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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

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

FROM: Debra Edwards, Director
Special Review and Reregistration Division
Office of Pesticide Programs

TO: Jim Jones, Director
Office of Pesticide Programs

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

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

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

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

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

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

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

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

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

Attachment A:

Organophosphates included in the OP Cumulative Assessment

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

April 09, 2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the U.S. 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 methidathion. 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 December 8, 1999. Additionally, the Agency held a Technical Briefing on December 8, 1999 where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on December 8, 1999 and closed on February 7, 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 methidathion. The EPA is now publishing its interim decision on the reregistration eligibility and risk management decision for the current uses of methidathion and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for methidathion will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Methidathion," which was approved and signed on September 28, 2001, contains the Agency's decision on the individual chemical methidathion.

A Notice of Availability for this Interim Reregistration Eligibility Decision (interim RED) for methidathion is being published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502C), USEPA, Ariol Rios Building, 1200 Pennsylvania NW, Washington, D.C. 20460-0001, telephone (703) 305-5805. Electronic copies of the interim RED and all supporting documents are available on the Agency's website at http://www.epa.gov/pesticides/op.

The interim RED is based on the updated technical information found in the methidathion 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 methidathion (drinking water assessment revised as of March 22, 2001 and dietary assessment revised as of April 27, 2001) and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment and any risk mitigation proposals submitted during Phase 5. For methidathion, a proposal was submitted by Gowan Company, the technical registrant, to mitigate the risks to workers associated with air blast application.

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 multistakeholder 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 methidathion risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to methidathion alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of methidathion. 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 a 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 toward 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 methidathion. The Agency will issue the final tolerance reassessment decision for methidathion once cumulative risk for all of the organophophates is considered.

This document contains a generic and a product-specific Data Call-In (DCI) that outlines further data requirements for this chemical. Note that registrants of products containing methidathion must respond to DCIs issued by the Agency within 90 days of receipt of this letter.

In this interim RED, the Agency has determined that methidathion 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 the current uses of methidathion may pose unreasonable adverse effects to human health and the environment and that such effects can be reduced by the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section 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 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 methidathion. 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 Special Review and Reregistration Division representative Carmen Rodia at (703) 306-0327. For questions about product reregistration and/or the Product DCI that accompany this document, please contact Jane Mitchell at (703) 308-8061.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Interim Reregistration Eligibility Decision

for

Methidathion

List A
Case 0034

Table of Contents

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
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.
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 an 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

The U.S. Environmental Protection Agency (hereafter referred to as EPA or the "Agency") has completed its review of public comments on the revised risk assessments and is issuing its risk management decision for methidathion. The decisions outlined in this document do not include the final tolerance reassessment decision for methidathion; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. These are examples of actions to be taken now: five tolerances are being revoked because they are covered by another tolerance; all of the meat, milk and egg tolerances are being revoked because of use deletions for livestock food items; one tolerance will be modified and several other commodity definitions will be corrected. The final tolerance reassessment decision for this chemical will be issued once cumulative risk for all of the organophosphates is considered. The Agency may need to pursue further risk management measures for methidathion once cumulative risk is finalized.

The revised risk assessments are based on review of the required database 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 methidathion. EPA developed its risk management decision for uses of methidathion that pose risks of concern after considering the revised risk estimates, mitigation measures proposed by Gowan Company (the technical registrant of methidathion) and comments and mitigation suggestions from other interested parties. This decision is fully discussed in this document.

Methidathion is a non-systemic, organophosphate insecticide/acaricide that was first registered in 1972 to control a broad spectrum of agricultural insect and mite pests on various crops, predominantly alfalfa, citrus and cotton. Use data from 1987 to 1997 indicate an average domestic use of approximately 241,000 pounds of active ingredient per year.

Overall Risk Summary

EPA's human health risk assessment for methidathion indicates some risk of concerns. Food risk, both acute and chronic, is well below the Agency's level of concern. Similarly, drinking water estimates based on screening models, from both ground and surface water for acute and chronic exposure, is not of concern. There are, however, some concerns for workers who mix, load and apply methidathion to agricultural sites. Also, EPA has identified acute and chronic risk to birds, mammals and aquatic species that are of concern.

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

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for dietary exposure to methidathion.

Residential Risk

There are no concerns because methidathion does not have any residential uses.

Occupational Risk

Of the 18 agricultural scenarios, five exceed the Agency's level of concern (i.e., Margins of Exposure or MOEs are less than 100). For these 5 scenarios, one has an MOE of 98 when workers use an organic vapor-removing respirator. Of the final four scenarios, two MOEs are 85 and 87 (mixing/loading the liquid formulation and applying with aircraft, respectively) using engineering controls and two others are 27 and 39 for mixing/loading the WSP for aerial application. EPA believes these risks can be mitigated with the following label restrictions: limit the use of water-soluble package formulation (WSP) to nonaerial applications, addition of personal protective equipment; use of closed systems and the application of a minimum of 500 gallons of water per acre to dilute methidathion products. Although these measures will not result in MOEs above 100 in all cases, the Agency believes that the remaining risks are reasonable given protective assumptions in the risk assessment and considering the benefits of methidathion use.

The risk to workers reentering treated fields is not of concern, provided the restricted entry intervals recommended in this document are established. Therefore, with the addition of the label restrictions and amendments detailed in this document, the Agency has determined that until the cumulative risks for all of the organophosphates have been considered, all currently registered uses of methidathion may continue.

Ecological Risk

Ecological risks are also of concern to the Agency. The environmental risk assessment suggests that exposure to methidathion could result in both acute and chronic risks of concern for terrestrial and aquatic organisms. In addition, methidathion may pose risks to beneficial insects that may be present at the treated area.

The Agency's risk assessment for avian species exceeds the level of concern for both acute and chronic exposure, though aspects of the use practices are expected to somewhat limit this exposure. Since many methidathion applications occur prebloom or to dormant trees when birds are not breeding, the Agency is less concerned about chronic effects to birds. Sprays to citrus, however, do coincide with the breeding period of many species of birds. Because citrus

orchards are attractive to birds, methidathion's use could present both acute and chronic risk. To

address risk to birds, the registrant has agreed to precautionary labeling.

The Agency's risk assessment suggests a concern for both estuarine and freshwater aquatic organisms. Methidathion's present use in California suggests that its adverse impact on estuarine organisms is likely to be limited because very little methidathion is used near estuaries. Methidathion may, however, have an impact on freshwater organisms. To mitigate these risks, the Agency is proposing buffer zones, improved labeling to limit spray drift and a surface water advisory statement on the label.

The Agency is also concerned about bees that may be exposed to treated foliage. The Agency believes that additional precautionary labeling will mitigate these risks.

For the uses of methidathion, the Agency has determined that with the adoption of all of the label amendments noted in this document, these uses may continue until the outcome of cumulative risks of all of the organophosphates has been decided.

The Agency is issuing this interim RED document for methidathion, as announced in a Notice of Availability published in the *Federal Register*. This interim RED includes guidance and time frames for complying with any necessary label changes for products containing methidathion. Note that there is no comment period for this document. 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 methidathion have already been subject to numerous public comment periods and a further comment period for methidathion was deemed unnecessary. With regard to complying with the risk mitigation measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for methidathion can be considered final, however, until the cumulative risks for all organophosphate pesticides is considered. The cumulative assessment may result in further risk mitigation measures for methidathion.

Methidathion Interim Reregistration Eligibility Decision Team

Office of Pesticide Programs:

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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 Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

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

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

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 September 29, 2000 a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's 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 that Worker Pesticide Registration Notice.

This document consists of seven sections. Section I contains the regulatory framework for reregistration/tolerance reassessment, as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, Section VII lists all Appendices related to the Data Call-In (DCI) information. The revised risk assessments and other related documents are available on the Agency's website at *http://www.epa.gov/pesticides/op*, and in the public docket.

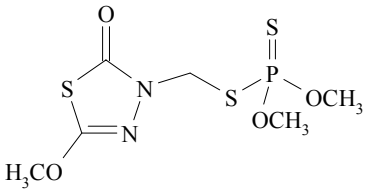
II Chemical Overview

A. Regulatory History

Methidathion was first registered in the United States in 1972 to control a broad spectrum of agricultural insect and mite pests on various crops, predominantly alfalfa, citrus and cotton. A Registration Standard was issued in 1983. In 1988, the Registration Standard was revised and reissued based on data submitted since 1983.

B. Chemical Identification

Methidathion:



- **Common name:** Methidathion
- **Chemical name:** S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)-yl) methyl] O,O-dimethyl-phosphorodithioate
- **Chemical family:** Organophosphate
- **Case number:** 0034
- **CAS registry number:** 950-37-8
- **OPP chemical code:** 100301
- **Empirical formula:** $C_6H_{11}N_2O_4PS_3$
- **Molecular weight:** 302.3 g/mole
- **Trade and other names:** Supracide®
- **Basic manufacturer:** Gowan Company

Methidathion is a colorless-to-white crystalline solid with an organophosphate odor and a melting point of 39° - 40° C. Methidathion is slightly soluble in water at 240 ppm (20° C) and is soluble in benzene, acetone, methanol and xylene at >60 g/100 mL (25° C). Methidathion is

only moderately soluble in chloroform and dichloromethane. The vapor pressure of methidathion is 2.5 X 10^{-4} Pa at 20° C.

