos limiting its use to before bloom, azinphos-methyl and phosmet are the only remaining OPs that provide effective control of key target pests. Azinphos-methyl is preferred over phosmet because it provides longer residual activity. 78% of the U.S. apple crop is treated with azinphos-methyl. National impacts of $50 to $85 million or up to 65 of the value of the crop could be lost without the use of azinphos-methyl.

Blueberries, lowbush	
Label rates	Maximum of 0.5 - 0.75 lbs ai/A per application; maximum of 3 applications per season; minimum of 10 days between applications.
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities. PHI: 7 days.
Proposed mitigation	• **time limited registration (4 years)** • maintain regional use restriction: use restricted to Eastern and North Central states • prohibit "pick your own" operations or restrict to early season application or increase PHI • limit to 2 applications of 0.75 lbs ai/A per year • increase REI to 10 days for all activities • prohibit hand pruning for 38 days after application • maintain 10 day application interval • increase PHI to 10 days to match REI • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • add 50-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs *NOTE:* cannot prohibit aerial application for this use (all acreage treated aerially).

Blueberries, lowbush	
Remaining Risks and Rationale	Aerial application is critical to lowbush blueberries. Use of closed mixing systems or water soluble bags results in estimated MOEs of 10 to 15 for aerial mixer/loaders. Assuming closed cockpits, estimated MOEs would be 19 to 29 for aerial applicators. Use of closed mixing systems or water soluble bags results in MOEs for groundboom mixer/loaders of 42 to 64. Use of closed cabs results in estimated MOEs for groundboom applicators of 83 to >100. EPA estimates that approximately 12,000 to 15,000 people perform hand labor activities such as harvesting in AZM-treated blueberry fields (both highbush and lowbush). Increasing the REI to 10 days (PHI also = 10 days) would result in an estimated MOE of 10 for high exposure activities like hand harvesting, and in an estimated MOE of 37 for low exposure activities such as irrigating and scouting. Prohibiting hand pruning for 38 days after application would result in an estimated MOE of >100. Azinphos-methyl is highly toxic to aquatic organisms, and there is a potential for exposure from spray drift associated with aerial application. Fifty foot no-spray zones around permanent water bodies will decrease risk of exposure to fish, aquatic invertebrates and other wildlife, particularly almost extinct species of trout, Atlantic salmon and sturgeon in the Northeast. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is to control blueberry maggot. Blueberry maggot has the potential to cause significant economic damage to blueberries, and there is zero tolerance for blueberry maggot infestation. Other than phosmet, no efficacious alternatives are available. 36% of total lowbush blueberry crop in the U.S. is treated with azinphos-methyl, and production is almost entirely in Maine. Without azinphos-methyl, growers could lose more than 10% of net revenues.

Blueberries, highbush	
Label rates	Maximum of 0.5 - 0.75 lbs ai/A per application; maximum of 3 applications per season; minimum of 10 days between applications.
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities. PHI: 7 days.
Proposed mitigation	• **time limited registration (4 years)** • maintain regional use restriction: use restricted to Eastern and North Central states • prohibit "pick your own" operations or restrict to early season application or increase PHI • limit to 2 applications of 0.75 lbs ai/A per year • increase REI to 7 days for all activities • maintain 10 day application interval • maintain 7 day PHI • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage use PMSPs

Blueberries, highbush	
Remaining Risks and Rationale	Risk to aerial mixers, loaders and applicators is addressed by elimination of aerial application to highbush blueberries. Use of closed mixing systems or water soluble bags results in estimated MOEs for airblast mixer/loaders of 83 to >100. Use of closed cabs results in estimated MOEs for airblast applicators of 43 to 66. Use of closed mixing systems or water soluble bags results in estimated MOEs of 42 to 64 for groundboom mixer/loaders; use of closed cabs or results in estimated MOEs of 83 to >100 for groundboom applicators. It is estimated that 12,000 to 15,000 people people perform hand labor activities such as harvesting in blueberry fields (both highbush and lowbush). Increasing the REI to 7 days (PHI also = 7 days) results in an MOE of 0.3 for high exposure activities like hand harvesting and pruning based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 3. The estimated MOE for low exposure activities such as irrigating, scouting, hand weeding and mulching would be 3 using the NOAEL and 30 using the LOAEL. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifying inward sprays on outside rows for airblast applications will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is to control fruitworms, blueberry maggot, and Japanese beetle. These pests have the potential to cause significant economic damage to blueberries, and there is zero tolerance for blueberries infested with these pests. Other than phosmet, none of the available alternatives control the broad spectrum of pests that azinphos-methyl controls, and some alternatives result in secondary pest outbreaks. 48% of total highbush/rabbiteye blueberry crop in the U.S. is treated with azinphos-methyl, mostly in MI, NY, NJ, GA, FL, and OR. Without azinphos-methyl, growers could lose 37% to 65% of their net revenues in North Central states and at least 9% to 15% in eastern states.

