United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-01-004
October 2001

EPA Reregistration Eligibility Decision (RED)

Pirimiphos-methyl

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-01-004 October 2001

EPA *Pirimiphos-methyl* Facts

EPA has assessed the risks of pirimiphos-methyl and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. Provided that risk mitigation measures are adopted, pirimiphos-methyl fits into its own "risk cup"-- its individual, aggregate risks are within acceptable levels. Pirimiphos-methyl also is eligible for reregistration, pending a full reassessment of the cumulative risk from all OPs.

Used primarily on stored corn and sorghum grain and seed, in cattle ear tags and for the fogging treatment of iris bulbs, pirimiphos-methyl residues in food alone do not pose risk concerns. With mitigation reducing worker exposure to pirimiphos-methyl by requiring closed system mixing and loading systems for admixture grain and seed treatment, and requiring additional personal protective equipment for workers, risk will not be of concern. Pirimiphos-methyl ecological risks are also below the Agency's level of concern.

EPA's next step under the Food Quality Protection Act (FQPA) is to complete a cumulative risk assessment and risk management decision encompassing all the OP pesticides, which share a common mechanism of toxicity. The interim decision on pirimiphos-methyl cannot be considered final until this cumulative assessment is complete. Further risk mitigation may be warranted at that time.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs need decisions about their eligibility for reregistration under FIFRA. OPs with residues in food, drinking water, and other non-occupational exposures also must be reassessed to make sure they meet the new FQPA safety standard.

The OP Pilot Public Participation Process

The organophosphates are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review under the Food Quality Protection Act.

EPA is encouraging the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency is releasing for review and comment its preliminary and revised scientific risk assessments for individual OPs. (Please contact the OP Docket, telephone 703-305-5805, or see EPA's web site, www.epa.gov/pesticides/op .)

EPA is exchanging information with stakeholders and the public about the OPs, their uses, and risks through Technical Briefings, stakeholder meetings, and other fora. USDA is coordinating input from growers and other OP pesticide users.

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides, and will make final decisions through a cumulative OP assessment.

The pirimiphos-methyl interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions presented in this interim decision document, which concludes the OP pilot process for pirimiphos-methyl.

Uses

- Pirimiphos-methyl is a post-harvest insecticide used on stored corn and sorghum grain and seed, incorporated into cattle ear tags, and used for the fogging treatment of iris bulbs. It is used to control various insects such as mealy bugs and mites (on iris bulbs), horn and face flies (on cattle), and cigarette beetle, confused flour beetle; corn sap beetle; flat grain beetle; hairy fungus beetle; red flour beetle; sawtoothed beetle, granary weevil, maize weevil, merchant grain beetle, rice weevil, lesser grain borer, and angoumois grain moth, Indian Meal moth and almond moth (on corn and sorghum grain and seed).

- Annual domestic use is low-- approximately 12,000 pounds of active ingredient per year. Total usage is allocated mainly to stored corn grain (39%) ear tags for cattle/calves (36%), stored sorghum grain (15%), corn seed (5%), and sorghum seed (5%). Regions with significant usage on cattle include the Gulf Coast, Midwest, and West, and states with significant usage on corn grain include Iowa and Texas.

- There are no residential uses for pirimiphos-methyl.

Health Effects

- Pirimiphos-methyl can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.

Risks

- Acute and chronic dietary risks from food alone do not exceed the Agency's level of concern. Drinking water exposure is not of concern because there are no outdoor uses which would result in water contamination. Therefore a drinking water assessment was not completed for this organophosphate.

- Worker risks are of concern for the mixer/loader/applicator when using pirimiphos-methyl as a top dress or admixture treatment for stored corn and sorghum grain and seed; a fogging treatment on iris bulbs, and when applying cattle ear tags.

- Ecological risks are not of concern to the Agency. Although pirimphos-methyl is highly toxic to birds and fish, these risks are not of concern based on the use pattern of pirimiphos-methyl.

Risk Mitigation

In order to support a reregistration eligibility decision for pirimiphos-methyl, the following risk mitigation measures listed below are necessary:

- To mitigate risks to agricultural workers (mixers/loaders) during admixture treatment to corn and sorghum grain and seed:
  - Require the use of engineering controls such as closed mixing and loading systems.
- To mitigate risks to workers (mixers/loaders/applicators) during top dress treatment to corn and sorghum grain and seed:
  - Require all mixers/loaders/applicators to wear coveralls over long sleeve shirt and pants, chemical resistant footwear, socks, and chemical resistant gloves. In addition, mixers and loaders must wear a chemical resistant apron.
- To mitigate worker risks from cattle ear tag use:
  - Handlers must wear chemical resistant gloves in addition to long sleeve shirt, long pants, shoes, and socks.
- To mitigate risks to agricultural workers for the fogging treatment of iris bulbs:
  - Require all mixers and loaders to wear coveralls and chemical resistant gloves.
  - Require applicators to use a stationary or cart-mounted fogging device, which when activated functions automatically without an operator present.
  - Require applicators to have available to them for use in case they must enter the area during treatment before ventilation requirements have been met, coveralls, chemical resistant gloves, chemical resistant headgear and a self-contained breathing apparatus (SCBA) (MSHA/NIOSHA approval number prefix TC-13F).
  - Require that entry by any person into the treatment area, other than a properly trained and equipped handler using the PPE specified, be prohibited until the area has been adequately ventilated.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The pirimphos-methyl IRED therefore is issued in final (see www.epa.gov/REDs/

or www.epa.gov/pesticides/op), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.

- The pirimiphos-methyl IRED contains a generic and product-specific Data Call-In (DCI) that outline(s) further data requirements for this chemical. A complete DCI, with all pertinent instructions, is being sent to registrants under separate cover.

- The pirimiphos-methyl IRED also describes labeling amendments for end-use products and data requirements necessary to implement the mitigation measures outlined in the document. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that is being sent under separate cover.

- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for pirimiphos-methyl and may request further risk mitigation measures. The Agency will revoke 14 tolerances and amend 5 tolerances for pirimiphos-mehtyl IRED, now. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

NOV 13 2001

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 pirimiphos-methyl. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on March 30, 2000. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on March 30, 2000, and closed on May 31, 2000.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of pirimiphos-methyl. The EPA is now publishing its interim reregistration eligibility and risk management decision for the current uses of pirimiphos-methyl and its associated human health and environmental risks. The tolerance reassessment decision for pirimiphos-methyl will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete. The Agency's decision on the individual chemical Pirimiphos-methyl can be found in the attached document entitled, "Interim Reregistration Eligibility Decision for pirimiphos-methyl."

A Notice of Availability for this Interim Reregistration Eligibility Decision for Pirimiphos-methyl is being published in the Federal Register. To obtain a copy of the interim RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), USEPA, 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/pirimiphos_methyl.HTM

The interim RED is based on the updated technical information found in the pirimiphos-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

for Pirimiphos-methyl (revised as of July 13, 1999), 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, and responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For pirimiphos-methyl, comments were received from Wilfarm, LLC, (former registrant). All comments were reviewed and given consideration before completing this document.

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

Please note that the pirimiphos-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 pirimiphos-methyl. The Agency will issue the final tolerance reassessment decision for pirimiphos-methyl once the cumulative assessment for all of the organophophates is complete.

In this interim RED, the Agency has determined that pirimiphos-methyl will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of pirimiphos-methyl may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this interim RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this interim RED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by pirimiphos-methyl. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Lorilyn Montford, at (703) 308-8170. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Venus Eagle at (703) 308-8045.

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Interim Reregistration Eligibility Decision
for
Pirimiphos-methyl

Case No. (2535)

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PIRIMIPHOS-METHYL TEAM

Office of Pesticide Programs:

Health Effects Risk Assessment

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JEFF DAWSON	Reregistration Branch I
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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 decisions for pirimiphos-methyl. The decisions outlined in this document do not include the final tolerance reassessment decision for pirimiphos-methyl; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. EPA has proposed to revoke tolerances in or on meat, eggs, kiwi, milk, corn oil, sorghum, and wheat for residues of pirimiphos-methyl for several reasons. First, for meat, eggs, and milk the Agency has determined that there are no reasonable expectations of detectable residues and tolerances are not necessary. Second, for kiwi, metabolism and magnitude of the residue data do not support this tolerance without a U.S. registration. Third, the Agency has concluded that a separate tolerance for pirimiphos-methyl residues in corn oil is not required based on more recent studies for corn oil that show residues concentrated in refined corn oil were used to derive the concentration factor and concomitant tolerance required for residues in corn oil; these studies did not include bleaching/deodorizing steps. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for pirimiphos-methyl once the cumulative assessment is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on pirimiphos-methyl. After considering the revised risks, as well as mitigation proposed by Agriliance, LLC, the technical registrant of pirimiphos-methyl, and comments and mitigation suggestions from other interested parties including Schering-Plough, registrant for the animal end-use products, the National Grain Sorghum Producers, several grower organizations, and agricultural extension agents, EPA developed its risk management decision for uses of pirimiphos-methyl that pose risks of concern. This decision is discussed fully in this document.

First registered in 1978, pirimiphos-methyl is an organophosphate insecticide used on stored corn, sorghum grain and seed, and livestock. It is used to control various storage insects, such as, beetles, weevils, and moths. Pirimiphos-methyl is used in cattle ear tags for horn flies and face flies, and also on iris bulbs in Washington State for mealy bugs. Annual domestic usage of pirimiphos-methyl is estimated at 12,000 pounds active ingredient.

Overall Risk Summary

Dietary risk from food treated with pirimiphos-methyl is not of concern. Drinking water exposure is not of concern because there are no outdoor uses which would result in water contamination. Therefore a drinking water assessment was not completed for this organophosphate. There are no residential uses of pirimiphos-methyl. Given that no exposure is expected from drinking water or in residential settings, the aggregate risk for pirimiphos-methyl is equivalent to the risk associated with dietary exposure from food.

Worker risks are of concern for handling pirimiphos-methyl. Mixer/loader/applicator risks are of concern when applying pirimiphos-methyl for admixture grain treatments, and as a top dress to stored grain using low pressure hand wands, high pressure hand wands, and backpack sprayers. There are also worker risk concerns when using equipment to load liquids for the fogging treatment of iris bulbs. EPA believes these risks can be mitigated to an acceptable level with the following: For iris bulb fogging treatment: change the label language to require coveralls, chemical resistant gloves, a self contained breathing apparatus (SCBA), and require ventilation prior to reentry; for cattle ear tag use: change the label language to specify chemical resistant gloves for use during application; for admixture grain treatment: require closed mixing and loading systems.