C. Use Profile

The following information is based on the currently registered uses of methidathion:

Type of Pesticide: Insecticide/Acaricide

Summary of Use Sites:

Food Crops: Almonds, apples, apricots, artichokes, carambola, cherries, cotton, grapefruit, kiwifruit, lemons, longan, mandarin, mango, nectarines, olives, oranges, peaches, pears, pecans, plums and prunes, safflower, sugar apple, sunflower and walnuts

Other Agricultural Sites: Alfalfa (grown for seed), clover (grown for seed), grass hay and timothy

Residential: None

Public Health: None

Other Nonfood: Tobacco, commercial applications to nursery stock, ornamental plants and shrubs

Target Pests: Peach twig borer, scale insects, artichoke plume moth, leafminers, spider mites, boll weevils, bollworms, lygus bug, whitefly, aphid, pear psylla, mealybugs, thrips, sunflower stern weevil, sunflower moth, sunflower seed weevil, sunflower midge, Banks grass mite, flea beetle, hornworm, tobacco budworm, codling moth and hickory shuckworm

Formulation Types Registered: Wettable powder in water-soluble bags (25% active ingredient) and emulsifiable concentrate (22% - 24% active ingredient)

Method and Rates of Application:

Equipment: Fixed wing aircraft, groundboom, air blast, low-pressure handwand or backpack sprayer

Method and Rate: Foliar treatment, 0.25 to 5.0 lbs active ingredient/acre

Timing: During dormant, delayed-dormant or postbloom phases, depending on the crop

Use Classification: Restricted Use Pesticide due to high acute oral toxicity

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of methidathion, based on available pesticide usage information for 1987 to 1997. A full listing of all uses of methidathion, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 241,000 lbs a.i. of methidathion are used annually, according to Agency and registrant estimates.

Table 1. Methidathion Estimated Usage[1] for Representative Sites[2]

Crop	Lbs. Active Ingredient Applied (Wt. Avg.)[3]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Alfalfa (grown for seed)	1,000	<0.5	<0.5
Almonds	44,000	9	6
Apples	8,000	3	1
Apricot	2,000	8	5
Artichokes	16,000	63	50
Cherries	2,000	3	1
Cotton	16,000	<0.5	<0.5
Grapefruit	1,000	1	1
Hay	4,000	<0.5	<0.5
Kiwifruit	<500	8	7
Lemon	1,000	2	1
Nectarine	4,000	11	5
Olive	2,000	5	2
Oranges	42,000	3	2
Peaches	25,000	11	6
Pears	2,000	5	1
Pecans	2,000	<0.5	<0.5
Plums and Prunes	35,000	21	11
Safflower	1,000	9	1
Walnuts	31,000	11	9

[1] Usage data primarily covers 1987 to 1997. Calculations of the above numbers are displayed as rounded.
[2] Where usage and percent-crop-treated data are not listed (carambola, clover [grown for seed], longan and mango), either no usage is observed or that information on the site is not available or insufficient.
[3] Weighted Average based on data for 11 years; most recent and more reliable data weighted more heavily.

Sources:
EPA data (Doane Marketing Research, Maritz Marketing Research, Mike Buckley and Associates).
California Department of Pesticide Regulation.
USDA, National Agricultural Statistics Service, Agricultural Chemical Usage: Fruits Summary (1991, 1993, 1995, 1997) and Field Crop Summary (1990-1997).

III Summary of Methidathion Risk Assessments

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide methidathion, as fully presented in the documents "Human Health Risk Assessment Methidathion," dated August 9, 2000 and "Methidathion - Environmental Fate and Effects Chapter," dated November 30, 1999, (including drinking water assessment addenda, dated March 22, 2001 and dietary exposure assessment addenda dated, April 27, 2001). The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to better understand the conclusions reached in the assessments.

These risk assessments for methidathion was presented at a December 8, 1999 Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. This technical briefing was held in Sacramento, California. The risk assessments presented here form the basis of the Agency's risk management decision for methidathion only; the Agency must consider cumulative 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 methidathion in 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 include: reconsideration of the dermal toxicity endpoint selection; inclusion of new data from the Agricultural Reentry Task Force (ARTF) and recalculation of the restricted entry intervals for workers; combining dermal and inhalation MOEs in the worker assessment and refinements to the dietary risk assessment.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of methidathion can be found in the "Human Health Risk Assessment Methidathion," dated August 9, 2000. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

The toxicology database provides evidence that cholinesterase inhibition (ChEI) is the most sensitive toxicological observation from exposure to methidathion in laboratory animals. In an acute neurotoxicity study in rats following a single oral dose, methidathion was associated with neurotoxicity in both sexes, as evidenced by decreases in maze activity and alterations in functional observation parameters at the highest dose tested (HDT). In addition, there were statistically-significant decreases in plasma, red blood cell (RBC) and brain cholinesterase activity at all dose levels.

In a subchronic neurotoxicity study in rats, following dietary administration, methidathion caused significant decreases in plasma, RBC and brain cholinesterase activity in both sexes. Following repeated dermal applications to rabbits, ChEI's (plasma, RBC and brain cholinesterase activity in males and RBC and brain cholinesterase activity in females) was seen under occlusive conditions, but no biologically or statistically-significant ChEI was seen under nonocclusive conditions. Chronic dietary exposures to dogs resulted in inhibition of RBC and brain cholinesterase activity, as well as elevation of hepatic enzymes, gross hepatic lesions and microscopic presence of bile plugs, distended bile canaliculi and chronic hepatitis.

No evidence of carcinogenicity was seen in male or female rats; however, there was evidence of carcinogenicity in male mice at the highest level tested (benign and malignant liver tumors were seen). The Agency has classified methidathion as a Group C, possible human carcinogen and did not recommend a quantitative risk assessment for human risk characterization. The Agency deemed that a quantitative cancer risk assessment was unnecessary because the evidence as a whole (i.e., one sex, one species, common tumor type, no increase in proportion of malignant tumors or apparent shortening of time to tumor) was not considered strong enough to warrant a quantitative estimation of human risk. This was supported by the lack of evidence of mutagenicity under both *in vivo* and *in vitro* conditions.

There was no evidence of increased susceptibility following *in utero* exposures to rats and rabbits as well as pre/post-natal exposure to rats. Additionally, there was no evidence of abnormalities in the development of the fetal nervous system in these studies.

An acute neurotoxicity study is available, but was not used to select an endpoint for the acute dietary risk assessment, since a No Observable Adverse Effect Level (NOAEL) was not identified. The NOAEL (0.2 mg/kg/day) and endpoint (cholinesterase inhibition), which were selected for use in the acute dietary risk assessment, were derived from the subchronic neurotoxicity study. The results of these two studies support one another because the effects and levels at which they are observed are similar.

b. FQPA Safety Factor

The FQPA Safety Factor for the protection of infants and children was removed (i.e., reduced to 1x) for methidathion since: (1) the toxicology data base is complete; (2) there was no evidence of increased susceptibility seen following *in utero* exposure to rats and rabbits; (3) there was no evidence of increased susceptibility in the offspring in the two-generation reproduction study in rats; (4) there was no evidence of abnormalities in the development of the fetal nervous system in the offspring; (5) there was no evidence for requiring a developmental neurotoxicity study; (6) adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary exposure and to provide a screening level drinking water exposure assessment; and (7) there are no registered residential (home owner) use.

Acute and chronic dietary exposure risk assessments were conducted for the U.S. population and various population subgroups including infants and children. Aggregate acute and chronic risk assessments addressed the potential dietary exposure to methidathion residues from food and drinking water. Because there are no registered uses of methidathion in residential settings, the aggregate assessment for the general population and specific subgroups includes only food and water exposures. Risk assessments were also conducted for dermal and inhalation exposures to occupational pesticide handlers (mixers/loaders/applicator) as well as for workers during postapplication activities.

For acute dietary risk assessment, a NOAEL of 0.2 mg/kg/day established in the subchronic neurotoxicity study in rats was selected. The NOAEL was based on significant plasma, RBC and brain ChEI seen at 0.6 mg/kg/day (LOAEL). An Uncertainty Factor (UF) of 100 was applied to the NOAELs to account for intraspecies extrapolation (10x), interspecies variation (10x) and the FQPA safety factor (1x). The acute Reference Dose (RfD) was 0.002 mg/kg/day.