Brussels sprouts	
Label rates	Maximum of 0.125-0.75 lb ai/A per application; maximum of 3 applications per year; applications interval not specified.
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities PHI: 7 days
Proposed mitigation	• **time limited registration (4 years)** • limit to 1 application of 0.75 lbs ai/A per year • restrict application to soil application at transplant to control cabbage root maggot only • increase REI to 7 days for all activities • maintain PHI at 7 days • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage use PMSPS
Remaining Risks and Rationale	Risk to aerial mixers, loaders and applicators is addressed by eliminating aerial application on Brussels sprouts. Use of closed mixing systems or water soluble bags results in estimated MOEs of 42 to 64 for groundboom mixer/loaders; use of closed cabs results in estimated MOEs of 83 to >100 for groundboom applicators. Only a portion of the 1100 acres treated with azinphos-methyl are applied to control cabbage maggot, thus, the population of handlers who will be exposed as a result of this use is expected to be small. With the proposed mitigation (application to soil at transplant), post-application exposure is expected to be negligible. Restricting use to soil applications will eliminate the potential for drift, thus decreasing the potential for adverse effects in fish and other aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. Warning language will address exposure to honeybees.
Benefits	Approximately 35% of the CA crop is treated with azinphos-methyl, and >90% of the U.S. production of Brussels sprouts is on the Central Coast of California. The critical uses of azinphos-methyl are for control of the cabbage root maggot and aphids. Chlopyrifos is the only potential alternative for the cabbage root maggot. Most of this use is for aphid control for which there are several viable alternatives.

Caneberries	
Label rates	Maximum of 0.25-0.5 lb ai/A per application; maximum of 2 applications per season; minimum number of days between applications not specified
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities. PHI: 14 days (foliar application) or 4 days (application to lower canes and soil)
Proposed mitigation	• **time limited registration (4 years)** • prohibit "pick your own" operations or restrict to early season application or increase PHI • restrict application to canes and soil for control of raspberry crown borer only • maintain maximum label rate of 2 applications at 0.5 lbs ai/A • increase REI to 7 days for all activities • require a 10 day application interval • increase PHI to 7 days (to match REI) • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require closed cabs or max. PPE for applicators • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage use PMSPS
Remaining Risks and Rationale	Risks to aerial mixers, loaders and applicators are addressed by eliminating aerial application on caneberries. Use of closed mixing systems or water soluble bags results in estimated MOEs of 63 to 96 for groundboom mixer/loaders; use of closed cabs results in estimated MOEs of >100 for groundboom applicators. With the proposed mitigation (application to soil and the lower portion of canes), postapplication exposure is expected to be negligible. Eliminating aerial applications will eliminate the potential for drift, thus decreasing the potential for adverse effects in fish and other aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is to control the raspberry crown borer. This pest can cause up to 50% plant damage with no pest control program. Currently, azinphos-methyl is rotated with diazinon, the alternative of choice, to prevent resistance (diazinon is half as expensive as azinphos-methyl). Without a suitable alternative, if resistance develops with the use of diazinon to control crownborer, the initial reduction in the cost of production due to the lower cost of diazinon would offset by the increased yield losses and replanting costs estimated to range between $2,000 and $4,000 per acre per year until viable production returns. The total estimated costs that Oregon growers may bear is estimated at $2.1 to $4.3 million in the first year not including total loss of sales revenue for those affected acres.