Ecological Risk

Ecological risks are assumed to be below the Agency's level of concern because of the low exposure potential from this use pattern. Pirimiphos-methyl insecticide is limited to seed, grain, and bulb treatment uses only, and incorporation into animal eartags. It is primarily used in closed systems when applied to seed and grain. The seed and bulb treatments are intended to preserve seed and bulbs during storage with no claimed benefits of pest control after planting. Therefore, the only environmental exposure from use of pirimiphos-methyl according to label directions may be exposure to terrestrial wildlife from possible ingestion of treated seeds.
Pirimiphos-methyl is highly toxic to birds, aquatic species and invertebrates. However, registered uses are not expected to result in significant exposure to avian or aquatic species.

The Agency is issuing this interim Reregistration Eligibility Document (RED) for pirimiphos-methyl, as announced in a Notice of Availability published in the *Federal Register*. This interim RED document includes guidance and time frames for complying with any necessary label changes for products containing pirimiphos-methyl. Note that there is no comment period for this document and the time frames for compliance with the label changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for pirimiphos-methyl have already been subject to numerous public comment periods, and a further comment period for pirimiphos-methyl was deemed unnecessary. Neither the tolerance reassessment nor the reregistration eligibility decision for pirimphos-methyl can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further risk mitigation measures for pirimiphos-methyl.

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 during reregistration. 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. Pirimiphos-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 reregistration eligibility decision for pirimiphos-methyl. It is intended to be only the first phase in the reregistration process for pirimphos-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 pirimiphos-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 reregistration eligibility and risk management decisions. Section V summarizes 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 list 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/pirimiphos_methyl.HTM , and in the Public Docket.

II. Chemical Overview

A. Regulatory History

Pirimiphos-methyl was first registered in the United States in 1978 for use on corn and grain sorghum to control various storage pests. In 1979 a label for corn and grain sorghum was

issued to ICI Americas. In 1979, the Agency included the two metabolites of pirimiphos-methyl in the tolerance expression due to limited plant and animal metabolism data and magnitude of residue feeding information. When the uses on stored corn and sorghum grains were registered, residue tolerances were established for the combined residues of the parent, the deethylated metabolite, and the free and conjugated hydroxypyrimidine metabolites at 8 ppm in /on corn grain and grain sorghum. Food/feed additive tolerances for the combined residues were also established at 40 ppm in corn and sorghum milled fractions, except flour, and in corn oil at 88 ppm. Later, an import tolerance for wheat flour was established at 8 ppm. In 1988, a label for export was issued to ICI Americas. In addition, in 1988, the Agency approved the label for animal ear tags for Cooper Animal Health Inc. In 1992, a label was approved for corn seed treatment. In 1995, Cooper Animal Health transferred their registration to Mallinckrodt Veterinary Inc. In 1996, Wilbur-Ellis petitioned to repeal the hydroxypyrimidine metabolites from the tolerance expression. In October 1997, Wilbur-Ellis submitted a request for the re-evaluation of the Reference Dose (RfD) and Uncertainty Factors (UF). In 1999, Wilbur-Ellis merged with another company to become Wilfarm LLC. In 2000, Wilfarm LLC merged with another company to become Agriliance LLC, the new technical registrant of pirimiphos-methyl.

B. Chemical Identification

Pirimiphos-methyl:

- **Common Name:** Pirimiphos-methyl
- **Chemical Name:** 0-(2-Diethylamino)-6-methyl-4-pyrimidinyl) 0,0-dimethyl phosphorothioate
- **Chemical family:** Organophosphate
- **Case number:** 2535
- **CAS registry number:** 29232-93-7
- **OPP chemical code:** 108102
- **Empirical formula:** $C_{11}H_{20}N_3O_3PS$
- **Molecular weight:** 305.34
- **Trade and other names:** Actellic 5E, Nu-Gro Insecticide, Nu-Gro 5E, Tomahawk Insecticide Ear Tags, LPM Insecticide Ear Tags
- **Basic manufacturer:** Grain and Seed Products (Agriliance LLC)
  Animal Ear-Tag Products (Schering-Plough Animal Health Corporation)

Technical pirimiphos-methyl is a straw-colored liquid with a boiling point of >139°C. Pirimiphos-methyl is soluble in water at 5ppm at 30°C and is miscible with or very soluble in most organic solvents.

C. Use Profile

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

Type of Pesticide: Insecticide

Summary of Use Sites:

Food: sorghum, corn (grain and seed); non-lactating dairy cattle, beef/range/feeder cattle, and calves;

Residential: No residential uses.

Public Health: No public health uses.

Other Non-food: Iris bulbs - used for fogging treatment in Washington State (24 c registration).

Target Pests: The types of pests that pirimiphos-methyl is used to control include, but are not limited to the following :
cigarette beetle; confused flour beetle; corn sap beetle; flat grain beetle; hairy fungus beetle; red flour beetle; sawtoothed beetle; granary weevil; maize weevil; merchant grain beetle; rice weevil; lesser grain borer; and angoumois grain moth; Indian meal moth and almond moth on corn (seed and whole-grain), rice (whole-grain), wheat (whole-grain), and grain sorghum (seed and whole-grain); mealy bugs; mites (iris bulbs) horn flies and face flies.

Formulation Types Registered:

Emulsifiable liquid concentrates at 57% a.i.
Treated Articles (Ear Tags) at 14% and 20% a.i.

Method and Rates of Application:

Equipment -closed systems for 15 and 30 gallon containers used in admixture grain and seed treatments

-low pressure handwand, high pressure handwands, and backpack sprayers for top dress
-hand held tagging equipment for ear tag treatment
-fogging equipment for iris bulb fogging

Method and Rate- 9.2 - 12.3 fluid ounces product per 30 tons of grain (60,000 lbs.) to seed/grain (field corn, popcorn, grain sorghum); for top dress: 3 fluid ounces per 1,000 sq. ft. of grain; for eartag use: 2 tags per animal (one in each ear) replace as necessary; for iris bulbs: 60 ml per 10 cu. m.

Timing -For top dress and proposed bin disinfestation on seed and grain - apply as often as necessary, but no more than one treatment per batch of grain.
-For cattle ear tag application - apply as often as necessary (possibly once in the Spring and once in the Fall). Efficacy lasts 5 months.

Use Classification: General classification

D. Estimated Usage of Pesticide

Estimated 12,000 pounds used annually. In terms of pounds of active ingredient of pirimiphos-methyl, usage is allocated mainly to stored corn (39%), ear tags for cattle/calves (36%), stored sorghum grain (15%), corn seed (5%), and sorghum seed (5%). On average, about half of sorghum seed, 6% of corn seed, less than 2% of cattle and less than 1% each of stored corn grain and stored sorghum grain are treated annually. Regions with significant usage on cattle include the Gulf Coast, Midwest and West; and states with significant usage on stored corn grain include Iowa and Texas. Pirimphos-methyl use on iris bulbs is limited to the state of Washington. Estimated annual usage on iris bulbs is approximately 1 gallon.

Table 1. Pirimiphos-methyl Estimated Usage for Representative Sites

Crop	Lbs. Active (000) Ingredient Applied (Wt. Avg.)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Stored Corn Grain	4	0.3%	0.1%
Ear Tags for Cattle/Calves	4.1	2.5%	1.3%
Stored Sorghum Grain	2	1.5%	0.7%
Corn Seed	0.6	9%	6%
Sorghum Seed	0.5	76%	52%

[1] Weighted Average is based on data for 1989-1997; the most recent years and more reliable data are weighted more heavily.
[2] Iris bulb use is less than 5 gallons total usage for years 1991-1998.

III. Summary of Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide pirimiphos-methyl, as fully presented in the documents, "Pirimiphos-methyl. Revised HED Chapter for the Reregistration Eligibility Decision Document,"dated July 13, 1999, and "Revised EFED Chapter for Pirimiphos-methyl", dated April 22, 1999. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to enhance understanding of the conclusions reached in the assessments.

The risk assessments presented here form the basis of the Agency's risk management decision for pirimiphos-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 risk assessments for pirimiphos-methyl in 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are listed below:

- The preliminary risk assessments for pirimiphos-methyl were based on endpoints selected from two human toxicity studies. The Agency is currently developing a policy on utilizing studies employing human subjects for testing pesticides. In the interim, the Agency selected animal toxicity studies to be used in the refined human health risk assessment.

- The Tier 1 dietary risk analyses were conducted two ways, one assuming tolerance level residues for all commodities (and ½ the limit of detection for high fructose corn syrup (HFCS)), and one assuming HFCS residues equal to zero.

- The refined Tier 3 acute dietary analysis, as well as the chronic, was conducted four ways, and is a highly refined assessment. All four of these analyses used anticipated residues for most commodities, but additional usage and monitoring data were used to assess the dietary risk contribution of popcorn.

Table 2. Tier 3 Acute and Chronic Assessments

Summary of Differences: Revised Tier 3 Acute and Chronic Assessments				
	Assessment 1	Assessment 2	Assessment 3	Assessment 4
% Crop Treated for Popcorn	<1% (BEAD estimate for corn)	34% based on % of detects in FDA monitoring data	100% (Default value-most conservative)	100% (Default value-most conservative)
Residue Level for popcorn	Average residue trial (RT) values for field corn	Average residue trial for field corn	Average of FDA monitoring detects	Average residue trial for field corn

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is not complete, but is adequate to support an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of pirimiphos-methyl can be found in the July 13, 1999, Human Health Risk Assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 3 in this document.

b. FQPA Safety Factor

The FQPA Safety Factor of 3X has been retained in accordance with the Food Quality Protection Act (FQPA) of 1996 due to the lack of a complete toxicity database for assessing the potential for increased sensitivity of infants and children to pirimiphos-methyl. Those studies necessary to complete the toxicity database include: a chronic toxicity study in dogs (870.4100); and a combined chronic toxicity/carcinogenicity study in rats (870.4300). As well, there is no indication of additional sensitivity to young rats or rabbits following pre and/or postnatal exposure to pirimiphos-methyl in the developmental and reproductive toxicity studies.

Table 3. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Pirimiphos-methyl:

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor[3]	PAD
Acute Dietary	15.0 (LOAEL)	Brain, RBC and Plasma ChEI	Acute Neurotoxicity, Rat MRID# 43594101	100X $10X_1$	3X	0.005
Chronic Dietary	0.2 (LOAEL)	Plasma ChEI	Subchronic Toxicity, Rat MRID# 43608201	100X $10X_2$	3X	0.000067

1 An additional 10X uncertainty factor was applied because of the use of a LOAEL as well as degree of plasma, RBC, and brain ChE inhibition. Also, at the highest dose tested, brain ChEI was observed for two weeks following the single dose, and alterations in motor activity and the functional observational battery (FOB) were found in the highest dose group as well.
2 An additional 10X uncertainty factor was applied to the chronic assessment to account for the use of a LOAEL and data gaps for long term studies.
3 3X is used for FQPA based on lack of a complete toxicity database.