For chronic dietary risk assessment, a NOAEL of 0.15 mg/kg/day, established in the chronic toxicity study in dogs, was selected. The NOAEL was based on significant RBC, and brain ChEI seen at 1.33 mg/kg/day (LOAEL). A UF of 100 was applied to the NOAELs to account for intraspecies extrapolation (10x), interspecies variation (10x), and FQPA safety factor (1x). The chronic RfD was 0.0015 mg/kg/day.

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

Assessment	Dose NOAEL (mg/kg/day)	Endpoint	Study	UF	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary	0.20	Plasma, red blood cell and brain ChEI at a LOAEL of 0.6 mg/kg/day	Subchronic neurotoxicity in rats	100	1	0.0020
Chronic Dietary	0.15	RBC ChEI and liver toxicity at a LOAEL of 1.33 mg/kg/day	Chronic toxicity in dogs	100	1	0.0015

c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical and reflects the RfD, either acute or chronic, that has been adjusted to account for the FQPA safety factor. Accordingly, since the FQPA safety factor for methidathion is 1x, the RfD is numerically equal to the PAD. Risk estimate that are less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

d. Exposure Assumptions

Methidathion residues are generally not expected to occur on any food commodities except citrus. Methidathion is non-systemic and is applied to plants or trees before the edible portion of the plant has formed (i.e., dormant treatments). Foliar treatments of citrus commodities while the fruits are on the tree do result in residues; however, these residues are limited almost entirely to the peel. Processing of these fruit results in very low residues in peeled fruit and juice.

A revised acute dietary risk analysis for methidathion was conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91. The highly refined acute dietary analysis used percent-crop treated data and residue distributions based on field trial or USDA Pesticide Data Program (PDP) monitoring data which reflect actual uses. In addition, zero residues were assumed for apples and stone fruits since: no residues were detected in field trials, PDP or FDA monitoring data; the timing of application is unlikely to leave residues in the edible crop and, environmental fate data show that methidathion dissipates rapidly.

The chronic dietary risk assessment for methidathion was conducted using the Dietary Risk Estimate System (DRES) analysis. This analysis incorporates percent-crop treated data and some anticipated residue data.

e. Food Risk Characterization

The acute dietary risk assessment, based on probabilistic exposure analysis (Monte Carlo), indicates that methidathion residues in the diet do not exceed the Agency's level of concern for any of the population subgroups examined. The highly refined assessment, based on an acute PAD of 0.0020 mg/kg and conducted at the 99.9th percentile of exposure, revealed that the percentages of the acute PAD occupied ranged from 14% for females (13+, nursing) to 64% for children (less than one year of age). Percent crop treated data, USDA Pesticide Data Program (PDP) monitoring data, and field trial data were used in this assessment. The acute dietary exposure to methidathion from its pesticidal use does not exceed the Agency's level of concern.

The chronic dietary risk assessment was partially refined, using both percent crop treated data and anticipated residues. The percent of the chronic PAD occupied from dietary exposure to residues of methidathion ranged from 3% for females (13+, nursing) to 23% for children (one

to six years). This assessment was based on a chronic PAD of 0.0015 mg/kg/day. The chronic dietary exposure to methidathion from its pesticidal use does not exceed Agency's level of concern.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment. Some ground water and surface water monitoring data were available for methidathion, but were not considered appropriate for estimating drinking water exposure; therefore, modeling was used to estimate drinking water risks from these sources.

Estimated environment concentrations (EECs) were obtained for ground and surface water by Tier I, SCI-GROW model for ground water and Tier II, PRZM-EXAMS model for surface water. The EECs were 0.4 ppb in ground water, and 5.6 ppb and 0.6 ppb, respectively, for the acute (peak) and average (56-day) in surface water. These concentrations are supported by limited California surface and ground water monitoring data. Because dietary risk assessments based on exposures solely from food do not exceed levels of concern, both acute and chronic drinking water levels of comparison (DWLOCs) were calculated and compared to EPA model estimates and monitoring results. For the most sensitive subgroup (children <1 year), the acute (7.2 ppb) and the chronic (13 ppb) DWLOCs do not indicate a risk concern from potential exposure to methidathion residues in drinking water.

For methidathion, the aggregate risks are limited to food and water exposure, as there are no residential uses. Both the acute and the chronic dietary (food) risk estimates, risk estimates for methidathion exposure, were less than 100% of the acute and chronic PAD's. Additionally surface and ground water acute and chronic EECs did not exceed the DWLOC. Therefore, aggregate acute and chronic dietary risk estimates associated with consumption of methidathion in food and water do not exceed the Agency's level of concern.

a. Surface Water

A Tier II, PRZM-EXAMS screening model is used to estimate the upper-bound concentrations of methidathion in drinking water derived from surface water. This model is based on more refined, less conservative assumptions than the Tier I, GENEEC screening model. The index reservoir represents a watershed that is more vulnerable than most that are sources of drinking water. It was developed from a real watershed in western Illinois and takes into account various soils, weather and cropping practices.

Based on rainfall records and crop production practices, citrus was chosen to represent the

methidathion site with the highest run-off potential. Modeling results are based on citrus use in California, with a typical application rate of 3.0 lbs. a.i./A and a maximum application rate of 5.0 lbs. a.i./A. The Agency estimates drinking water concentrations from surface water of 17.1 and 1.8 ppb, respectively, for peak value and annual average value at the 3.0 lbs. rate and 28.5 and 3.01 at the 5.0 lbs. rate.

b. Ground Water

A Tier I, SCI-GROW screening model was used to estimate drinking water concentrations of methidathion derived from ground water. Tier I, SCI-GROW is an empirical screening model based on actual ground water monitoring data collected from small-scale prospective ground water monitoring studies for the registration of a number of pesticides that serve as benchmarks for the model. The current version of SCI-GROW provides realistic estimates of pesticide concentrations in shallow, highly vulnerable ground water (i.e., sites with sandy soils and depth to ground water of 10 to 20 feet). Because of the conservative nature of the monitoring data on which the model is based, Tier I, SCI-GROW provides an upper bound estimate of pesticide residues in ground water. The Agency estimates 0.2 ppb as the upper bound estimate of methidathion in ground water.

c. Monitoring Data

The Agency considered monitoring data from several sources for its drinking water assessment. None of these monitoring data were used for the drinking water assessment because samples could not be linked to drinking water sources in methidathion use areas because of other uncertainties associated with the data. For example, EPA's STORET database contains a total of 274 well samples in California from 1984 to 1987, however, no detection limit was reported. A second source of monitoring data is the Department of Health Services, California Public Drinking Water Sources. The methidathion database included a total of 265 drinking water samples (259 from ground water sources and 6 from surface water sources). The results indicated no positive detections.

d. Drinking Water Levels of Comparison

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

For acute risk, the potential drinking water exposure derived from either ground or surface water was modeled using both the typical application rate for citrus of 3.0 lbs. a.i./A and the maximum application rate of 5.0 lbs. a.i./A. At the typical rate, the acute risk is not of concern for all populations because the peak methidathion Estimated Environmental Concentrations (EECs) of 17.1 ppb for surface water and 0.1 ppb for ground water are less than the acute DWLOC. At the maximum rate, acute risk to infants, the most sensitive subgroup, is of concern for those whose drinking water is derived from surface water because the DWLOC of 19 is less than the surface water EEC of 28.5. As stated earlier, modeling with the index reservoir and the Percent Crop Area is intended for use as a screen. Actual concentrations of methidathion in surface water and finished drinking water are likely to be less. Furthermore, the 5 lbs. a.i./A rate is used only intermittently. The table below presents the calculations for the acute drinking water assessment.

Table 3. Summary of DWLOC Calculations for Acute Risk

Population Subgroup	Acute PAD (mg/kg/day)	Acute Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water Peak EEC (ppb)	Surface Water Acute EEC[1] (ppb)	Surface Water Acute EEC[2] (ppb)	DWLOC (ppb)
U.S. Population	0.0020	0.000318	0.001682	0.2	28.5	17.1	59
Adult Females	0.0020	0.000233	0.001767	0.2	28.5	17.1	53
Infants <1 yr.	0.0020	0.001280	0.00072	0.2	28.5	17.1	7
Children 1-6	0.0020	0.000558	0.001442	0.2	28.5	17.0	22

[1] EEC based on 5.0 lbs. a.i./A, which is the maximum rate used infrequently on citrus only
[2] EEC based on 3.0 lbs. a.i./A use, which is the typical rate for citrus and the maximum rate for all other crops

For chronic risk, potential exposures to drinking water derived from either ground or surface water is not of concern for any population because the EECs in ground and surface water are less than the chronic DWLOC at both the 3.0 lbs. a.i./A and the 5.0 lbs. a.i./A rates. The table below presents the calculations for the chronic drinking water assessment.