Cherries, sweet	
Label rate	Maximum of 0.75 lbs ai/A per application; maximum of 3 lbs ai/A per season; minimum of 14 days between applications.
Current REI and PHI	REI: 14 days for hand harvesting (cherries are not thinned); 2 days for all other activities. PHI: 15 days.
Proposed mitigation	• **time limited registration (4 years)** • prohibit "pick your own" operations or restrict to early season application or increase PHI • limit to 2 applications of 0.75 lbs ai/A per year • increase REI to 19 days for all activities • maintain 14 day application interval • increase PHI to 19 days to match REI • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs
Remaining Risks and Rationale	Risks to aerial mixers, loaders, and applicators is addressed by eliminating aerial applications. Use of closed mixing systems or water soluable bags results in MOEs of 83 to >100 for airblast mixer/loaders; use of closed cabs results in estimated MOEs for airblast applicators of 43-66. EPA estimates that there are about 8,000 harvesters working in sweet cherry orchards. Increasing the REI to 19 days (PHI also = 19 days) results in an estimated MOE of 3 for high exposure activities like hand harvesting, based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an estimated MOE of 30. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Sweet cherries are not hand thinned. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.

Cherries, sweet	
Benefits	The critical use of azinphos-methyl is to control fruit flies and plum curculio. There is no alternative for azinphos-methyl that is efficacious enough to meet the zero tolerance requirement for these pests. Phosmet is not available as an alternative to control fruit flies and plum curculio because it is phytotoxic to sweet cherries. 44% of the U.S. crop is treated with azinphos-methyl, mostly in MI, CA, OR, and WA. The Agency anticipates significant impacts if azinphos- methyl were not available.

Nursery stock	
Label rates	Maximum of 0.375-2.0 lb ai/A per application; maximum of 4 applications for field use and 6 applications for quarantine use; minimum number of days between applications not specified.
Current REI and PHI	REI: 2 days for mowing, irrigating and scouting; 4 days for all other activities. PHI: N/A
Proposed mitigation	• **time limited registration (4 years)** • limit to quarantine use, only • prohibit sale to general public for 30 days after application • limit to 4 applications at 1.0 lb ai/A • increase REI to 4 days for all activities • require a 10 day application interval • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs

Nursery stock	
Remaining Risks and Rationale	Risk to aerial mixers, loaders, and applicators is addressed by eliminating aerial applications to nursery stock. Use of closed mixing systems or water soluble bags result in estimated MOEs of 31 to 48 for airblast mixer/loaders. Use of closed cabs or full PPE result in estimated MOEs of 16 to 25 for airblast applicators. Use of closed mixing systems or water soluble bags results in estimated MOEs of 16 to 24 for groundboom mixer/loaders. Use of closed cabs results in MOEs of 31 to 48 for groundboom applicators. The EPA has no reliable data to estimate the nursery number of workers potentially exposed to azinphos methyl. There are a number of activities on potted plants including righting fallen plants, pruning, training, and irrigating that can result in exposure. Lowering the maximum application rate to 1.0 lb ai/A and increasing the REI to 4 days results in an estimated MOE of 1 for high exposure post-application activities such as pruning, based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an estimated MOE of 10. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. The risks to post-application workers were estimated using transfer coefficients from a study of worker exposure in a cut flower nursery, which may overestimate exposure experienced by a worker in other nursery environments. Eliminating aerial applications and specifying inward sprays on outside rows will decrease the potential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potentialfor exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical uses of azinphos-methyl are to control apple ermine moth in ornamental trees and to control black vine weevil in a variety of woody ornamentals and herbaceous perennials in container and field nurseries (both quarantine uses). With the removal of bendiocarb, azinphos-methyl is the most effective remaining alternative to control black vine weevil. The other alternatives are acephate, bifenthrin, chlorpyrifos, and some pyrethroids. Based on comments from growers in Ohio, Oregon, California, and New York, azinphos-methyl is used to control black vine weevil in the west and mid-west, but not in the northeast.