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 Pirimiphos-methyl, the FQPA safety factor is 3X; therefore, the acute or chronic RfD divided by 3 equals 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.

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses 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.

A refined Tier 3 analysis was conducted using four scenarios to account for inconsistencies in usage and residue data regarding popcorn: BEAD estimated 1% of corn is treated, but the FDA monitoring data showed 34% of popcorn samples had detectable residues. Therefore, popcorn was evaluated at 1% CT, 34% CT and 100% CT. Anticipated residue values were calculated for all commodities using PDP and FDA monitoring data, anticipated residues from residue trials conducted on grain; and anticipated residues in livestock commodities. The anticipated residue values were held constant among the four probabilistic assessments for all commodities with the exception of popcorn.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concerns. The pirimiphos-methyl acute dietary risk from food is below the Agency's level of concern. That is, less than 100% of the acute PAD is utilized. For example, for the most exposed subgroups, children (1-6 years) and children (7-12 years) (<1 year), the % acute PAD values are 83 and 64 respectively at the 99.9th percentile of exposure. These values represent the most realistic approach of the 4 popcorn assessments conducted in the Tier 3 analysis using the average of the residue trial data for field corn and the 34% FDA detection rate for the %CT. For the U.S. population, the % acute PAD value is 54.

The chronic dietary risk from food alone is well below the Agency's level of concern. For the most exposed subgroups, children 1-6 years and children 7-12 years, the % chronic PAD values are 51 and 48, respectively. For the U.S. population, the % chronic PAD value is 32.

f. Drinking Water Risk

Drinking water exposure is not of concern because there are no outdoor uses which would result in water contamination. Therefore, a drinking water assessment was not completed for this organophosphate.

2. 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 pirimiphos-methyl include: individual farmers or growers who mix, load, and/or apply pesticides, commercial grain and seed operators, and 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 exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern. For short-term dermal and inhalation exposure to pirimiphos-methyl, an MOE of 1000 is used for occupational exposure risk assessments. This includes the conventional 100 and an additional 10X for the use of a LOAEL, as well as severity of effects (marked plasma, RBC and brain cholinesterase inhibition observed at the lowest dose tested). For intermediate dermal and inhalation exposure, an MOE of 300 is used for occupational exposure risk assessments. This includes the conventional 100 and 3x for the use of a LOAEL. (It's important to note that because long-term occupational exposures are not expected, no additional uncertainty factor was deemed necessary to account for the missing long-term studies.)

a. Toxicity

The toxicity of pirimiphos-methyl is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for pirimiphos-methyl. The toxicological endpoints and other factors used in the occupational risk assessments for pirimiphos-methyl are listed below.

Table 4. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Exposure/Risk Assessment for Pirimiphos-methyl

Assessment	Dose	Endpoint	Study	Absorption factor
Short-term dermal[1]	LOAEL =15 mg/kg/day	Marked Plasma, RBC and brain cholinesterase inhibition at the lowest dose level.	Acute Neurotoxicity in Rats MRID # 43594101	100%
Intermediate-term[2] dermal	LOAEL =0.2 mg/kg/day	Plasma cholinesterase inhibition in both sexes at the lowest dose tested.	Subchronic Toxicity in Rats MRID # 43608201	100%
Short-term inhalation[1]	LOAEL= 15 mg/kg/day	Marked plasma, RBC and brain cholinesterase inhibition at the lowest dose tested	Acute Neurotoxicity- Rat MRID # 43594101	100%
Intermediate - term[2] inhalation	LOAEL= 0.2mg/kg/day	Plasma cholinesterase inhibition in both sexes at the lowest dose tested	Subchronic Rat MRID # 43608201	100%

[1] Target MOE for short-term dermal and inhalation is 1000.
[2] Target MOE for Intermediate-term dermal and inhalation is 300.

The following is the acute toxicity profile for pirimiphos-methyl:

Table 5. Acute Toxicity Profile for Technical Pirimiphos-methyl.

Route of Exposure	MRID	Toxicity Category	Results
Dermal	00126257	III	LD_{50}=>3.5g/Kg for females and between 2.2-3.5 g/kg for males
Oral	00126257	III	LD_{50}=2.4g/kg
Inhalation	41556304	IV	LC_{50}=>4.7mg/L
Eye Irritation	00126257	II	Irritant
Dermal Irritation	00126257	III	Moderate Irritant
Dermal Sensitizer	00126257	N/A	Non-sensitizer

b. Exposure

Chemical-specific exposure data were not available for pirimiphos-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 pirimiphos-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 Human Health Assessment document for pirimiphos-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 pirimiphos-methyl labels range from 9.2 - 12.3 fluid ounces of active ingredient per 5 gallons of water in agricultural settings to treat each 30 tons of grain or seed. For cattle eartags, application rates are two tags per head on beef and non-lactating dairy cattle and calves. Each tag contains 9.5 grams of the active ingredient. For use on iris bulbs, application rates are 1 gallon of product at 5 lbs. a.i. per 100 gallons of water.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than the target MOE), increasing levels of risk mitigation (personal protective equipment (PPE) and engineering controls (EC)). The current labels for pirimiphos-methyl require handlers to wear

goggles, a face shield and chemical-resistant gloves. The levels of protection that formed the basis for calculations of exposure from Pirimiphos-methyl activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical resistant gloves.
- Maximum PPE: Baseline + coveralls, chemical resistant gloves.
- Maximum PPE: Baseline + chemical resistant coveralls, chemical resistant gloves and self contained breathing apparatus (SCBA).
- Engineering controls: Engineering controls such as a closed cab tractor or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods; there are no known devices that can be used to routinely lower the exposures for these methods.

Total risks for occupational handlers were assessed using the short-term and intermediate-term toxicological endpoints. A chronic risk assessment was not completed as the Agency believes that pirimiphos-methyl use patterns do not lend themselves to chronic exposure scenarios.

There are currently no pirimiphos-methyl products that are marketed for application in residential settings. As such, no exposure/risk analysis was completed for these use scenarios.

Finally, exposure to workers through entry into agricultural structures (such as grain elevators or silos) treated with pirimiphos-methyl, and post-application exposure were also considered. The Agency believes that most postapplication exposures attributable to the use of pirimiphos-methyl should be nominal based on the cultural practices associated with its use.

c. Occupational Risk Summary

Risks for handlers were assessed using separate toxicological endpoints for both dermal and inhalation exposures. The resulting risks (MOE values) were then added in order to obtain an overall risk for each handler that accounted for both dermal and inhalation exposures because the effects are the same. Dermal and inhalation risks are mitigated using different types of protective equipment, so it may be acceptable to add a pair of gloves, a double layer of clothing, and respirator. All of the risk calculations for handlers completed in this assessment are included in the HED chapter, dated June 1, 1999.

The Agency has determined that exposure to pesticide handlers is likely during the occupational use of pirimiphos-methyl in a variety of environments including agricultural and in commercial/industrial premises (e.g., grain storage facilities and loading/shipping facilities). The anticipated use patterns and current labeling indicate 7 major occupational exposure scenarios based on the types of equipment and techniques that can potentially be used to make applications.

3. Agricultural Handler Risk

For pirimiphos-methyl, the Agency has determined that there are potential exposures to workers as a result of mixing, loading, and applying pirimiphos-methyl. The Agency has determined that agricultural handler risk will only occur in a short-term or intermediate-term pattern. Intermediate term risks are included, although the Agency believes the likelihood of an intermediate term exposure scenario is somewhat unlikely for treatments made with hand-held and fogging equipment (top dress and iris bulbs) given the use pattern of pirimiphos-methyl.

For agricultural uses of pirimiphos-methyl, 7 different exposure scenarios were assessed at different levels of personal protection. (Note: Although the registrant proposed a new use for disinfestation of grain storage bins, this use was considered, but is no longer pending at this time.) Within each of the scenarios, further analyses were conducted to determine the MOE at minimum and maximum application rates, and at maximum and typical application parameters, where applicable. Each of these analyses is included in the ORE aspects of the HED chapter for pirimiphos-methyl. The reader is referred to these tables for more information on this comprehensive assessment. The seven exposure scenarios reviewed are:

(1a) closed system mixing/loading liquids for admixture grain treatment;
(1b) closed system mixing/loading liquids for seed treatment;
(1c) open mixing/loading of liquids for fogging treatment of iris bulbs;
(2) fogging treatment of iris bulbs;
(3) applying cattle ear tags;
(4a) applying the ready-to-use formulation to livestock using a self-totalizing pour-on package; (Note: This use was proposed, but is no longer pending.)
(4b) applying the ready-to-use formulation to livestock using a trigger sprayer package;(also proposed but no longer pending.)
(5) mixing/loading/applying with a low pressure handwand sprayer (top-dress and the proposed bin disinfestation scenarios are assessed);
(6) mixing/loading/applying with a backpack sprayer (top dress and proposed bin disinfestation scenarios are assessed); and
(7) mixing/loading/applying with a high pressure handwand sprayer (top dress and proposed bin disinfestation scenarios are assessed).

Table 6, on the following page, summarizes the risk concerns after all assessments were revised (for those scenarios that were considered feasible) using the most current data and assumptions for agricultural handlers, based on combined dermal and inhalation exposures. The shaded areas represent the scenarios where risk is not of concern, and where additional mitigation is not necessary (i.e., MOEs<1000 for short-term exposure, or <300 for intermediate-term exposure).