Table 4. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	Chronic PAD (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water Peak EEC (ppb)	Surface Water Chronic EEC[1] (ppb)	Surface Water Chronic EEC[2] (ppb)	DWLOC (ppb)
U.S. Population	0.0015	0.000137	0.001363	0.1	3.0	1.8	48
Adult Females	0.0015	0.000040	0.001460	0.1	3.0	1.8	44
Infants <1 yr.	0.0015	0.000179	0.001321	0.1	3.0	1.8	13
Children 1-6	0.0015	0.000338	0.001162	0.1	3.0	1.8	17

[1] EEC based on 5.0 lbs. a.i./A, which is the maximum rate used infrequently on citrus only
[2] EEC based on 3.0 lbs. a.i./A use, which is the typical rate for citrus and the maximum rate for all other crops

3. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and residential risk, when appropriate. Because methidathion has no residential uses, the risk from food and drinking water sources alone serves as the aggregate risk assessment. As discussed in the drinking water section above, the only scenario potentially of concern is the risk to infants from the use of the maximum rate on citrus.

4. Occupational Risk

Occupational workers can be exposed to methidathion through mixing, loading and/or applying a pesticide or re-entering treated sites. Occupational handlers of methidathion include individual farmers or growers who mix, load and/or apply pesticides and professional or custom agricultural applicators. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determine how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

a. Toxicity

The toxicity of methidathion is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for methidathion, including a 21-day dermal toxicity study. The toxicological endpoints and other factors used in the occupational risk assessments for methidathion are listed below.

Table 5. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Risk Assessment for Methidathion

Assessment	Dose NOAEL (mg/kg/day)	Endpoint	Study	Dermal Absorption Factor
Short-term dermal	NOAEL = 20 mg/kg/day	LOAEL not established	21-day dermal toxicity in rabbits	Not Applicable
Intermediate-term dermal	NOAEL = 0.2 mg/kg/day	Plasma, red blood cell and brain cholinesterase inhibition at the LOAEL of 0.6 mg/kg/day	90-day subchronic neurotoxicity in rats	30%
Short-term inhalation	NOAEL = 0.2 mg/kg/day	Plasma, red blood cell and brain cholinesterase inhibition at the LOAEL of 0.6 mg/kg/day	90-day subchronic neurotoxicity in rats	100%
Intermediate-term inhalation	NOAEL = 0.2 mg/kg/day	Plasma, red blood cell and brain cholinesterase inhibition at the LOAEL of 0.6 mg/kg/day	90-day subchronic neurotoxicity in rats	100%

The short-term dermal endpoint is based on a NOAEL of 20 mg/kg/day established in the 21-day dermal toxicity study in rabbits. Generally, dermal toxicity studies with thio-organophosphates such as methidathion tend to underestimate the toxicity of these chemicals because rabbits possess high concentrations of plasma carboxyl esterases, which deactivate the chemical before it is converted into the active oxon. However, in the case of methidathion, the weight of evidence from the oral and dermal toxicity data in rats and rabbits indicates that the dose used in risk assessment would not underestimate any potential dermal risk from methidathion exposure.

For assessments that rely on an oral study to approximate dermal toxicity, the Agency applies a dermal absorption factor to the data derived from the oral study to estimate the amount of methidathion that may be absorbed through the skin. The Agency believes that the ratio of the NOAELs of 6 mg/kg/day in the oral developmental toxicity study in rabbits and the NOAEL of 20 mg/kg/day in the 21-day dermal toxicity study in rabbits yield a 30% dermal absorption factor. Although 30% may overestimate dermal absorption for the technical product, its physical/chemical properties (i.e., low melting point and good water solubility) support a moderate dermal absorption.

Table 6. Acute Toxicity Profile for Occupational Exposure to Methidathion

Route of Exposure	MRID No.	Toxicity Category
Dermal	00139326	II
Inhalation	00011449	III
Eye Irritation	00159199	III
Dermal Irritation	00159200	IV
Dermal Sensitizer	00252433	Not Applicable

The toxicology database is complete and provides evidence that cholinesterase inhibition (ChEI) is the most sensitive toxicological observation in laboratory animals. Technical methidathion has high acute oral toxicity (Toxicity Category I) and moderate acute dermal and inhalation toxicity (Toxicity Categories II and III, respectively). Methidathion is a mild eye irritant (Toxicity Category III), is not a skin irritant (Toxicity Category IV) and is not a dermal sensitizer. Methidathion did not induce organophosphate induced delayed neuropathy (OPIDN) in the hen. In an acute neurotoxicity study in rats, following a single oral dose, methidathion was associated with neurotoxicity in both sexes as evidenced by decreases in maze activity and alterations in functional observation parameters at the highest dose tested (HDT). In addition, there were statistically-significant decreases in plasma, red blood cell (RBC) and brain cholinesterase activity at all dose levels. (MRIDs 00139328, 00139326, 00011449, 00159199, 00159200, 00252433, 00011704, 43145903 and 43590304)

b. Exposure

Chemical-specific exposure data were not available for methidathion, so risks to pesticide handlers were satisfied using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. 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 methidathion product 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 are of lower quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the "Human Health Risk Assessment Methidathion," dated August 9, 2000, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates and daily amount treated were derived from current labeling. Application rates specified on methidathion labels range from 0.5 to 5.0 pounds of active ingredient per acre in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent eight solid hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest suite of PPE is baseline PPE. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) are applied. If MOEs are still less than 100, engineering controls (ECs) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from methidathion activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Wettable Powder Label: Baseline + chemical-resistant gloves.
- Emulsifiable Concentrate Label: Baseline + chemical-resistant gloves and a respirator.
- Minimum PPE: Baseline + chemical-resistant gloves and a respirator.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a farm closed mechanical transfer system for liquids or a packaged-based system (e.g., Lock-*N*-Load for granulars or water soluble

packaging for wettable powders). Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods, there are no known devices that can be used to routinely lower the exposures).

c. Occupational Handler Risk Summary

Occupational exposure risk assessments for handlers (mixer/loaders/applicators) were based on the Pesticide Handler's Exposure Database (PHED); and MOEs were calculated for dermal and inhalation exposures. An MOE of 100 or greater does not exceed EPA's level of concern. For methidathion, the Agency has identified 12 major exposure scenarios for handlers mixing, loading and applying products containing methidathion to agricultural crops. Of the 12 scenarios, 11 have MOEs greater than 100 with minimum personal protective equipment (PPE) [with water soluble packets (WSP), single layer clothing (SLC) which includes long sleeve shirt, long pants, shoes and socks and gloves], or with additional PPEs, [that include WSP, coverall over SLC (i.e., double layer clothing (DLC)], gloves and dust/mist respirator] or with engineering controls [WSP, SLC, gloves and closed cabs]. For one remaining scenario (mixing/loading in support of aerial application), risk estimates are of concern since even with engineering controls, the MOEs for dermal (MOE = 91) and inhalation (MOE = 95) are below the required MOE of 100 (EPA's level of concern).

Because the dermal and inhalation NOAELs are based on different toxicological endpoints (i.e., lack of systemic toxicity via the dermal route and ChEI via the oral route), it is inappropriate to combine the exposures for these pathways. Therefore, only route-specific MOEs are appropriate for evaluation. However, since ChEI is the principal toxicological endpoint of concern for OP's via the dermal and inhalation routes, an analysis of the total MOEs was conducted for risk characterization purpose only. The combined exposure (dermal+ inhalation), resulted in MOEs that were less than 100 for two additional exposure scenarios for which the route-specific MOEs were greater than 100: mixing/loading WSP in support of aerial application (Dermal MOE = 140, Inhalation MOE = 170, Total MOE = 77) and liquid aerial application with a fixed-wing aircraft (Dermal MOE = 150, Inhalation MOE = 120, Total MOE = 67). The 12 major handler exposure scenarios identified for methidathion include the following; they are summarized in Table 7 below.

Table 7. Summary of Occupational Exposure Scenarios

Scenario No.	Description	Product Form	Application Method	Crops	Acres Treated
1a, 1b, 2a and 2b	Mixer/Loader	WSP/EC	Aerial	Citrus/Cotton	350
1b and 2b	Mixer/Loader	WSP/EC	Groundboom	Cotton/Artichoke	80
1c and 2c	Mixer/Loader	WSP/EC	Air Blast	Citrus/Apples	40
3	Applicator	Liquid	Aerial	Citrus/Cotton	350
4	Applicator	Liquid	Groundboom	Citrus/Cotton	80
5	Applicator	Liquid	Air Blast	Citrus/Apples	40
6	M/L/A	Liquid	Low-Pressure Hand Wand	Nursery Stock	10 gal[a]
7	M/L/A	Liquid	Backpack Sprayer	Nursery Stock	40 gal[a]
8	Flagger	Liquid	Aerial	Citrus	350

M/L/A = Mixer/Loader/Applicator
WSP = Water Soluble Packets
EC = Emulsifiable Concentrate
[a]0.5 lb. a.i./100 gallons of water

1) Agricultural Handler Risk

Typically, the Agency combines the exposure from both dermal and inhalation pathways when the toxicity endpoints are the same. In the case of methidathion, the 21-day dermal study which serves as the basis for the dermal assessment of methidathion, did not identify a LOAEL (or endpoint) and the highest dose tested was selected as the NOAEL. The inhalation endpoint for methidathion is based on cholinesterase inhibition (see Table 5). Because methidathion is an organophosphate, it is reasonable to assume that cholinesterase inhibition would also occur via the dermal route. Thus, it is appropriate to combine exposures from both pathways in assessing the risk to workers from using methidathion, as reflected in this document.