Pears	
Label rate	Maximum of 1.0-1.5 lb ai/A per application; maximum of 4.5 lb ai/A per year; minimum of 7 days between applications
Current REI	REI: 14 days hand harvesting and hand thinning; 2 days for all other activities. PHI: 14 days ($\leq$ 1.0 lb ai/A); 21 days ($>$ 1.0 lb ai/A).
Proposed mitigation	• **time limited registration (4 years)** • prohibit "pick your own" operations or restrict to early season application or increase PHI • limit to 2 applications and 2.5 lbs ai/A per year • maintain maximum application rate at 1.0 lbs ai/A or 1.5 lbs ai/A in conjunction with an IPM program • increase REI to 14 days for all activities • maintain 7 day application interval • increase PHI to 21 days • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • prohibit aerial application • add spray drift language • add language on the label for inward nozzle spray (airblast) • prohibit dormant use (not a current use) • add 25-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs

Pears	
Remaining Risk and Rationale	Risk to aerial mixers, loaders, and applicators is addressed by elimination of aerial applications on pears. Use of closed mixing systems or water soluble bags results in estimated MOEs of 42 to 64 for airblast mixer/loaders. Use of closed cabs results in estimated MOEs of 22 to 33 for airblast applicators. EPA estimates that 1,500 to 2,000 people perform hand labor activities such as harvesting in AZM treated pear orchards. With a PHI of 21 days, the estimated MOE is 2 for hand harvesters based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 20 for harvesters. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. With an REI of 14 days for other high exposure activities such as hand pruning, the estimated MOE is 1 based on the NOAEL of 0.56 mg/kg/day. Minimal (15-16%) RBC ChE inhibition was measured at the LOAEL of 5.6 in the same study. Basing the estimated MOE on this LOAEL would result in an MOE of 10 for pruners. See the toxicity discussion in the Occupational Risk section of this document for a complete discussion of these estimates. Eliminating aerial applications and specifing inward sprays on outside rows will decrease the potentential for spray drift and runoff into water bodies, thus decreasing the potential for adverse effects in fish, including endangered salmonids in the Pacific Northwest, aquatic invertebrates, and other wildlife. Establishing 25-foot no-spray zones around permanent water bodies will also decrease risks to aquatic organisms. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.

Pears	
Benefits	The critical use of azinphos-methyl is for control of codling moth and grape mealybug. There is a zero-tolerance for codling moth in pears. Only azinphos-methyl and phosmet provide effective codling moth control, and azinphos-methyl is preferred over phosmet for first (and often second) generation CM control because it is perceived to be more effective and has longer residual activity. Azinphos-methyl cannot be used close to harvest due to its 14/21 day PHI, so phosmet is used to control late season infestations. 66% of the crop is treated with azinphos-methyl, mostly in CA, OR and WA. Without azinphos-methyl, net revenues could fall by 24% to 39% in the Pacific Northwest and 9% to 13% nationally.

Southern pine seed orchards	
Label rates	Maximum of 1.5 lbs ai/A per application; maximum of 3 applications per year; maximum of 4.5 lbs ai/A per year; minimum number of days between applications not specified.
Current REI and PHI	REI: 2 days for mowing, irrigating & scouting; 4 days for all other activities. PHI: N/A.
Proposed mitigation	• **time limited registration (4 years)** • limit to 2 applications of 1.0 lbs ai/A per year and restrict application to after pollination • increase REI to 45 days • require a 30 day application interval • require closed cabs for mowing • require closed mixing systems or water soluble bags and closed transfer systems for mixing/loading • require enclosed cabs or max. PPE for applicators • add spray drift language • add 50-foot buffer zones for permanent surface water • add bee warning statement on label • encourage development of PMSPs *NOTE:* cannot prohibit aerial application for this use (all acreage treated aerially).