Table 6. Occupational Risk Estimates for Pirimiphos-methyl

Exposure Scenarios	Baseline Clothing		Protective Clothing/PPE		Engineering Controls	
	Short-Term Risk (MOE)[1]	Intermediate Term[3] Risk (MOE)[2]	Short-Term Risk (MOE)[1]	Intermediate Term[3] Risk (MOE)[2]	Short-Term Risk (MOE)[1]	Intermediate-Term Risk (MOE)[2]
Mixer/Loaders						
(1a) Mixing/loading Liquids For Admixture Grain Treatments	Not evaluated. (See note below.)*[4]				17,000 (min rate) 14,000 (max rate)	240 (min rate) 180 (max rate)
(1b) Mixing/loading Liquids For Seed Treatment					68,000	910
(1c) Loading Liquids For Fogging Treatment of Iris Bulbs	13	<1	2100	27	N/F	N/F
Applicators						
(2) Fogging Treatment of Iris Bulbs	No empirical data are available for this scenario, instead, the maximum application rate served as the basis for this assessment. The assessment was considered using the maximum PPE (tyvek coveralls, rubber gloves and SCBA equipment.)					
(3) Cattle Ear Tags	No Data	No Data	No Data	No Data	N/F	N/F
Mixer/Loader/Applicator						
(5) M/L/A Liquids Using Low Pressure Handwand (top dress)	15	<1	4,200	55	Not evaluated; no engineering controls are feasible for these occupational scenarios	
(6) M/L/A Liquids Using Backpack Spray (top dress)	600	8	940	13		
(7) M/L/A Liquids Using High Pressure Handwand (top dress)	580	8	940	13		

1 Target MOE for short-term exposure = 1,000

2 Target MOE for intermediate term exposure = 300

3 Intermediate Term Risk not expected for pirimiphos-methyl due to use pattern. Although respirators were considered in calculated numbers, due to the use pattern of pirimiphos-methyl, inhalation risks are not of concern. (With the exception of iris bulb fogging).

4 The registrant had indicated that only closed systems would be supported, therefore only engineering controls for grain admixture treatments were evaluated in the risk assessment. Information provided by USDA, however, indicated that some users, particularly small farmers with on-farm grain storage capacity, would prefer to retain open-pour mixing and loading. EPA has therefore evaluated risks associated with open-pour mixing and loading for this scenario. Since EPA expects grain harvest, storage and treatment to frequently exceed seven days, the intermediate-term scenario is considered to be appropriate. Calculations indicate that without engineering controls (closed-systems), handler risks would be of concern even if maximum PPE consisting of coveralls over long-sleeved shirt and long pant, chemical-resistant gloves, and an organic-vapor-removing respirator, were employed (intermediate-term MOE=118 with a target MOE of 300).

Note: Shaded boxes are those where no additional mitigation is necessary.

4. Post-Application Occupational Risk

The Agency believes that most post-application exposures attributable to the use of pirmiphos-methyl should be negligible based on actual use patterns. The one exposure scenario that the Agency is concerned about however, is entry into previously fogged iris bulb holding areas. The Agency believes that the level of risk associated with this scenario is acceptable provided that ample time is allowed for residue dissipation, treated areas are properly aerated prior to entry, mechanical handling of treated iris bulbs or chemical-resistant rubber gloves are used, and the proper PPE is used for excursions into treated areas for intervals prior to the normal post-application bulb holding time of 3 to 4 weeks.

5. Residential (Homeowner) Handler Risk

Residential post-application risks were not assessed as pirimiphos-methyl products are not labeled for homeowner use or for occupational use in a residential environment.

6. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes). Given that no exposure is expected from drinking water or in residential settings, the aggregate risk for pirimiphos-methyl is equivalent to the risk associated with dietary exposure from food.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated April 22, 1999, available in the public docket.

1. Environmental Fate and Transport

Pirimiphos-methyl hydrolyzes rapidly at acidic pHs and is relatively stable at neutral and alkaline pH; calculated half-lives were 7.3 days at pH 5, 79.0 days at pH 7, and 54.0-62.0 days in pH 9. The main hydrolysis degradate recovered from all three pHs was 2 (diethylamino)-4-hydroxy-6-methyl pyrimidine which did not retain the organophosphate moiety. A second degradate, O-2-diethylamino-6-methylpyrimidin-4-yl o-methyl-phosphorothioate, was recovered at significant amounts in the pH 7 and 9 solutions did still contain the organophosphate moiety and therefore, may still have significant toxicological activity.

Since there are no significant outdoor uses, the impact to water resources is negligible; therefore, no drinking water assessment was completed for this chemical.

2. Risk to Birds and Mammals

No levels of concern (LOCs) are exceeded for birds or mammals due to lack of exposure. The risk quotients do not exceed the endangered species, restricted use, or the high acute risk level of concern. Therefore, pirimiphos-methyl does not present a high risk to birds. However, two (2) studies are required to assess potential reproduction risks to birds. Pirimiphos-methyl is much less acutely toxic to mammals than it is to birds. The LD50 value for mammals is 2,400 mg/kg. Therefore, it does not present an acute risk to mammals.

3. Risk to Aquatic Species

The registered uses for pirimiphos-methyl are not expected to result in significant exposure to aquatic organisms. Therefore, it does not pose a high risk to aquatic organisms.

IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing pirimiphos-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 pirimiphos-methyl, as well as a pirimiphos-methyl-specific dietary 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 pirimiphos-methyl, EPA has sufficient information on the human health and ecological effects of pirimiphos-methyl to make an interim determination of reregistration eligibility and to make some interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that pirimiphos-methyl is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risk assessment for the organophosphates support a final reregistration eligibility decision. Label changes are described in Section V. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of pirimiphos-methyl, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet completed its cumulative risk assessment for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk

reduction measures that are necessary to support the continued use of pirimiphos-methyl. Based on its current evaluation of pirimiphos-methyl alone, the Agency has determined that pirimiphos-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 identified in this document, the Agency may take regulatory action to address the risk concerns from use of pirimiphos-methyl.

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

Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing pirimiphos-methyl food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, pirimiphos-methyl tolerances will be reassessed in that light. At that time, the Agency will reassess pirimiphos-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 requesting mitigation measures now for the individual chemical pirimiphos-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. The Agency has come to the following regulatory decisions based on all data concerning exposure, use, and usage that have been received to date. If and when more conclusive data is received, the Agency will reevaluate the risk assessment and exposure scenarios at that time.

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. The registrant, Wilfarm LLC, submitted a set of comments on the toxicological issues on pirimiphos-methyl. On behalf of the

registrant, the comments were prepared by Compliance Services International. A brief summary of the comments and the Agency response is summarized below. These comments in their entirety are available in the docket.

Comment:
The registrant does not consider that a study in which bulk seed treated at the maximum 1X label rate and is subsequently planted where the residues of concern are measured in corn forage/stover and grain sorghum forage/stover is warranted. The registrant contends that pirimiphos-methyl is rapidly degraded in sunlight or under acidic conditions, and the calculated estimates of potential pirimiphos-methyl residues are greatly exaggerated.

Agency Response: The data are necessary to support the bagged/bulk seed use since the potential exists for pirimiphos-methyl to reach forage stover when treated seeds are planted. To determine potential risk from this use, these data are needed.

Comment:
The registrant does not agree with the Agency's decision to ignore human data that establishes no observed effect levels. The registrant supports the American Crop Protection Association (ACPA) position that extra uncertainty factors in the reference dose (RfD) as required by the Food Quality Protection Act (FQPA) are only needed when the data are lacking to firmly establish the safety and possible effects from exposure to a compound. In addition, the registrant refers to an *in vitro* dermal absorption study submitted to the Agency for consideration as further justification for not adding another 10X uncertainty factor in chronic and subchronic RfDs.

Agency Response: The initial human health risk assessment incorporated doses and endpoints for risk assessment which were derived from two oral human studies which were not statistically valid. The Agency is currently developing policy to assess sound science and ethics in the conduct of human studies. The revised risk assessment incorporates new endpoints derived from animal studies. In addition, the *in vitro* dermal absorption study was reviewed and deemed unacceptable for use in the risk assessment.

Comment:
The registrant maintains that avian reproduction studies are not necessary for the ecological risk assessment for pirimiphos-methyl. The registrant contends that pirimiphos-methyl is not used in aquatic systems or in areas where waterfowl would likely ingest pirimiphos-methyl treated seeds, that the pesticide is stable under dry conditions, does not persist in the environment, and is rapidly broken down on exposure to sunlight and moist acidic conditions.

Agency Response: The avian reproduction studies are required for pirimiphos-methyl for the following reasons: 1) Birds may be subject to repeated exposure to the pesticide, especially during and preceding the breeding season; 2) Pirimiphos-methyl is stable in the environment to the extent that potentially toxic amounts may persist in animal feed; 3) Several million acres of pirimiphos-

methyl treated seeds are planted each year. Organophosphate insecticides are known to show negative chonic effects on avian reproduction.

Comment:
The registrant contends that the Agency continues to be inconsistent in the risk assessments by using registered and proposed uses in conducting dietary and worker exposure estimates. The registrant disagrees with the additional uncertainty factors used in the risk assessments and maintains that pirimiphos-methyl is one of the least toxic organophosphate compounds. The registrant also disagrees with the 100% dermal absorption factor used in the risk assessment in relation to ear tag use and the proposed pour-on formula. In addition, the registrant contends that there is no justification for lowering or removing tolerances for fat, meat and meat by-products in light of proposed uses.

Agency Response: The Agency recommends for the revocation of all milk and certain meat tolerances based on the currently registered uses of pirimiphos-methyl. Should the registrant pursue the pour-on formula, dermal metabolism and magnitude of residue studies are required. Additional uncertainty factors are needed due to the lack of NOAELs (No Observed Adverse Effect Levels). Scientifically sound studies are still needed in order to change the 100% dermal absorption factor used in the risk assessments.

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

EPA has determined that risk from exposure to pirimiphos-methyl is within its own "risk cup." In other words, if pirimiphos-methyl did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for pirimiphos-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, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from

these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to pirimiphos-methyl "fit" within the individual risk cup.

b. Tolerance Summary

In the individual assessment, tolerances for residues of pirimiphos-methyl in/on plant commodities [40 CFR §180.241] are presently expressed in terms of parent only. Since the des-ethyl metabolite was not identified in stored grain in metabolism studies, and has not been found in residue trials, the anticipated residues and dietary exposure analysis for grain include residues of parent only.

Acceptable ruminant and poultry feeding studies were submitted and reviewed by the Agency. The results of these studies (and residue trials conducted on stored grains) indicated that residues in certain livestock commodities could be classified under category 3 of 40 CFR §180.6(a), i.e., there is no reasonable expectation of detectable residues. Therefore, the Agency recommends revocations of tolerances for residues in meat (of cattle, goats, hogs, horses, sheep and poultry), milk and eggs.

Corn processing studies submitted by the registrant were reviewed and deemed unacceptable. More recent acceptable processing studies in which residues concentrated in refined corn oil were used to derive the concentration factor and concomitant tolerance required for residues in corn oil; these studies did not include bleaching/deodorizing steps. However, upon examination of the older processing data, the Agency noted that residues in refined oil were reduced by an average of 0.06X following bleaching and deodorizing. The Agency's guidance stipulates that tolerances for residues in oil should be established in food grade oil, which has been refined, bleached, and deodorized. Therefore, the Agency now concludes a separate tolerance for pirimiphos-methyl residues in corn oil is not required.