Current methidathion Water-Soluble Package (WSP) product labels require long-sleeved shirt, long pants, waterproof gloves and shoes plus socks. In addition to this PPE, current EC (liquid) products require a respirator. Four of the eighteen exposure scenarios result in MOEs that do not exceed the Agency's level of concern (i.e., MOEs are greater than 100) when workers wear minimum PPE (single layer of clothing and gloves). Of the remaining fourteen scenarios, one has an MOE of 98 and two others have MOEs greater than 100, when workers use an organic vapor-removing respirator. Of the remaining eleven scenarios, seven are not of concern if a closed system is used. For the final four scenarios, two MOEs are 85 and 87 (mixing/loading the liquid formulation and applying with aircraft, respectively) using engineering controls and two others are 27 and 39 for mixing/loading the WSP for aerial application. There are no data for the two aerial scenarios with the open cockpit applications, therefore, only closed cockpit risk estimates are provided.

Table 8. MOEs for Methidathion Mixers, Loaders and Applicators

Scenario	Acres	Rate (lb a.i./day)	Min. PPE[1]	Max. PPE[2]	Engineering Controls[3]		
					Dermal MOE	Inhalation MOE	Combined MOE
Mixing/Loading Water-Soluble Pkg. (WSP) Aerial (1a & 1b)	350	1750	See engineering controls		140	33	27
	1200	1200			200	49	39
Mixing/Loading WSP - Groundboom (1c & 1d)	80	80			1780	730	520
	200	200			714	290	207
Mixing/Loading WSP - Air blast (1e)	20	100			1430	580	410
Mixing/Loading Liquids - Aerial (2a & 2b)	350	1750	6	28	93	964	85
	1200	1200	8	40	136	1410	124
Mixing/Loading Liquids-Groundboom (2c & 2d)	80	80	122				
	200	200	49	200 (respirator only)			
Mixing/Loading Liquids - Air blast (2e)	20	56	175				
	20	100	98				
Applying with Aircraft (3a & 3b)	350	1750	See engineering controls		360	118	87
	1200	1200			530	170	129
Applying with Groundboom (4a & 4b)	80	80	199				
	200	200	80	327 (respirator only)			
Applying with Air blast Sprayer (5)	20	56	30	95	> 1000	555	391
	20	100	17	53	737	311	219
Mixing/Loading/Applying with Low-Pressure Handwand (6)	N/A	0.05	8163				
Mixing/Loading/Applying with Backpack Sprayer (7)	N/A	0.2	1300				
Flaggers - liquid application (8)	350	1750	17	59	3600	1100	870

[1] Long pants, long-sleeve shirt, shoes, socks and chemical-resistant gloves (same as current label for WSP formulation).
[2] Minimum PPE, plus coveralls and organic vapor-removing respirator.
[3] Engineering controls refer to: water-soluble packages (scenarios 1a, 1b, 1c, 1d and 1e); closed systems (scenarios 2a and 2b); closed cockpit (3a, 3b and 5); flagger in enclosed cab vehicle (8). For mixing/loading WSPs (scenarios 1a through 1e), MOEs only provided for engineering control because wettable powder products are formulated as WSPs. PPE to be used with engineering controls include long pants, long-sleeve shirt, shoes, socks, chemical-resistant gloves and apron based on the Worker Protection Standard and methidathion's toxicity.

2) Post-Application Occupational Risk

The postapplication occupational risk assessment considered exposures to workers entering treated sites in agriculture. All of the postapplication risk calculations for handlers completed in this assessment are included in the "Human Health Risk Assessment Methidathion," dated August 9, 2000.

The Agency has determined that there is considerable potential for postapplication occupational exposure to methidathion residues. The results of the Dislodgeable Foliar Residue (DFR) studies conducted with methidathion on cotton and citrus crops indicate that workers (i.e., scouts, pickers) require entry restrictions or restricted entry intervals (REIs) before engaging in postapplication activities. Postapplication risks were estimated using crop-specific DFR data for citrus and cotton. The citrus data were also translated to minor tree crops and kiwis. The combined results of citrus DFR studies conducted in California and Florida were used for safflower scouting and irrigation, as well as for artichoke cultivation and harvesting. An MOE of 100 or greater does not exceed the Agency's level of concern.

For cotton scouting in North Carolina and Texas, the REIs are one day after treatment (DAT) for early scouts, and for late scouts the REIs are at six days after treatment and seven days after treatment in North Carolina and Texas, respectively.

Based on a DFR study in citrus, adjusted for average application rate, a MOE of 100 is achieved for citrus hand pruning and harvesting 9 days after treatment. A MOE of 100 is achieved 5 days after treatment for lower-contact activities such as propping and worker scouting. For other tree crops including mango, carambola, longan and sugar apple, the DFR data were translated from the citrus studies and adjusted for label application rate. The MOEs exceeded 100 for hand harvesting these tree crops at 8 days after treatment. Other lower-contact activities, such as scouting or propping, achieve an MOE of 100 three days after spraying.

Translating the dissipation rate from the submitted citrus and cotton DFR studies data, a REI of 2 days was obtained for workers scouting and irrigating safflower, while a REI of 15 days is required for cultivating/harvesting/packing artichokes. Because methidathion is applied pre-bulb formation, and the bulb requires 3 weeks to mature, it is not anticipated to present an exposure risk for artichoke harvesters.

It was determined from labeling that methidathion is applied prior to foliation or at budding to all other tree crops (stone and pome fruit, nuts and olive trees) and kiwifruit vines. Therefore, there should be no foliar residue present, *per se*, during harvesting. Based on these agricultural practices, the Agency has concluded that there should be negligible postapplication methidathion chemical exposure to workers from major tree or vine crops other than citrus.

There are no registered uses of methidathion at the present time that could result in residential exposures. The Agency recognizes that there are many issues related to the use of agricultural chemicals in the general population, i.e., spray drift exposures and exposures to farm

worker children and farm residents. The Agency is in the process of developing guidance and procedures for characterizing these kinds of exposures. An assessment of the potential exposure and risk from these kinds of exposures associated with the agricultural use of methidathion are not addressed in this document. Table 9 below shows the MOEs for various crops and activities.

Table 9. Agricultural Post-Application MOEs

Crop	Activity	MOE	Days after Treatment
Artichokes	Scouting, hoeing, irrigating	155	0
	Hand cultivating/harvesting	88 110	18 19
Citrus	Scouting, irrigating, weeding	150	0
	Pruning and propping	98 120	3 4
	Harvesting	89 110	7 8
Cotton	Scouting (late season) in NC	98 130	2 3
	Scouting (late season) in TX	90 115	2 3
	Scouting (late season) in CA	94 130	1 2
Tree crops (longan, sugar apple, carambola)	Scouting, irrigating, weeding	210	0
	Pruning and propping	87 110	1 2
	Harvesting	78 98 120	5 6 7
Dormant Trees (stone and pome fruit, nuts and olive trees)	See tree crops		
Safflower, timothy, alfalfa and clover	See cotton		
Tobacco	Harvesting/bundling	100	3

d. Human Incident Data

In assessing the incidents for methidathion, the Agency consulted four sources: the national Poison Control Centers, California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991), the National Pesticide Information Center (NPIC) and the Office of Pesticide Programs Incident Data System.

In the Poison Control Center (PCC) database, there were a total of 46 methidathion cases. Of these, 21 cases were occupational exposure; 15 (72%) involved exposure to methidathion alone and 6 (28%) involved exposure to multiple chemicals, including methidathion.

The incidence of systemic poisoning cases in agricultural workers reported to California was compared to the number of applications of methidathion. Between 1982 and 1989, there were 31 worker incidents where methidathion was the primary pesticide and 39 where methidathion was part of multiple pesticide exposure. When used alone, methidathion ranked number 3 (in comparison to the other 28 chemicals) in the ratio of poisonings per 1,000 applications in field workers. Only methamidophos and azinphos-methyl ranked higher.

The Agency also considered the number of methidathion poisonings when compared to the quantity used. According to both California and Poison Control Center data for handlers and workers, when used alone, methidathion ranked third highest in number of poisoning incidents and health care referrals per 1,000 applications. However, this determination included fourteen grape pickers who were exposed when methidathion was applied to a nearby field. Considering this event as a single exposure incident, the number of methidathion exposure incidents per 1,000 applications is comparable to the median handler and field worker exposure incidents per 1,000 applications of 29 pesticides.