Southern pine seed orchards	
Remaining Risks and Rationale	Aerial application is the only viable application method for southern pine seed orchards. With the reduced maximum application rate of 1.0 lbs ai/A, the use of closed mixing systems or water soluble bags results in estimated MOEs of 7 to 11 for aerial mixer/loaders. Assuming closed cockpits, estimated MOEs would be 14 to 22 for aerial applicators. Risk to aerial mixers, loaders, and applicators may be lower than those indicated by the estimated MOEs, because the average orchard size for southern pine seed production is approximately 150 acres, less than the 350 acres used to calculate handler risk for aerial application. Newer orchards are even smaller, approximately 50 acres in size. Most hand activities (except harvesting) in pine seed orchards occur prior to an azinphos methyl applications. EPA estimates that 200 to 300 people perform harvesting activities in AZM treated pine seed orchards. Reducing the maximum application rate to 1.0 lb ai/A and increasing the REI to 45 days would result in an MOE of 10 for harvesters. The risk from cone harvesting may be less than that indicated by the estimated MOE. Worker exposure from harvesting cones is expected to be less than for other hand harvested tree crops because the cones tend to be on the outer limbs, reducing the potential for worker contact with treated surfaces. To verify this lower exposure, a pine seed orchard harvester exposer study is required. Azinphos-methyl is highly toxic to aquatic organisms, and there is a potential for exposure from spray drift associated with aerial application. Fifty foot no-spray zones around permanent water bodies will decrease risk of exposure to fish, aquatic invertebrates, and other wildlife in southern and gulf areas. This use, like all uses of azinphos-methyl, continues to pose some potential for adverse ecological effects due to runoff into water bodies. There is also a potential for exposure to birds and other terrestrial organisms through residues and direct spray. Warning language will address exposure to honeybees.
Benefits	The critical use of azinphos-methyl is for control of coneworms and seedbugs. If phosmet (registered in 2000) proves to be as effective as AZM, it would provide a mid-season alternative to azinphos-methyl. Pyrethroids are used for the first and last applications of the season, but cannot be used mid-season (right after pollination and through the summer) because they kill beneficial insects and trigger a secondary outbreak of scale. Should phosmet prove to be effective alternative to azinphos methyl, the loss of azinphos methyl would be negligible. If not, yield loss would be 30-70% without an effective alternative. Approximately 21% of total U.S. acreage is treated with azinphos-methyl, and 95% of production is located in southern and gulf areas.

E. Other Labeling

In order to continue use of azinphos-methyl during the period of time-limited registration and phase-out, other use and safety information need to be placed on the labeling of all end-use products containing azinphos-methyl. 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 interim REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticides uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will include consideration of the regulatory changes recommended in this interim RED. 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.

At present, the program is being implemented on an interim basis as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989). A final program, which may be altered from the interim program, will be proposed in a *Federal Register* notice scheduled for publication in autumn 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, do not apply within 25 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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 other airblast applications, do not apply within 25 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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, do not apply within 50 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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 , do not apply within 25 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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."

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 (except mosquito adulticides), 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 continue the use of azinphos-methyl during the period of time-limited registration and phase-out, registrants need to implement the risk mitigation measures outlined in Section IV and V, which include, among other things, submission of the following:

A. For azinphos-methyl technical grade active ingredient products, registrants need to submit the following items.

Within 90 days from the receipt of this document:

(1) submit five copies of the draft label incorporating all label amendments outlined in Table of this document.

Within 90 days from receipt of the generic data call-in (DCI):

(1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form);

(2) submit any time extension and/or waiver requests with a full written justification;

(3) submit two copies of the confidential statement of formula (EPA Form 8570-4);

(1) submit a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration."

Within the time limit specified in the generic DCI:

(1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Véronique LaCapra (703-605-1525) with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
Véronique LaCapra
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Véronique LaCapra
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway

Arlington, VA 22202

B. For products containing the active ingredient azinphos-methyl, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

(1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

(1) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

(1) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

(2) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

(3) the product-specific data responding to the PDCI.

Please contact Jane Mitchell at 703-308-8061 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (PDCI/PRB)
Jane Mitchell
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Jane Mitchell
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of azinphos-methyl for the above eligible uses has been reviewed and determined to be substantially complete. 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 additional data. Instructions for submitting these data and more detail on the specific data requirements will follow in a separate data call-in (DCI) that will be issued in the near future. Below is a brief description of the data that the Agency intends to require:

Human Health

- Biomonitoring Studies - Monitor study of worker activities that would measure both cholinesterase and the AZM biomarker levels. Specific Activity/Crop that will be required for:
  -Apple- harvesting & thinning in Northwest, Northeast, and California
  -Highbush blueberry - hand harvesting or tying/training in Michigan.
  -Lowbush blueberry - hand harvesting in Maine.
  -Sweet cherry - harvesting Michigan and Northwest.