The Agency recommends for revocation of the import tolerances on wheat flour and kiwi fruit. A tolerance for residues in wheat flour is not needed; additional data would be needed to support uses on both wheat and kiwi fruit.

Table 10. Tolerance Summary for Pirimiphos-methyl.

Commodity	Current Tolerance, ppm	Interim Tolerance Decision (a), ppm	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.409(a)(1):			
Corn	8.0	8.0	Corn, field, grain;corn, pop, grain
Cattle, fat	0.2	0.02	The tolerance can be reduced based on an adequate cattle feeding study.
Cattle, kidney and liver	2.0	Reassign	Separate tolerances for residues in liver and kidney can be removed since those uses are covered under the tolerance for residues in meat by products.
Cattle, mbyp	0.2	0.02	The tolerance can be reduced based on an adequate cattle feeding study. [cattle, meat by products]
Cattle, meat	0.2	Revoke	Residues may be classified under Category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues.
Eggs	0.5	Revoke	
Goats, fat	0.2	0.02	See comment under "cattle, fat, and [goat fat].
Goats, kidney and liver	2.0	Reassign	See comment under "cattle, kidney and liver".
Goats, mbyp	0.2	0.02	See comment under "cattle, mbyp."[goat, meat by products]
Goats, meat	0.2	Revoke	See comment under "cattle, meat".
Hogs, fat	0.2	0.02	See comment under "cattle, fat, and [hog fat].
Hogs, kidney and liver	2.0	Reassign	See comments under "cattle, kidney and liver."
Hogs, mbyp	0.2	0.02	See comments under "cattle mbyp".[hog meat by products]
Hogs, meat	0.2	Revoke	See comment under "cattle, meat."
Horses, fat	0.2	0.02	See comment under "cattle fat".
Horses, kidney and liver	2.0	Reassign	See comment under "cattle, kidney and liver."
Horses; mbyp	0.2	0.02	See comment under "cattle,mbyp."[horse, meat by products]
Horses, meat	0.2	Revoke	See comment under "cattle meat"
Kiwi fruit	5.0	Revoke	Available metabolism and magnitude of the residue data do not support this tolerance without a U.S. registration. Registrant does not support this use.
Milk, fat (0.1 ppm(N) in whole milk)	3.0	Revoke	Residues may be classified under Category 3 of 40 CFR §180.6(a), i.w. there is no reasonable expectation of detectable residues.
Poultry, fat	0.2	0.02	The tolerance can be reassessed based on an adequate hen feeding study.
Poultry, mbyp	2.0	Revoke	Residues may be classified under Category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues.
Poultry, meat	2.0	Revoke	

Commodity	Current Tolerance, ppm	Interim Tolerance Decision (a), ppm	Comment/ *[Correct Commodity Definition]*
Sheep, fat	0.2	0.02	See comment under "cattle ,fat"
Sheep, kidney and liver	2.0	Reassign	See comment under "cattle, kidney, and liver."
Sheep, mbyp	0.2	0.02	See comment under "cattle mbyp."[sheep, meat by products]
Sheep, meat	0.2	Revoke	See comment under "cattle, meat"
Sorghum, grain	8.0	8.0	Sorghum, grain, grain
Tolerances listed under 40 CFR §180.409(a)(2)			
Corn milling fractions (except flour)	40	Revoke	Residues do not concentrate in milling fractions
Corn oil	88	Revoke	Residues do not concentrate in refined oil (bleached/deodorized.)
Sorghum milling fractions (except flour)	40	Revoke	Residues in sorghum milling fractions are no longer included in Table 1 of OPPTS 860.1000 and are not considered in Agency dietary risk assessment.
Tolerances listed under 40 CFR §180.409(a)(3):			
Wheat Flour	8.0	Revoke	Available data do not support use on wheat since residues do not concentrate in wheat flour. The tolerance should be revoked even if the registrant eventually supports use on wheat grain. [Label directions to treat wheat "for export only" are considered to be impractical.]
Grain aspirated, grain fractions	none	20	A tolerance is required, based on residue and processing data which demonstrated concentration in aspirated grain fractions.
Tolerances needed under 40 CFR §180.409(a)(1):			
Sorghum, grain, forage	none	TBD[b]	Data depicting residues in sorghum forage are required.
Sorghum, grain, stover	none	TBD	Data depicting residues in sorghum stover are required.
Corn, field, stover	none	TBD	Data depicting residues in corn stover are required.
Corn, field, forage	none	TBD	Data depicting residues in corn forage are required.

a 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. The tolerance levels provided here are for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data. The Agency will commence proceedings to revoke, lower the existing tolerances, and correct commodity definitions.

b TBD=to be determined, additional residue data are needed to determine an appropriate tolerance level, and the establishment of any new tolerances will be deferred, pending the outcome 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 was 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, pirimiphos-methyl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Required Label Modifications

For reregistration eligibility, it is necessary for pirimiphos-methyl labels to be amended to mitigate risk to occupational handlers. Provided the following risk mitigation measures are incorporated in their entirety into labels for pirimiphos-methyl-containing products, the Agency finds that all currently registered uses of pirimiphos-methyl are eligible for interim reregistration, pending a cumulative assessment of the organophosphates. The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of required mitigation measures.

a. Agricultural Uses

- To reduce dermal and inhalation exposure from pirimiphos-methyl admixture grain and seed treatments, handlers must use a closed mixing and loading system. All products in containers greater than 64 fluid ounces labeled for admixture grain and seed treatments must be formulated into containers that meet the definition of a closed transfer system. Mixers/loaders using closed systems will be required to wear baseline attire (long-sleeved shirt, long pants, shoes, and socks) plus chemical-resistant gloves. In addition, mixers/loaders need to have the following personal protective equipment (PPE) immediately available for use in case of an emergency, such as breakage or failure of the closed system: coveralls, and chemical-resistant footwear. Labels must be modified to prohibit open-pour mixing/loading for admixture treatments.

- To reduce dermal exposure from pirimiphos-methyl applications for all hand-held equipment when applying as a top-dress to grain and seed, mixers/loaders and applicators must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. In addition, mixers and loaders must wear an apron.

- To protect from dermal exposure when mixing and loading pirimiphos-methyl for fogging treatment to iris bulbs, mixers and loaders must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. To protect from inhalation exposure when applying pirimiphos-methyl as a fogging treatment to iris bulbs, applicators must not use hand-held fogging equipment, and wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. A self-contained breathing apparatus (SCBA) must also be immediately available for use in an emergency, such as entry while fogging is in process or before ventilation is complete. Calculations indicate that the use of a respirator during fogging treatments is not sufficient to protect from inhalation exposure to pirimiphos-methyl.

- Directions for treating iris bulbs using any means other than fogging such as with direct sprays must be removed from labels.

- For products labeled for iris bulb treatment, labels must be modified to prohibit use of hand-held fogging equipment. Applicators must use stationary or cart-mounted fogging devices which, when activated, function automatically without an operator present.

- For products labeled for iris bulb fogging treatments, labels must state that workers (other than appropriately trained and equipped handlers) are prohibited in the entire closed area until the ventilation criteria specified in table 11, (equivalent to the criteria in The Worker Protections Standard (40 CFR Part 170.110(c)) have been met.

- For ear tag treatments, handlers must wear baseline attire (long-sleeved shirt, long pants, shoes, and socks) plus chemical-resistant gloves.

In addition to mitigation measures necessary to reduce occupational risk such as the use of PPE and closed systems, the Agency also will require annual reporting of pirimiphos-methyl production. In September, 1999, the Agency issued a data call-in for all OP's to complete a Developmental Neurotoxicity Study (DNT). The registrant requested a waiver based on low volume production/minor use, and presented forecasts of production volume for the next several years. EPA granted the waiver contingent upon production volume remaining at or below the forecast figures. Therefore, EPA is placing the DNT data requirement in reserve at this time, and will require annual reporting of production figures. If production exceeds amounts projected in the waiver request, or if other factors such as registration status or risk estimates change, EPA will reconsider the DNT waiver/reserve status.

D. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

(1) Acute Dietary (Food)

The acute dietary risk for pirimiphos-methyl is below the Agency's level of concern for the general U.S. population and all population subgroups, including infants and children at the 99.9th percentile. The most highly exposed subgroup is children 1-6 years with 83% of the acute Population Adjusted Dose (aPAD) occupied. No mitigation is necessary for acute dietary exposure.

(2) Chronic Dietary (Food)

The chronic dietary risk for pirimiphos-methyl is below the Agency's level of concern for the general U.S. population and all population subgroups, including infants and children at the 99.9th percentile. The most highly exposed subgroup is children 1-6 years with 51% of the chronic PAD occupied. No mitigation is necessary for chronic dietary exposure.

(3) Drinking Water

There are no outdoor uses which would reasonably result in water contamination associated with pirimphos-methyl: Therefore, no drinking water risk mitigation is necessary.

b. Occupational Risk Mitigation

Based on the Agency's revised occupational risk assessment, handlers of pirimiphos-methyl are exposed by dermal and inhalation routes, with dermal exposure being the most significant route for most scenarios. Handler risks are not of concern if exposure is reduced through the use of closed mixing/loading systems and/or PPE.

Admixture Grain and Seed Treatment: Occupational risks do not exceed the Agency's level of concern for the mixing and loading of liquids for admixture seed and grain when closed systems are used. Closed systems are currently the standard method of mixing and loading for seed and grain admixture treatments at commercial grain storage operations and larger farms. The Agency has concern for open-pour mixing and loading of pirimiphos-methyl on seed and grain due to the potential for intermediate-term exposure to commercial seed and grain operators, as well as mixers and loaders making on-farm treatments when the harvest and treatment period exceeds 7 days. EPA believes that grain harvest, storage, and treatment typically exceeds seven days, and that it is appropriate to protect workers from risks associated with intermediate-term exposures. Further, the risk assessment considers only the mixing and loading component of seed and grain admixture treatments because adequate data to assess potential operator exposure during application is unavailable. EPA expects that exposures during application, resulting from activities such as adjusting equipment and monitoring grain treatment and movement, would be intermittent and

lower than mixer/loader exposure, though it is difficult to determine what the contribution to overall risk would be. As such, EPA believes that measures to reduce handler exposure associated with admixture treatments are necessary, and labels need to be amended to prohibit open mixing and loading. Containers larger than 64 fluid ounces must be designed and labeled for use only with a closed mixing/loading system. Containers 64 fluid ounces and smaller must prohibit use in admixture grain and seed treatments. A significant portion of pirimiphos-methyl sold for admixture grain and seed treatment is currently packaged in containers designed for closed mixing and loading. Other feasible, cost effective closed systems are commercially available which can accommodate a range of container sizes. Therefore, EPA has determined that use of closed systems for mixing/loading pirimiphos-methyl for seed and grain admixture treatments are appropriate. Finally, this approach to worker risk management is consistent with the Worker PR Notice (PRN 2000-9).