Detailed descriptions of 59 cases submitted to the California Pesticide Illness Surveillance Program were reviewed. In these incidents, methidathion was either used alone or with one other chemical (dicofol, dimethoate or xylene), but methidathion was judged to be responsible for the health effects. Accidents, such as hoses breaking or pressure building up in cans were responsible for 5 exposures. Two reports noted that workers were not wearing personal protective equipment.

As of March 23, 1996, there were 3 reports in the Office of Pesticide Programs Incident Data System of adverse effects to workers attributable to methidathion. In two reports, the same person mixed Supracide® with fertilizer and then spread the mixture on the ground on two separate occasions. He developed systemic signs of illness (dizziness, nausea, sore throat and shortness of breath) on both occasions. In the other incident, a mixer/loader in California spilled Supracide® on his coveralls, but continued to work before changing clothes. Two days later, he developed ataxia, dizziness and vomiting and was treated for organophosphate poisoning. This incident occurred in 1995 and is not included with the analysis of the California data discussed above.

The number of poisoning cases due to methidathion exposure reported to the Poison Control Center and the California Pesticide Illness Surveillance Program is small in relation to the numbers of poisoning cases associated with other OP and carbamate pesticides. Methidathion was not on the list of top 20 chemicals for which the National Pesticide Information Center (NPIC) received calls from 1984 through 1991, inclusive.

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 November 30, 1999, and its addendum, dated April 4, 2001, available in the public docket. Several revisions have been made since the preliminary risk assessment was completed and include the following: determining that the environmental fate database is adequate for the reregistration action; revising the assessment to use a foliar dissipation half-life of 6.6 days based on open literature, which did not significantly change the Agency's overall risk conclusions; correcting an error in the toxicity value used to calculate the chronic risk quotients for freshwater invertebrates, which significantly lowered the risk estimates for these organisms.

The Agency's risk assessment is based principally on methidathion's use on cotton, citrus, stone fruits, nut crops, and artichokes. Methidathion is registered for single as well as multiple applications (up to 8 per season for artichokes), but is typically applied only 1 - 2 times per season. A further refinement of methidathion's potential for ecological risk is possible due to its predominant use in California. The majority of methidathion is used on citrus as a foliar spray. Methidathion is also used on other orchard crops as a nonfoliar dormant spray from mid November through February and on cotton as an early season foliar spray.

The Agency's assessment suggests that the use of methidathion can result in adverse acute and chronic effects to terrestrial and aquatic organisms. The methidathion ecological risk assessment integrates the results of the exposure and ecotoxicity data to evaluate the potential for adverse ecological effects. The method divides exposure estimates by ecotoxicity data to derive risk quotients (RQs) for acute and chronic effects. RQs are then compared to levels of concern (LOCs), which are criteria used to indicate potential effects to nontarget organisms. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. An acute RQ equal to or greater than 0.5 and/or a chronic RQ equal to or greater than 1.0 results in some concern to the Agency, while RQs as low as 0.05 may be of concern under special circumstances (e.g., for endangered aquatic species).

Based on estimated environmental concentrations (EECs) from modeling and toxicity data for aquatic organisms, the Agency's levels of concern are exceeded for acute and chronic effects to fish and invertebrates. On avian and mammalian food items, methidathion's calculated foliar dissipation rate of 6.6 days combined with its toxicity result in levels of concern for potential chronic effects to birds which are exceeded for several weeks following application.

1. Environmental Fate and Transport

Methidathion is relatively nonpersistent in soil with aerobic and anaerobic soil half-lives of 11 and 10 days, respectively. Dissipation half-lives of 5 to 30 days were reported in the top six inches of soil in supplemental field studies. Methidathion is moderately mobile with soil-water partitioning coefficients (K_{ad}s) of 2 to15 mL/g. It is unlikely to persist in soil long enough to result in significant contamination of ground water. Methidathion may enter surface water via spray drift, in solution in runoff water and as residues adsorbed to eroding soil particles. With an aerobic soil half-life of 11 days and an anaerobic half-life of 10 days, methidathion is unlikely to persist in water long enough to be a serious ground water or drinking water problem.

The relatively low octanol/water partition coefficient for methidathion of 295 suggests that it will only moderately partition into the waxy component of leaves. At the time of foliar application, substantial amounts of applied methidathion could reach exposed soil and (to a lesser extent) penetrate the canopy to reach canopy shielded soil. It can also reach soil via washoff during post-application rainfall events.

The relatively low to moderate soil/water partitioning of methidathion (MRID 00158529) indicates that the methidathion reaching soil may have limited to moderate potentials for leaching and uptake by plants, and moderate to substantial potentials for runoff depending upon the soil and other conditions. However, the calculated overall half-lives of methidathion are 11.3 and 3 days from aerobic soil metabolism studies (MRIDs 44545101 and 42262501) and 10 days in an anaerobic soil metabolism study (MRID 42262501). Therefore, substantial fractions of the methidathion reaching soil may degrade and no longer be available for such physical removal processes within 1-3 weeks after reaching the soil.

None of the known degradates of methidathion are of toxicological concern. Therefore, these degradates are not included in this assessment.

2. Risk to Birds and Mammals

A study conducted using the mallard duck showed that methidathion was highly toxic to avian species on an acute oral basis. Two subacute dietary studies on the mallard duck (a waterfowl) and bobwhite quail (an upland gamebird) showed that methidathion was moderately to highly toxic on a subacute basis. (MRIDs 00157347, 00159201 and 42081701)

Table 10. Toxicity Endpoints to Assess Risk to Terrestrial Organisms from Methidathion

Species	Test Type	Results	Source of Data (MRID)
Bobwhite quail	sub acute dietary	LC_{50} = 224 ppm	42081701
Mallard duck	reproduction	NOAEC = 1 ppm LOAEC = 10 ppm (increased cracked eggs)	44381602
Laboratory rat	acute oral	LD_{50} = 12 mg/kg	00012714
Laboratory rat	acute dietary	1-day LC_{50} = 12 to 400 ppm[1]	N/A
Laboratory rat	2-generation reproduction	NOAEL = 5 ppm LOAEL = 25 ppm (lower mating index/pup weight)	40079812 40079813
Honey bee	acute contact	LD_{50} = 0.236 ug/bee	00036935
Honey bee	acute foliar residue	RT_{25} > 3 days at 5.0 lb a.i./A[2]	42081708

[1] 1-day LC_{50} = LD_{50} (mg/kg) / proportion of body weight consumed. The mammalian LD_{50} of 12 mg/kg was used to estimate 1-day LC_{50}s ranging from 12 ppm for a 15-gram herbivore (consumes 95%) to 400 ppm for a 1,000 gram granivore (consumes 3%)

[2] RT_{25} (residual time) time required to reduce mortality of caged bees to field weathered spray deposits

The following table shows predicted residues on terrestrial food items that result from single and multiple applications of methidathion calculated from Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994):

Table 11. Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1.0 lb. a.i./A

Food Items	EEC (ppm) Predicted Maximum Residue	EEC (ppm) Predicted Mean Residue
Short grass	240	85
Tall grass	110	36
Forage and small insects	135	45
Fruits, pods, seeds and large insects	15	7

These residues served as the initial concentrations from which first-order residue declines were calculated. When considering repeat applications, degradation over time is simulated from the first application to a period following the last application. The time period modeled varies, depending on the number of applications, the interval between applications and the length of time the residues were expected to exceed the chronic risk LOC. The program generates a peak value as well as a time-weighted average value for the time period modeled. The Fletcher peak maximum value for the food item was compared to the acute toxicity value to produce the acute RQ. For chronic exposure, the Fletcher mean value was used as the initial input. Both the peak mean and time-weighted average mean EECs were used to compute chronic RQs.

The Agency's assessment suggests the potential for acute effects to nontarget terrestrial organisms from all single and multiple applications at or above 0.5 lb a.i./A for all contaminated food items except seeds. Though the RQ at 0.5 lb. a.i./A from ingesting contaminated seeds exceeds the endangered species LOC for granivores, the Agency is more concerned about risk to

nontarget animals that ingest contaminated vegetation. The avian acute RQs range from less than 0.1 on contaminated seeds (single application at 0.5 lb. a.i./A) to 5.5 on short grass (3 applications with 7 day intervals at 3.0 lbs. a.i./A). For the same use patterns/food items, mammalian acute RQs range from less than 0.1 to 97. The following table illustrates that for typical application rates, with only one or two applications per year, acute LOCs (0.5) for birds are slightly exceeded, but small mammal LOCs are exceeded by a substantial margin.