- Dislogible foliar residue (DFR) for pine seed harvesters.
- DFR for high exposure nursery activities.
- Study comparing the exposure reduction form closed cabs and full PPE.

Ecological Effects

-Full fish life cycle study (Submission of raw data from a previously submitted study may satisfy this requirement.)
-Ground water monitoring in areas with karst terrain

Benefits

-For all time-limited uses, use & usage data for 2002 through September 30, 2004. These data should include the number of acres treated, the typical and maximum application rate, the frequency of application, the timing of the application, and the target pests.
-Information on the registrant's alternatives in development or new registrations. For new registrations, provide use and usage information as described above.

Exposure Reduction Feasibility

Conduct a feasibility study for potential exposure reduction approaches for postapplication workers. In particular, explore the use of gloves by harvesters for reducing pesticide exposure. Because a large potion of harvester exposure is through the hand, if gloves could used in a way that maintains the flexibility needed for harvesting, risks to harvesters could be significantly reduced. Currently, gloves are used for harvesting a number of crops. In cases where leather or other fabrics are used, the Agency has been concerned that the gloves may not reduce pesticide exposure, but may act as a pesticide sink for exposure. For some crops, fabric glove with open figure tips are used. If well maintained

and cleaned, they may reduce exposure if the palm is the primary sources of hand exposure. Alternatively, a full chemical resistant glove would likely provide the greatest exposure reduction, but may present problems for fruit harvesting. The purpose of the study is to explore the feasibility of requiring the use of gloves or other exposure reduction approaches for high exposure hand labor activities. Feasibility includes such things as the practicality of using gloves or other approaches in an agronomic sense, as well as the feasibility of implementing the use of approach as a requirement. For each feasible approach, the Agency needs data demonstrating the exposure reduction for each approach that would be practical in a real world agricultural environment.

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.

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 MP 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 registrant may sell and distribute azinphos-methyl products bearing old labels/labeling until June 30, 2002. Persons other than the registrant may distribute or sell such products for 12 months from the date of the issuance of this interim RED. 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.

A. 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 Azinphos-methyl		
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)." "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 liquid end-use products or 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	"Environmental Hazards:" "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

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use (WPS Only)		
Handler PPE requirements (all formulations)	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain AZM, 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. For **multiple-active-ingredient** end-use products that contain AZM, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7. 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.	Handler PPE Statements

Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the RED for liquid products	"**Personal Protective Equipment (PPE)**" "Some materials that are chemical-resistant to this product are" *(registrant inserts correct chemical resistant material).* "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." "Mixers, loaders, applicators using aerial equipment, and other handlers using engineering controls must wear: - Long-sleeved shirt and long pants - Shoes plus socks" "In addition to the above, mixers and loaders must wear: - Chemical-resistant gloves - Chemical-resistant apron" "Applicators using motorized ground equipment, and handlers engaged in those activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves, -- chemical-resistant footwear plus socks, -- chemical-resistant apron if exposed to the concentrate, -- chemical-resistant headgear for 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." "See Engineering Controls for additional requirements". *Note: The registrant must drop the N-series filter from the respirator filter designation if the pesticide product contains or is used with oil.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the RED for wettable powder Only products marketed in water soluble packets will be eligible for reregistration	"**Personal Protective Equipment (PPE)**" "Some materials that are chemical-resistant to this product are" *(registrant inserts correct chemical resistent material).* "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." "Mixers, loaders, applicators using aerial equipment, and other handlers using engineering controls must wear: - Long-sleeved shirt and long pants - Shoes plus socks" "In addition to the above, mixers and loaders must wear: - Chemical-resistant gloves - Chemical-resistant apron" "Applicators using motorized ground equipment, and handlers engaged in those activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear: -- coveralls over long-sleeve shirt and long pants, -- chemical-resistant gloves, -- chemical-resistant footwear plus socks, -- chemical-resistant apron if exposed to the concentrate, -- chemical-resistant headgear for 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." "See Engineering Controls for additional requirements." *Note: The registrant must drop the N-series filter from the respirator filter designation if the pesticide product contains or is used with oil.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
User Safety Requirements	"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." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for Liquid Formulations	**"Engineering Controls"** "Mixers and loaders must use a closed mixing and loading system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for providing dermal and inhalation protection. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 ml per disconnect point." "In addition, mixers and loaders must: -- wear the personal protective equipment required in the PPE section of this labeling for mixer/loaders, -- wear protective eyewear if the system operates under pressure, -- be provided and have immediately available for use in case of an emergency, such as a broken package or spill, the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible." "Pilots must use an enclosed cockpit in a manner he requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];" "Human flagging is prohibited". "When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)