Top Dress Treatments: PPE consisting of chemical resistant gloves and double layer clothing need to be worn for mixing, loading and applying for all hand-held equipment when applying pirimiphos-methyl as a top dress. A proposed bin disinfestation use was also assessed. However, the risk exceeded the Agency's level of concern with the maximum PPE that could be allowed for bin disinfestations.

Ear Tags: The Agency has concern for exposure risks during the application and removal of cattle ear tags. However, when chemical resistant gloves are worn during application and removal of cattle ear tags, the risks don't exceed the Agency's level of concern. Therefore, EPA has concluded that labels must specify chemical-resistant gloves for eartag application and removal.

Iris Bulb Treatments: For mixing and loading of liquids for iris bulb treatment, risks exceed the Agency's level of concern if PPE consisting of coveralls and chemical resistant gloves are not worn. For fogging of iris bulbs, the Agency's level of concern is exceeded if the maximum PPE (coveralls, chemical resistant gloves and SCBA equipment) are not used. EPA notes that this is a highly specialized use which is currently done at a nursery in Washington state. According to nursery management, applications are only performed by commercial applicators using stationary or cart-mounted fogging equipment which, when activated, functions automatically without an operator present. Also, treatments are infrequent and never exceed seven consecutive days. Therefore, the Agency's level of concern will not be exceeded with this practice.

The Agency believes that most post-application exposures attributable to the use of pirmiphos-methyl should be negligible based on actual use patterns. The one exposure scenario that the Agency is concerned about however, is entry into previously fogged iris bulb holding areas. The Agency believes that the level of risk associated with this scenario is acceptable provided that ample time is allowed for residue dissipation, treated areas are properly aerated prior to entry, mechanical handling of treated iris bulbs or chemical-resistant rubber gloves are used, and the proper PPE is used for excursions into treated areas for intervals prior to the normal post-application bulb holding time of 3 to 4 weeks. Therefore, EPA has determined that product labels must be revised to specify ventilation requirements and PPE for use following fogging treatments.

Finally, the developmental neurotoxicological (DNT) study which was required for all the organophosphates, was waived for pirimiphos-methyl based on low volume production and minor use provided pirimiphos-methyl production remains within the estimates outlined in the waiver request dated 12/20/99. Therefore, the Agency is placing the DNT requirement in reserve at this time. Should production exceed the projected sales forecasts in the 12/20/99 memo for Agriliance or for Schering-Plough Animal Health, or if registration, exposure or risk status changes, EPA may require this study. Annual reporting of production volume is required as a condition of the waiver.

EPA will consider any additional information and data regarding pirimiphos-methyl toxicity, exposure, and use patterns that would enable refinement of risk estimates. If EPA determines, before final implementation of the IRED, that any of the conclusions reached in this document are no longer appropriate, the Agency will pursue appropriate action such as reconsideration of risk management decisions outlined in this document.

2. Environmental Risk Mitigation

No environmental risk mitigation is necessary.

E. Other Labeling - Endangered Species Statement

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

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 will eliminate the adverse impacts. 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), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not requiring label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. What Registrants Need to Do

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

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

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); and

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

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 Lorilyn Montford at (703) 308-8170 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)
Lorilyn M. Montford
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Lorilyn M. Montford
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient pirimiphos-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

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

Within eight months from the receipt of the PDCI:

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

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

(3) five copies of the draft label incorporating all label amendments outlined in Table 11. of this document;

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

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

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

Please contact Venus Eagle-Kunst at (703) 308-8045 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)
Venus Eagle
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Venus Eagle
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 pirimiphos-methyl for the above eligible uses has been reviewed and determined to be substantially complete. However, the following data gaps remain:

(1) Avian reproduction studies 71-4(a) and (b)
(2) Chronic toxicity study in dogs 83-1(b)
(3) Combined chronic toxicity/carcinogenicity study in rats (83-5)
(4) 21 Day Dermal toxicity study in rats; (82-2)
(5) UV/Visible absorption data; (830.7050)

(6) Storage stability data to support residue trials on grain; (171-4e)

(7) Magnitude of the residue in forage/stover grown from treated bulk/bagged seed. (860.1500)

(8) DNT data requirement (reserve)

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: These requirements are being placed in reserve. If production volume, registration status, use, risk, or other information changes substantially, these data may be required.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in Table 11 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 11 at the end of this section. Registrants should include the following items: a completed EPA application form 8570-1, five copies of the draft label with all required label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. The Product Reregistration contact is Venus Eagle at (703) 308-8045.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this interim document. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this interim RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell pirimiphos-methyl products bearing old labels/labeling for 12 months from the date of issuance of this interim RED. Persons other than the registrant may distribute or sell such products for 24 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.

D. Required Labeling Changes Summary Table

In order to be eligible for reregistration, the registrant must 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 11: Summary of Labeling Changes for pirimiphos-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 pirimiphos-methyl 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
Environmental Hazards Statements Required by the RED and Agency Label Policies	This chemical is very highly toxic to fish and wildlife. 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." (Insert any additional chemical specific manufacturing use environment hazards here.)	Precautionary Statements: Hazards to Humans and Domestic Animals. (Immediately following the PPE requirements.)

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED for all products registered for Admixture and Top Dress; Grain and Seed Treatments, and 24(c) Labels for Iris Bulb Treatments.[1]	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (registrant inserts correct material as per supplements 3 of PR Notice 93-7). "If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistant category selection chart." "Mixers, and loaders and other handlers supporting admixture seed and/or grain treatments must wear: * long sleeve shirt and long pants * shoes, plus socks * chemical resistant gloves See engineering controls for additional requirements. "All other mixers, loaders, applicators and other handlers must wear: * coveralls over long sleeve shirt and long pants, * chemical resistant footwear, plus socks * chemical resistant gloves In addition, mixers and loaders must wear * chemical resistant apron."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals.
PPE Requirements Established by the RED for Cattle Ear Tags.	"Personal Protective Equipment (PPE) "Handlers must wear long sleeved shirt, long pants, shoes, plus socks, and chemical resistant gloves such as those made from any waterproof material."	Immediately following/ below Precautionary Statements: Hazards to Humans and Domestic Animals.
User Safety Requirements (All Products)	"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.	Precautionary Statements: Hazards to Humans and Domestic Animals. (Immediately following the PPE requirements.)
User Safety Requirements (For All Liquid Products)	In addition to the statement above, add the following: "Discard clothing and other absorbent material that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	
User Safety Requirements (For 24(c) Label for Iris Bulb Treatments)	In addition to the above two statements, add the following: "Any handler who enters the treated area before the ventilation requirements have been met, must maintain continuous visual or voice contact with another handler. That other handler must have immediate access to the PPE required on this labeling for handlers in the event entry into the fumigated area becomes necessary for rescue."	24c Label

Description	Amended Labeling Language	Placement on Label
Engineering Controls (For products marketed in containers greater than 64 fluid oz. in size)	"Engineering Controls For all seed and/or grain treatments, handlers must use a closed mixing/loading system designed by the manufacturer to enclose the pesticide in a manner that prevents it from contacting handlers. This product is formulated into a container designed for closed mixing and loading. In addition: – handlers must wear the PPE specified above for handlers supporting admixture seed and/or grain treatment, – handlers must have available to them in case of accident or spill: coveralls, and chemical resistant footwear. – handlers must wear protective eye wear if the closed system operates under pressure."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Engineering Controls For 24(c) Label for Iris Bulb Treatments	"Engineering Controls For treatment of iris bulbs handlers must use a stationary or cart-mounted fogging device which, when activated, functions automatically without an operator present. In addition: - handlers must wear the following PPE: * coveralls over long sleeve shirt and long pants, * chemical resistant footwear, plus socks * chemical resistant gloves In addition, mixers and loaders must wear * chemical resistant apron. In addition to the above, -handlers must have available to them for use in case they must enter the area during treatment, or before ventilation requirements have been met: - chemical resistant headgear, and - a self-contained breathing apparatus (SCBA) (MSHA/NIOSHA approval number prefix TC-13F)."	On 24C Label Precautionary Statements: Hazard to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations for All Products	"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 pesticides 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 under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of waste."	Precautionary Statements immediately following the User Safety Recommendations

Description	Amended Labeling Language	Placement on Label
Entry Restrictions for Grain and Seed Treatment Products	"Do not enter treated areas or have contact with treated grain or seed until sprays have dried."	Directions for Use
Entry Restrictions for 24(c) Label for Iris Bulb Treatments	"Entry by any person - other than properly trained and equipped handlers using the PPE specified above for reentry - is PROHIBITED in the entire enclosed treatment area from the start of application until the treated area is ventilated as follows: • 10 air exchanges, or • 2 hours of ventilation using fans or other mechanical ventilating systems, or • 4 hours of ventilation using vents, windows or other passive ventilation, or • 11 hours with no ventilation followed by 1 hour of mechanical ventilation, or • 11 hours with no ventilation followed by 2 hours of passive ventilation, or • 24 hours with no ventilation. For the first 48 hours after ventilation has been completed, reentry workers must wear chemical resistant gloves."	Directions for Use on 24(c) Label
General Application Restrictions for All Products (Except Cattle Ear Tag Products)	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use under General Precautions and Restrictions
General Application Restrictions for Ear Tag Products	"Do not handle or apply this product in a way that will contact workers or others."	
General Application Restrictions for Grain/Seed Treatment Products	"Do not make more than one application per crop. Only treat corn or sorghum which has not previously been treated with any pirimiphos-methyl containing product." All products marketed in containers of 64 fl. oz. or less may not be used for admixture grain and seed treatments and must contain the following statement: "Do not use for admixture grain and seed treatments".	
General Application Restrictions for 24(c) Label for Iris Bulb Treatment	"(1) Application must only be made with stationary or cart-mounted automated fogging devices. (2) Use of hand-held foggers is prohibited. (3) All entries to the structure must be blocked/barricated and posted with the required fumigant warning signs. (4) All area vents must be closed and all circulating fans must be turned off. (5) All misting systems must be turned off. (6) Immediately after activating the fogging device, the applicator must exit the treatment area."	Place in the Directions for Use on the 24(c) Label.