Table 12. Avian/Mammalian Acute Risk Quotients[1] for Single Application of Methidathion

Site	App. Rate (Lbs. a.i./A)	Food Items	Peak Maximum[1] EEC (ppm)	Acute RQ (EEC/ LC50)
Avian Acute LC_{50} = 224 ppm (Bobwhite Quail)				
Almonds, walnuts, stone fruits	1.5 (1 application)	Short grass	360	2
		Forage	270	1.2
Citrus	2 (1 application)	Short grass	480	2
		Forage	270	1.2
Artichoke	1 (2 applications, 14 days apart)	Short grass	295	1.3
		Forage	166	0.7
Cotton	0.5 (2 applications, 5 days apart)	Short grass	191	0.8
		Forage	107	0.5
Mammalian (Herbivore/Insectivore) Acute LC_{50} = 12 to 80 ppm [2]				
Citrus	2 (1 application)	Short grass	480	6 - 38
		Forage	270	2 - 21
Almonds, walnuts, stone fruits	1.5 (1 application)	Short grass	360	4 - 28
		Forage	202	2 - 16
Artichokes	1 (2 applications, 14 days apart)	Short grass	295	166
		Forage	166	2 - 13
Cotton	0.5 (2 applications, 5 days apart)	Short grass	191	2 - 15
		Forage	107	1 - 8

[1] A foliar dissipation half-life 6.6 days (Willis et al. 1987) was assumed.
[2] One-day LC50 = LD50 (mg/kg) / proportion of body weight consumed. The mammalian LD50 of 12 mg/kg was used to estimate 1-day LC50s ranging from 12 ppm for a 15-gram herbivore (consumes 95%) to 400 ppm for a 1000 gram granivore (consumes 3%).

When the NOAECs from reproduction studies are compared to estimated exposure levels, the avian chronic RQs range from 1.0 (the 30-day time-weighted mean on seeds for a single application at 0.5 lbs. a.i./A) to 436.0 (the peak mean on short grass for 3 applications at with 7 day intervals at 3.0 lbs. a.i./A). When the NOAEL in the 2-generation rat study is used as an endpoint, the chronic RQs range from less than 1 to 87. For both birds and mammals, most of the RQs are well above the Agency's level of concern. The following table illustrates that for typical

application rates, with only one or two applications per year, chronic LOCs are exceeded by a substantial margin and may last for several weeks. In most cases, the time weighted average mean as well as the peak mean and estimated exposure levels exceed the test levels at which effects were observed (LOAECs).

Table 13. Avian/Mammalian Chronic Risk Quotients[1] for Methidathion

Site	Application (lb a.i./A)	Food Items	Peak Mean EEC (ppm)	RQ	Time Wgt Avg. Mean EEC (ppm)	RQ	# Days Peak Mean > LOC
Avian Chronic NOAEL = 1 ppm, LOAEL = 10 ppm							
Almonds Walnuts Stone Fruits	1.5 lbs./A (1 application)	Short grass	128	128	40	40	> 30
		Forage	68	68	21	21	
Artichoke	1.0 lb./A 2 apps /14 days	Short grass	104	104	50	50	> 30
		Forage	55	55	27	27	
Cotton	0.5 lb./A 2 apps/5 days	Short grass	68	68	27	27	> 30
		Forage	36	36	14	14	
Mammal Chronic NOAEL = 5 ppm, LOAEC = 25 ppm							
Almonds Walnuts Stone Fruits	1.5 lb./A 1 app	Short grass	128	25	40	8	> 30
		Forage	68	13	21	4	25
Artichoke	1.0 lb/A 2 apps/14 days	Short grass	104	21	50	10	> 30
		Forage	55	11	27	5	
Cotton	0.5 lb/A 2 apps/5 days	Short grass	68	14	27	5	> 30
		Forage	36	7	14	3	24

[1] A foliar dissipation half-life 6.6 days was assumed, FATE model run was for 30 days.

The acute and chronic RQs are based solely on dietary exposure via contaminated food sources. Other routes of exposure, including dermal, inhalation and drinking from contaminated puddles might also be important (Driver *et al.* 1991) and could increase acute risks if methods were available to include them in the risk assessment. Other factors contributing to uncertainty (especially for chronic effects) include the point during the reproductive cycle that exposure occurs and the duration of exposure required to cause physiological or sublethal effects to adults that may impact breeding and nurturing behavior.

3. Risk to Aquatic Species

Although Tier II PRAM EXAM modeling with Index Reservoir and Percent Crop Area input was used to refine the Drinking Water Assessment, those EECs were not used for an Ecological Aquatic Risk Assessment. Whereas, EECs for a Drinking Water Assessment are to reflect concentrations found in reservoirs providing drinking water to a community, the EECs for an ecological assessment reflect what non target, non human organisms would be exposed to in a shallow pond adjacent to an area treated with a pesticide. Tier II modeling for only the typical use on three crops – apples (surrogate for nut and stone fruits), citrus and cotton – concentrations of methidathion in surface water, when combined with toxicity values, exceed LOCs for acute and chronic effects to fish and invertebrates. The risk would be higher for the present maximum labeled rates for the same uses. In, California where the majority of methidathion is used, mostly as a dormant spray, aquatic organisms are likely to be exposed through runoff during the winter rainy season. During the remainder of the year, surface water contamination would be primarily through drift. The following table contains the toxicity values used in the risk assessment.

Table 14. Toxicity Endpoints to Assess Risk of Aquatic Organisms from Methidathion

Species	Test Type	Results (ppb of a.i.)	Source of Data (MRID)
Freshwater Species			
Bluegill	Acute	LC_{50} = 2.2	00011841
Fathead minnow	Early Life Stage	NOAEC = 6.1 LOAEC = 12.0 (reduced post hatch survival and growth)	00015735
Water flea (*Daphnia magna*)[1]	Acute	LC_{50} = 3.0	42081704
Water flea	Life Cycle	NOAEC = 0.66 LOAEC = 1.13 (reduced young per female per day)	42081707
Marine Species			
Sheepshead minnow	Acute	LC_{50} = 7.8	00157350
Eastern oyster larvae	Acute	EC_{50} = 7.9	40079815
Mysid[1]	Acute	EC_{50} = 0.59	42207902
Mysid	Life Cycle	NOAEC = 0.022 LOAEC = 0.061 (reduced adult survival)	00157351

[1] Study conducted on 2E (25.5% a.i.).

Freshwater Species

For freshwater fish, the acute RQs based on Tier II modeled EECs range from 0.4 (2 aerial applications of 0.5 lb a.i./A to cotton in California) to 4.0 (1 air blast application of 2.0 lbs a.i./A to citrus in Florida). The acute risk LOC is exceeded by multiple applications at rates greater than or equal to 0.5 lb a.i./A, and single applications at rates greater than or equal to 1.5 lbs a.i./A. For freshwater fish, the chronic RQs for the same scenarios ranged from 0.19 (2 aerial applications of 0.5 lb a.i./A to cotton in California) to1.88 (1 air blast application of 2.0 lbs a.i./A

to citrus in Florida). Multiple applications of methidathion at 0.5 lb a.i./A and greater, and single applications of 2 lbs a.i./A and greater resulted in exceedance of the chronic LOC.

For freshwater invertebrates, the acute RQs based on Tier II modeled EECs range from 0.9 (2 aerial applications of 0.5 lb a.i./A to cotton in California) to 8.9 (1 air blast application of 2.0 lbs a.i./A to citrus in Florida). The acute risk LOC is exceeded by multiple applications at rates greater than or equal to 0.5 lb a.i./A, and single applications at rates greater than or equal to 1.5 lbs a.i./A. Chronic RQs for the same scenarios ranged from 2.8 (2 aerial applications of 0.5 lb a.i./A to cotton in California) to 28.5 (1 air blast application of 2.0 lbs a.i./A to citrus in Florida). All application rates exceed the chronic LOC.

The monitoring data mentioned by the registrant is not sufficiently robust enough for use in an ecological risk assessment. As stated in the USGS NAWQA report - "Pesticide data for surface water are insufficient to calculate loads or yearly trends, but can be used to assess geographic and seasonal occurrence of select pesticides and to relate their agricultural use in the study unit." The monitoring results thus can only be used as an indication of seasonal occurrence and not for quantitative aquatic exposure purpose. NAWQA data are usually not targeted specifically to methidathion and its use and therefore have limited utility in an ecological assessment. There is a lack of correlation between sampling dates and the use patterns of the pesticide within the study's drainage basin. Due to different analytical detection limits, no specified detection limits, or high detection limits, a detailed interpretation of the monitoring data is not always possible. Even based on the limited monitoring data, the methidathion concentration has been detected as high as 15.1 ug/L. (the more typical range is 0.07 – 2.25 ug/L) in the Sacramento-San Joaquin drainage system. The monitoring data are comparable with the peak concentrations of the modeling results for the typical California citrus (5.65 ug/L) and California cotton (2.69 ug/L) scenarios, even though the modeling simulates standing water environment (e.g., a farm pond), where the monitoring focuses on moving water (e.g., creek, stream or river).