Description	Amended Labeling Language	Placement on Label
Engineering Controls for Wettable Powder Formulations	"**Engineering Controls**" "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 : -- 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: the PPE specified in the PPE section of this labeling for handlers engaged in those activities for which use of an engineering control is not possible." "Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];" "Human flagging is prohibited." "When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately Following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "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."	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	"This pesticide is extremely toxic to fish and wildlife. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in neighboring areas." "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 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 over-laying tile drainage systems that drain to surface water."	Precautionary Statements (Immediately following the User Safety Recommendations)
Restricted-Entry Interval (REI)	"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 Intervals (REI)	*The Directions for Use amendments to reflect the following REIs:* **The REI for the following crops is 7 days:** Blueberries, highbush and rabbiteye Brussels sprouts Caneberries (blackberries, boysenberries, longanberries, raspberries) Cotton Cranberries **Blueberries, lowbush, the REI is 10 days** **The REI for the following tree crops is 14 days:** Apples and crab apples Peaches Pears **The REI for the following tree crops is 19 days** Cherries, sweet Cherries, tart **The REI for the following nut crops is 30 days:** Almonds Pistachios Walnuts **Nursery stock, the REI is 4 days** **Southern pine seed orchards, the REI is 45 days**	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Early Re-entry Personal Protective Equipment established by the RED.	"PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and involves contact with anything that has been treated, such as plants, soil, or water, is: Coveralls over long sleeved shirt and long pants; Chemical resistant gloves made out of any waterproof material; Chemical resistant footwear plus socks; Protective eyewear; Chemical Resistant headgear for over head exposures."	Directions for Use, Agricultural Use Requirements Box
Notification Requirements	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
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."	Directions for Use, Just Above Agricultural Use Requirements Box