Description	Amended Labeling Language	Placement on Label
Double Notification Statement for 24(c) Label for Iris Bulb Treatment	"Notify workers of the application by warning them orally and by posting fumigant warning signs at all entrances to the treated area. The signs must bear the skull and crossbones symbol and state: (1)"Danger/Peligro", (2) "Area under Fumigation, DO NOT ENTER/NO ENTRE", (3) the date and time of fumigation, (4) (insert name of product) in use, and (5) name, address and phone number of the applicator.	Place in the Directions for Use on the 24(c) Label Under General Precautions and Restrictions.
Spray Drift Restrictions for Outdoor Products Applied as a Liquid	"Do not allow this product to drift."	Directions for Use in General Precautions and Restrictions

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Related Documents and How to Access Them

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

The docket initially contained preliminary risk assessments and related documents as of January 9, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on March 30, 2000

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

VII. APPENDICES

Appendix A. Table of Use Patterns Eligible for Reregistration

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications	Use Limitations
Corn, pop Corn, grain (field, forage) Sorghum (grain)				
Admixture Spray Post-Harvest Low-Pressure Hand-wand	57% E [1381-170]	12.3 fl.ounces/5 gallons water to treat 30 tons of grain	One application per crop	-Do not apply to previously treated grain. -Avoid dusty application sites
Top Dress Spray Post-Harvest Low Pressure Handwand	57% E [1381-170]	3 fl.ounces/2 gallons water to treat 1,000 sq. ft.	One application per crop	- Do not apply to previously treated grain. -Avoid dusty application sites
Top Dress Spray Post-Harvest High Pressure Handwand	57% E [1381-170]	3 fl. ounces/2 gallons water to treat 1,000 sq. ft.	One application per crop	- Do not apply to previously treated grain. -Avoid dusty application sites
Top Dress Spray Post-Harvest Backpack Sprayer	57% E [1381-170]	3 fl. ounces/2 gallons water to treat 1,000 sq. ft.	One application per crop	- Do not apply to previously treated grain. -Avoid dusty application sites
Dairy Cattle, lactating Dairy Cattle, nonlactating Beef Cattle Cattle (calves, heifers)				

Ear Tag 2 Applications per year Hand-held device	20% I [773-68] 14% I [773-81]	-Up to 2 tags per animal (one in each ear).	2 Tags, Twice per year	-Remove tags before slaughter -Do not contaminate water, food or feed with tags
Iris Bulbs				
Fogging Pre-storage Fogging Device - (cart-mounted)	57% E [WA90003800]	1% or 1gal./100 gals. water (60 ml. per 10 cu. m. cell content)	One application	Must use a stationary or cart-mounted fogger.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ABCDEFGHIJKLMNO	00129333, 42458201
61-2(a)	Starting Material & Mnfg. Process	ABCDEFGHIJKLMNO	00129333, 00130874, 42458201
61-2(b)	Formation of Impurities	AIJKLMNOBCDEFGH	00129333, 00130874, 00140880, 42458201
62-1	Preliminary Analysis	ABCDEFGHIJKLMNO	92147002 42458201
62-2	Certification of Limits	ABCDEFGHIJKLMNO	00129333 92147002
62-3	Analytical Method	ABCDEFGHIJKLMNO	00129333
63-2	Color	ABCDEFGHIJKLMNO	00129333
63-3	Physical State	ABCDEFGHIJKLMNO	00129333
63-4	Odor	ABCDEFGHIJKLMNO	129333
63-5	Melting Point	ABCDEFGHIJKLMNO	N/A
63-6	Boiling Point	ABCDEFGHIJKLMNO	00129333
63-7	Density	ABCDEFGHIJKLMNO	00129333
63-8	Solubility	ABCDEFGHIJKLMNO	00129333 9217003
63-9	Vapor Pressure	ABCDEFGHIJKLMNO	00129333
63-10	Dissociation Constant	ABCDEFGHIJKLMNO	N/A
63-11	Oct/Water Partition Co	ABCDEFGHIJKLMNO	92147003
63-12	pH	ABCDEFGHIJKLMNO	92147003
830.7050	UV/Visible Absorption	ABCDEFGHIJKLMNO	Data Gap
63-13	Stability		00129333 92147003
63-14	Oxidizing/Reduction Ac		N/A
63-15	Flammability		N/A
63-16	Explodability		N/A
63-17	Storage Stability		N/A
63-18	Viscosity		N/A
63-19	Miscibility		N/A
63-20	Corrosion Characteristic		N/A
63-21	Dielectric Breakdown		N/A
ECOLOGICAL EFFECTS			
71-1(a)	Acute Avian Oral, Quail/Duck (TGAI)	A, B, L, M, O	434421-01

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
71-1(b)	Acute Avian Oral, Quail/Duck (TEP)		N/A
71-2(a)	Acute Avian Diet, Quail	A, B, L, M, O	097679
71-2(b)	Acute Avian Diet, Duck	A, B, L, M, O	097679
71-3	Wild Mammal Toxicity	A, B, L, M, O	00126257, 43726801, 43206301
71-4(a)	Avian Reproduction Quail	A, B, L, M, O	Data Gap
71-4(b)	Avian Reproduction Duck	A, B, L, M, O	Data Gap
71-5(a)	Simulated Terrestrial Field Study	A, B, L, M, O	N/A
71-5(b)	Actual Terrestrial Field Study		N/A
72-1(a)	Acute Fish Toxicity Bluegill (TGAI)	A, B, L, M, O	0976770
72-1(b)	Acute Fish Toxicity Bluegill (TEP)		N/A
72-1(c)	Acute Fish Toxicity Rainbow Trout (TGAI)	A, B, L, M, O	0976770
72-1(d)	Acute Fish Toxicity Rainbow Trout (TEP)		N/A
72-2(a)	Acute Aquatic Invertebrate Toxicity (TGAI)	A, B, L, M, O	097679
72-2(b)	Acute Aquatic Invertebrate Toxicity (TEP)		N/A
72-3(a)	Acute Estu/Mari Tox Fish (TGAI)		N/A
72-3(b)	Acute Estu/Mari Tox Mollusk (TGAI)		N/A
72-3(c)	Acute Estu/Mari Tox Shrimp (TGAI)		N/A
72-3(d)	Acute Estu/Mari Tox Fish (TEP)		N/A
72-3(e)	Acute Estu/Mari Tox Mollusk (TEP)		N/A
72-3(f)	Acute Estu/Mari ox Shrimp (TEP)		N/A
72-4(a)	Early Life-Stage Fish		N/A
72-4(b)	Live-Cycle Aquatic Invertebrate		N/A
72-5	Life-Cycle Fish		N/A
72-6	Aquatic Org. Accumulation		N/A
72-7(a)	Simulated Aquatic Field Study		N/A
72-7(b)	Actual Aquatic Field Study		N/A
122-1(a)	Seed Germ./Seedling Emerg..		N/A
122-1(b)	Vegetative Vigor		N/A
122-2	Aquatic Plant Growth		N/A
123-1(a)	Seed Germ./Seedling Emerg.		N/A
123-1(b)	Vegetative Vigor		N/A
123-2	Aquatic Plant Growth		N/A

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
124-1	Terrestrial Field Study		N/A
124-2	Aquatic Field Study		N/A
141-1	Honey Bee Acute Contact		N/A
141-2	Honey Bee residue on Foliage		N/A
141-5	Field Test for Pollinators		N/A
TOXICOLOGY			
81-1	Acute Oral Toxicity	A, B, L, M, O	00126257
81-2	Acute Dermal Toxicity	A, B, L, M, O	00126257
81-3	Acute Inhalation Toxicity	A, B, L, M, O	41556304
81-4	Primary Eye Irritation	A, B, L, M, O	00126257
81-5	Dermal Irritation	A, B, L, M, O	00126257
81-6	Primary Dermal Sensitization	A, B, L, M, O	00126257
81-7	Delayed Neurotoxicity	A, B, L, M, O	Literature Study
81-8	Acute Neurotoxicity Screening	A, B, L, M, O	43594101
82-1	Subchronic Feeding	A, B, L, M, O	00129343
82-1(b)	Subchronic Non-Rodent Oral Tox.	A, B, L, M, O	00080743
82-2	Repeated Dose Derm.Tox.-21/28-Day	A, B, L, M, O	00129342; Data Gap
82-3	Subchronic Dermal Toxicity- 90-Day	A, B, L, M, O	N/A
82-5(b)	90-Day Neurotoxicity- Mammal	A, B, L, M, O	00126254
82-7	90-Day Subchronic Neurotoxicity	A, B, L, M, O	43608201
83-1(a)	Chronic Toxicity	A, B, L, M, O	92147036, 92147014
83-1(b)	Chronic Toxicity	A, B, L, M, O	Data Gap
83-2(b)	Oncogenicity- Mouse	A, B, L, M, O	43968401
83-3	Prenatal Developmental Tox. Study	A, B, L, M, O	00151623,43726801 43206301
83-4	Reproduction and Fertility Effects	A, B, L, M, O	92147035
83-5	Combined Chronic Tox./ Carcinogen.	A, B, L, M, O	92147035; Data Gap
83-6	Developmental Neurotoxicity Study	A, B, L, M, O	Reserved
84-2	Chronic Toxicity Studies	A, B, L, M, O	00126256
84-4	Other Mutagenic Mechanisms	A, B, L, M, O	41556303, 41599502, 41556302
85-1	General Metabolism	A, B, L, M, O	00047987
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1(a)	Foliar Residue Dissipation		N/A
132-1(b)	Soil Residue Dissipation		N/A
133-3	Dermal Passive Dosimetry		N/A

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
133-4	Inhalation Passive Dosimetry		N/A
ENVIRONMENTAL FATE			
161-1	Hydrolysis	A, B	42982401, 43177601
161-2	Photodegradation- Water		N/A
161-3	Photodegradation- Soil		N/A
161-4	Photodegradation- Air		N/A
162-1	Aerobic Soil Metabolism		N/A
162-2	Anaerobic Soil Metabolism		N/A
162-4	Aerobic Aquatic Metabolism		N/A
163-1	Adsorption/Desorption Studies		N/A
163-2	Volatility- Lab	A, B	42930301
163-3	Volatility- Field		N/A
164-1	Terrestrial Field Dissipation		N/A
164-5	Long Term Soil Dissipation		N/A
165-1	Confined Rotational Crop		N/A
165-2	Field Rotational Crop		N/A
165-4	Bioaccumulation in Fish		N/A
RESIDUE CHEMISTRY			
171-4(a)	Nature of Residue- Plants	A, B, L	00129339, 42903501, 42903504
171-4(b)	Nature of Residue- Livestock	A, B, L	00143313, 00153188, 42903502
171-4(c)	Residue Analytical Method- Plant	A, B, L	00072586 00080777, 00130402, 44046401, 44055001, 44057701, 44073901, 44073902, 44097801, 44129601, 44155701
171-4(d)	Residue Analytical Method- Animal	A, B, L	
171-4(e)	Storage Stability	A, B, L	44073901, 44073902, 44039501, 44046403, 44046404; Data gap for grains

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
171-4(j)	Mag. of Residue in Meat/Milk/ Poultry/Eggs	A, B, L	44059901, 41556301, 44046402
171-4(k)	Crop Field Trials	A, B, H	00080766, 00135415, 00164580, 44073902, 40774001,44129601, 44155701, 00072579; Data gap for forage/stover from seed
171-4(l)	Processed Food/Feed	A, B, H	44155701, 44097801, 44129601

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 am to 4 pm.

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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:

www.epa.gov/pesticides/op

These documents include:

HED Documents:

1. Rowland, Jess (USEPA/OPPTS/HED) Pirimiphos-methyl FQPA Requirement: Report of the Hazard Identification Assessment Committee. January 29, 1998.

2. Stokes, Jerry (USEPA/OPPTS/HED) Conclusions of the Metabolism Assessment Review Committee at Meeting of 11/14/97 for Pirimiphos-methyl. May 15, 1998.

3. Diwan, Sanju Ph.D. (USEPA/OPPTS/HED) Memo to Christina Swartz of HED on Toxicology Chapter of the Reregistration Eligibility Document for Pirimiphos-methyl. May 18, 1998.

4. Dawson, Jeff (USEPA/OPPTS/HED) Memo to Christina Swartz of HED on The ORE Aspects of the HED Chapter of the Reregistration Eligibility Document (RED) for Pirimiphos-methyl. April 9, 1998.

5. Swartz, Christina B. (USEPA/OPPTS/HED) Memo to Meryle Sykes of SRRD on Product and Residue Chemistry Chapters of the Reregistration Eligibility Document of Pirimiphos-methyl. June 1, 1998.

6. Swartz, Christina B. (USEPA/OPPTS/HED) Memo to Meryle Sykes of SRRD on Acute and Chronic Dietary Risk Analyses for the Reregistration Eligibility Document for Pirimiphos-methyl. July 12, 1998.

7. Swartz, Christina B. (USEPA/OPPTS/OPP/HED) Memo to Dennis Deziel/Mark Wilhite of SRRD on HED Human Health Risk Assessment and Supporting Documentation for the Reregistration Eligibility Document (RED). October 23, 1998.

8. Swartz, Christina B. (USEPA/OPPTS/OPP/HED) Pirimiphos-methyl Revised Tolerance Reassessment Summary and Anticipated Residues for Acute and Chronic Dietary Risk Assessment. July 7, 1999.

9. Swartz, Christina B (USEPA/OPPTS/OPP/HED) Pirimiphos-methyl Revised Acute and Chronic Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment. July 13, 1999.

10. Olinger, Christina (USEPA/OPPTS/OPP/HED) Pirimiphos-methyl Revised Human Health Risk Assessment and Supporting Documentation for the Reregistration Eligibility Decision (RED). July 13, 1999.

11. Blondell, Jerry (USEPA/OPPTS/OPP/HED) Review of Pirimiphos-methyl Incident Report. July 27, 1999.

12. Hanley, Susan (USEPA/OPPTS/OPP/HED) Pirimiphos-methyl ORE Aspects of the HED Chapter of the Reregistration Eligibility Decision (RED). June 1, 1999.

13. Rowland, Jess (USEPA/OPPTS/OPP/HED) Pirimiphos-methyl: Replacement of Human Study Used in Risk Assessment. May 26, 1999.

EFED Documents:

1. Parsons, Laura and Balluf, Daniel (USEPA/OPPTS/OPP/EFED) Memo to Myerle Sykes of SRRD on EFED RED Chapter on Executive Suammary and Environmental Risk Assessement for Pirimiphos-methyl. April 23, 1998.

2. Balluf, Daniel (USEPA/OPPTS/OPP/EFED) EFED Revised Ecological Risk Assessment for Pirimiphos-methyl. April 22, 1999.

3. Balluff, Daniel (USEPA/OPPTS/OPP/EFED) Response to Pirimiphos-methyl RED Rebuttal. April 22, 1999.

Other Related Documents:

1. Angulo, Karen (USEPA/OPPTS/OPP/SRRD) Organophosphate Pesticides Availability of Revised Risk Assessment (Pirimiphos-methyl). March 29, 2000.

2. McKay, Lorilyn (USEPA/OPPTS/OPP/SRRD) Response to Public Comments on the Preliminary Risk Assessment(s) for the Organophosphate Pirimiphos-methyl. March 2, 2000.

3. Willett, Stephanie (USEPA/OPPTS/OPP/SRRD) Summary of February 15, 2000 Meeting Between Wilfarm LLC, Schering Plough and OPP Regarding Pirimiphos-methyl. February, 8, 2000.

4. McKay, Lorilyn (USEPA/OPPTS/OPP/SRRD) Letter to Registrant, Robert Sielaty, Forwarding Copies of Unacceptable DER's for Review. June 16, 1999.

5. Halvorson, Alan (USEPA/OPPTS/OPP/BEAD) Quantitative Usage Analysis for Pirimiphos-methyl. April 8, 1999.

6. Layne, Arnold (USEPA/OPPTS/OPP/SRRD) Memo to Robert Sielaty Regarding 30-Day comment Period for HED and EFED Chapters on the Human Health and Ecological Risk Assessment. October 28, 1998.

7. McKay, Lorilyn (USEPA/OPPTS/OPP/SRRD) Services International Response to 30-Day Preliminary Risk Assessment Comments. December 23, 1998.

8. McKay, Lorilyn (USEPA/OPPTS/OPP/SRRD) Questions and Answers for Pirimiphos-methyl. December 23, 1998.

9. Sielaty, Robert (Wilbur-Ellis) Letter to Lorilyn McKay on Registrant's Comments from 30-Day Error Only Preliminary Risk Assessment. November 30, 1998.

10. Housenger, Jack (USEPA/OPPTS/OPP/SRRD) Note to Reader on Pirimiphos-methyl. January 8, 1999.

11. USEPA/OPPTS/OPP/SRRD Pirimiphos-methyl Overview. August 16, 1999.

12. USEPA/OPPTS/OPP/SRRD. Pirimiphos-methyl Summary. August 16, 1999.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Interim Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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Appendix E. Generic Data Call-In

See attached table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all the pertinent instructions, is being sent to registrants under separate cover.

DRAFT COPY

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 001381
AGRILIANCE, LLC
BOX 64089
ST. PAUL MN 55164

2. Case # and Name
2535 Pirimiphos-methyl
Chemical # and Name 108102
Pirimiphos-methyl

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
1381-170 1381-171					

8. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/90

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary

1. Company name and Address 001381
AGRILIANCE, LLC
BOX 64089
ST. PAUL MN 55164

2. Case # and Name
2535 Pirimiphos-methyl
Chemical # and Name 108102
Pirimiphos-methyl

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
830.7050	U/V Visible Absorption					ABLM	TGAI	12 mos.	
71-4(a)	Avian repro. quail		Y			AB	TGAI	24 mos.	
71-4(b)	Avian repro. duck		Y			AB	TGAI	24 mos.	
82-2	21-day dermal-rabbit/rat		Y			ABLM	TGAI	24 mos.	
83-5	Chronic Toxicity/Carcinogenicity - Ra		Y			ABLM		24 mos.	
83-1(b)	Chronic tox - non-rodent		Y	Y	Y	ABLM	TGAI	48 mos.	
171-4(e)	Storage stability		Y			ABL		24 mos.	
860.1500	Cropfield trials		Y			AB	TEP	24 mos.	
870.6300	Developmental Neurotoxicity Study					ABLM		12 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

Appendix F. Product Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2535 Pirimiphos-methyl

3. Date and Type of DCI
PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claimimg a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2535 Pirimiphos-methyl

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
830.1550	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1600	Description of materials used to produce the product (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1620	Description of production process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1650	Description of formulation process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1670	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1700	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1750	Certified limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1800	Enforcement analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6302	Color (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6303	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6304	Odor (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2535 Pirimiphos-methyl

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
830.7000	pH	(9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7050	UV/Visible absorption						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7100	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7300	Density						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6314	Oxidation/reduction: chemical incompatability	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6315	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6316	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6317	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6319	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6320	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6321	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
870.1100	Acute oral toxicity	(1,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1200	Acute dermal toxicity	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1300	Acute inhalation toxicity	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2400	Acute eye irritation	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2500	Acute dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2600	Skin sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2535 Pirimiphos-methyl

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.
17 Not required unless efficacy data are required.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2535 Pirimiphos-methyl

Footnotes (cont.):

37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Appendix G. EPA's Batching of Pirimiphos-methyl Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing ***Pirimiphos-methyl*** the primary active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note the Agency is not describing batched products as "substantially similar" since some products with in a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within in a batch, or to generate all the required acute toxicological studies for each of their own products. If the registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If the registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by to-days standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, the registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response, " asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing data (Option 1), Submitting an existing Study (Option 4), Upgrading an existing Study (Option 5), or Citing an

Existing Study (Option). If a registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option

3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Four products were found which contain ***Pirimiphos-methyl*** as the active ingredient. These products have been placed into a ***No Batch*** in accordance with the active and inert ingredients and type of formulation.

No Batch	EPA Reg. No.	Percent active ingredient	Formulation Type
	1381-171	90.0	Liquid
	1381-170	57.0	Liquid
	773-68	20.0	Liquid
	773-81	Pirimiphos-methyl - 14.70 Lamda Cyhalothrin - 7.14	Liquid

Appendix H. List of Registrants Sent this Data Call-In

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 2535 Pirimiphos-methyl

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
000773	SCHERING-PLOUGH ANIMAL HEALTH CORP		1095 MORRIS AVENUE	UNION NJ	07083
001381	AGRILIANCE, LLC		BOX 64089	ST. PAUL MN	55164
064428	WASHINGTON BULB CO,INC		16031 BEAVER MARSH ROAD	MOUNT VERNON WA	98273

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hard copy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Reregistration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of A Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Speical Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32/pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/oppprmsd1/PR Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/oppprmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/oppprmsd1/PR Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opprmsd1PR Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List
   G. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   H. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which

identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.