Description	Amended Labeling Language	Placement on Label
Application Restrictions	*Labels must be amended to reflect the following application restrictions which supercede or are in addition to restrictions currently on labels:* **Apples and crab apples:** PHI= 14 days for rates $\leq$ 1.0 lb ai/A PHI= 21 days for rates > 1.0 lb ai/A Limit maximum applications of 3.5 lbs ai/A per year east of the Mississippi Limit maximum application of 4.0 lbs ai/A per year west of the Mississippi Maintain maximum application rate at 1.0 lbs ai/A or 1.5 lbs ai/A in conjunction with an IPM program. Minimum of 7 days between applications "Use during dormant season is prohibited." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Do not graze livestock in treated orchards." Any other conflicting grazing restrictions must be removed from the label. Restrictions on "pick your own" operations to be determined after the 60-day comment period. **Blueberries, lowbush:** PHI= 10 days Limit to 2 applications of 0.75 lbs ai/A per year Minimum of 10 days between applications "This product may only be applied in Maine." Restrictions on "pick your own" operations to be determined after the 60-day comment period.	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	**Blueberries, highbush and rabbiteye:** PHI= 7 days Limit to 2 applications of 0.75 lbs ai/A per year Minimum of 10 days between applications "This product may only be applied in the following States: Alabama, Arkansas, Florida, Georgia, Indiana, Michigan, New Jersey, New York, and North Carolina." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." Restrictions on "pick your own" operations to be determined after the 60-day comment period. **Brussels sprouts:** PHI= 7 days Limit to 1 applications of 0.75 lbs ai/A per year "Apply to soil at transplant." All other applications must be removed from the label. "For control of cabbage root maggot only." Any other pests must be removed from the label. **Caneberries (blackberries, boysenberries, longanberries, raspberries)** PHI= 7 days Limit to 2 applications of 0.5 lbs ai/A per year Minimum of 10 days between applications "Apply to lower portion of canes and soil." All other applications must be removed from the label. "For control of raspberry crown borer only." Any other pests must be removed from the label.	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restriction	**Cherries, sweet** PHI = 19 days Limit to 2 applications of 0.75 lbs ai/A per year Minimum of 14 days between applications "Use during dormant season is prohibited." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Do not graze livestock in treated orchards." Any other conflicting grazing restrictions must be removed from the label. Restrictions on "pick your own" operations to be determined after the 60-day comment period. **Cherries, tart** PHI = 19 days Limit to 2 applications of 0.75 lbs ai/A per year Minimum of 14 days between applications "Use during dormant season is prohibited." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Do not graze livestock in treated orchards." Any other conflicting grazing restrictions must be removed from the label. Restrictions on "pick your own" operations to be determined after the 60-day comment period. **Cotton:** PHI= 7 days Limit to 3 applications of 0.5 lbs ai/A per year Minimum of 5 days between applications "This product may only be applied in Texas and Missouri."	Directions for Use Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	**Cranberries:** PHI= 21 days Limit to 2 applications of 1.0 lbs ai/A per year Minimum of 14 days between applications **Nut crops (almonds, pistachios, and walnuts)** PHI = 30 days Limit to 1 application of 2.0 lbs ai/A per year For Pistachios: Restrict use to California & Arizona "Use during dormant season is prohibited." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Do not graze livestock in treated orchards." Any other conflicting grazing restrictions must be removed from the label. **Peaches** PHI= 21 days Limit to 2 applications of 1.125 lbs ai/A per year Minimum of 14 days between applications "Use during dormant season is prohibited." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Do not graze livestock in treated orchards." Any other conflicting grazing restrictions must be removed from the label. Restrictions on "pick your own" operations to be determined after the 60-day comment period.	Directions for Use Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	**Pears:** PHI = 21 days Limit to 2 applications of 2.5 lbs ai/A per year Maintain maximum application rate at 1.0 lbs ai/A or 1.5 lbs ai/A in conjunction with an IPM program Minimum of 7 days between applications "Use during dormant season is prohibited." "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Do not graze livestock in treated orchards." Any other conflicting grazing restrictions must be removed from the label. Restrictions on "pick your own" operations to be determined after the 60-day comment period. **Nursery stock:** Limit to 4 applications at 1.0 lbs ai/A Minimum of 10 days between applications "For quarantine use only." "For control of apple ermine moth and black vine weevil only." "For use only on woody shrubs, vines, seedling trees, and non-bearing fruit trees in outdoor commercial nursery settings." "Use in greenhouses is prohibited." "Do not use on Christmas trees." "Use of handheld application equipment is prohibited.**"** "Aerial application is prohibited." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows." "Sale of treated plants is prohibited for 30 days after application." **Southern pine seed orchards:** Limit to 2 applications of 1.0 lbs ai/A per year "Do not apply until hand pollination has been completed." Minimum of 30 days between applications	Directions for Use Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	**Aerial application restrictions:** All formulations: "Aerial application is prohibited for all crops with the exception of cranberries, cotton, lowbush blueberries, and southern pine seed orchards." **Other restrictions:** "Do not apply to the point of runoff. " "Do not apply when bees are in the area." Restrictions on "pick your own" operations to be determined after the 60-day comment period. "This product may not be reformulated or used under State Special Local Needs Registrations for use on sugarcane, ornamentals, Christmas trees, shade trees, or forest trees, except as specified on this label."	Directions for Use Under Application Restrictions
Drift Language	*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.* "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, do not apply within 25 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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 other airblast applications, do not apply within 25 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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."	Directions for Use in General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Drift Language	"For aerial applications, do not apply within 50 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. 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 , do not apply within 25 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds. Apply only when wind speed is 10 mph or less." "The applicator also must use all other measures necessary to control drift."	Directions for Use in General Precautions and Restrictions

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 well as public comments on these preliminary assessment and EPA's formal "Response to Comments" document. The docket now contains revised risk assessments and related documents, benefits assessments, and public comments submitted during phase 6.

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."