The primary area of uncertainty associated with the freshwater aquatic risk assessment is for chronic risk due to the use of the fathead minnow Fish Early Life Stage test. The NOAEC of 6.1 ppb is virtually the same as the LC_{50}s of several other test species including: rainbow trout ranging from 6.6 ppb (MRID 420081703) to 14 ppb (MRID 40098001); bluegill ranging from 2.2 ppb (MRID 00011841) to 9 ppb (MRID 40098001) and gold fish at 6.8 ppb (MRID 00011841). In the absence of a fathead minnow LC_{50} and application factor cannot be calculated to estimate chronic values for these other fresh water fish. However, a preliminary interpretation of the existing data suggests that if any of these other species were tested, the NOAEC would be lower. Therefore, unless there was a further refinement of methidathion residues in water, the potential for chronic risk to fish will be greater than the current estimate.

Estuarine Species

For estuarine fish, the acute RQs based on Tier II modeled EECs range from 0.34 (2 aerial applications of 0.5 lb a.i./A to cotton in California) to 3.4 (1 air blast application of 2.0 lbs a.i./A to citrus in Florida). The acute risk LOC is exceeded by applications of 0.5 lb a.i./A and greater. Chronic risk to marine/estuarine fish from methidathion cannot be assessed at this time due to a lack of acceptable early life-stage or life-cycle data. Since the acute toxicity of methidathion to freshwater fish (2.2 to 14 ppb) is similar to the toxicity to marine/estuarine fish (7.8 ppb), it is likely that the chronic toxicity would also be similar. Comparable or greater risk should be assumed for marine/estuarine species until acceptable data are received and a complete risk assessment can be performed. In light of the earlier discussion that the freshwater fish chronic NOAEC is probably less than 6.1 ppb, there is uncertainty as to the potential risk to estuarine fish.

For estuarine invertebrates, the acute RQs based on Tier II modeled EECs range from 0.3 for oysters and 3.84 for mysids (2 aerial applications of 0.5 lb a.i./A to cotton in California) to 38 for mysids (1 air blast application of 2.0 lbs a.i./A to citrus in Florida). Mysid chronic RQs range from 92 to 944 for these same use patterns. Except for acute risk to oysters, acute and chronic LOCs are exceeded for estuarine invertebrates at all application rates; suggesting that part of this group of organisms may be negatively effected at least temporarily. Methidathion's use in areas near estuaries could potentially impact invertebrates, including shrimp and oyster operations. Effects on invertebrate numbers and/or diversity could also affect commercial and recreational fisheries, since aquatic invertebrates are the basis of the food supply for many fish species.

Currently the predominant usage area for methidathion is California. One of the estuaries that has been surveyed for pesticide contamination is Monterey Bay. While it is difficult to determine the actual ecological impacts of agricultural pesticides on the Monterey Bay, nearly twenty years of monitoring data demonstrate that a host of agricultural pesticides flushing from adjacent agricultural land are bioaccumulating in the Region's fish and shellfish. Monitoring data collected by the California State Water Resources Control Board and the California Department of Fish and Game through their State Mussel Watch Program (SMWP) provide information on agricultural chemical contamination in the Monterey Bay Area.[1] These data are based on sampling from 41 sites flowing into the Monterey Bay from Santa Cruz to Carmel. The SMWP provides a uniform statewide approach to the detection and evaluation of the occurrence of toxic substances in the waters of the California's bays, harbors and estuaries through the analysis of mussels and clams. Similar findings of pesticide residues in fish in the drainages to Monterey Bay by the State Board's Toxic Substances Monitoring Program[2] support these SMWP findings. While most of the data collection has occurred in inland drainages without the benefit of seawater dilution, data from more limited points in harbors and coastal locations indicate that pesticides

[1] State Mussel Watch Program, 11987-93 Data Report, 94-1WQ, State Water Resources Control Board, Cal-EPA, March, 1995.

[2] Toxic Substances Monitoring Program, 1991 Data Report, 93-1WQ, State Water Resources Control Board, Cal-EPA, June, 1993.

may be accumulating in the biota of the Bay itself. Residues found in mussels (estuarine and fresh water) and relocated fresh water clams indicate that pesticides are entering into Monterey Bay. According to Victor De Vlaming of the California State Water Resources Control Board, neither of these two monitoring programs analyze for methidathion. However, two other organophosphate pesticides used as dormant sprays in orchards, diazinon and chlorpyrifos, are found in tissues of sentinel organisms.

Methidathion's present use in California suggests that its adverse impact on estuarine organisms is likely to be limited because very little methidathion is used near estuaries. Artichokes, principally in Monterey county, are grown along the Salinas and Pajaro Rivers within a quarter mile of Pajaro lagoon in Monterey Bay. However methidathion is applied to artichokes during June and July (USDA Crop Profiles) when there is little or no rainfall resulting in runoff. Therefore, a quarter of a mile may provide a sufficient buffer for spray drift contamination. All other California uses of methidathion (e.g., cotton, orchards) are either in noncoastal counties or in coastal counties where the treated acreage is extremely low and some distance from estuaries. Along with dilution and mixing by salt water, methidathion residues may be below levels of concern for estuarine organisms including invertebrates.

The Agency acknowledges that there is uncertainty associated with extrapolating EECs from its freshwater aquatic scenario to estuarine and marine environments. In the absence of relevant data, it is not possible to determine whether the modeled exposure is higher, lower or comparable to residue values that would be monitored in estuaries. EPA recognizes that the field-edge pond is not an estuarine habitat, yet at the same time, the assessment must accommodate edge of field estuaries that are relatively slow moving backwater areas with minimal exchange and minimal freshwater flow-through. Many estuaries are not fast moving, fast exchanging bodies of water that are diluted and replenished regularly. Some backwater areas simply rise and fall with tidal action, and only are exchanged over days, as water passes through narrow channels to the larger saltwater habitat or as runoff events cause freshwater recharge. Irrespective of uncertainties in the exposure estimates used for estuaries, methidathion's impact to non-target estuarine organisms is likely to be limited because most current uses of this insecticide are not in close proximity to estuaries. However, should the future use of methidathion expand to include treated areas adjacent to estuaries there is the potential for adverse effects to fish and invertebrates which could result in damage to ecological and commercial resources.

4. Risk to Nontarget Insects

Methidathion is classified as very highly toxic to bees on an acute contact basis. The results of the residual toxicity study indicate that not only will bees be at acute risk when sprayed directly, but also from exposure to foliage as long as 3 days after treatment at 5.0 lbs. a.i./A. The maximum and typical single application rates for Supracide® 25WP are 3.0 and 2.0 lbs. a.i./A respectively. Therefore, the available residual study does indicate how long bees would be at risk from these lower rates. According to the reference Pollinator Protection, A Bee and Pesticide Handbook, C.A. Johansen and D.F. Mayer (pg 179), the honey bee RT_{25} is 1– 3 days at 1 lb. a.i./A for methidathion. To reduce the likelihood for significant mortality to bees precautionary labeling must be followed.

Additionally, quoting directly or paraphrasing, Johansen *et. al* reports; The time of day an insecticide is applied directly impacts its risk to foraging bees (pg 71). Bee kills are often 2-4 times greater when applications are made in early morning as when they are made in late evenings (pg 73). Methidathion should not be applied to crops in bloom and when adjacent crops, interplants and weeds in orchard cover crops or field edges are flowering (pg 128). To reduce the risk to bees, flowering weeds should be eliminated from orchard cover crops or field edges (pg 129). This is especially important when there is a dearth of pollen and nectar plants in the area and bees may fly for several miles in search of flowers (pg 129). The potential risk to bees is greatest from aerial applications (pg 82). Spray drift off the target areas causes most bee kills (pg 82). Small pesticide particles in the air blown into blooming crops or weeds are a major factor in bee poisoning (pg 82-83). Ground sprays are generally considered safer than aerial applications because there will be less drift and smaller areas are treated at one time (pg 129). Johansen also recommends that during aerial applications, the aircraft should not be turned, nor the materials transported back and forth across blossoming fields (pg 128).

5. Endangered Species

All uses of methidathion exceed the endangered species LOC for all forms of endangered animal species: avian acute and chronic, mammalian acute and chronic, freshwater fish acute and chronic, freshwater invertebrate acute and chronic, marine/estuarine fish acute and chronic. Although the endangered species LOCs for estuarine invertebrates have been exceeded, there are no listed species. 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 imposing label modifications at this time through the interim RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

6. Incident Reports

In spite of methidathion's high acute toxicity to all classes to organisms, the Agency has received documented field kills only for birds. California monitors the impact of dormant sprays on raptors wintering in the central valley. The Agency received 5 reports from the California Department of Fish and Game. Four red-tailed hawks (*Buteo jamaicensis*) and one northern harrier (*Circus cyaneus)*, sent to the Pesticide Investigation Unit from January 1994 through December 1997 contained residues of methidathion. Four of the five birds were found in or adjacent to orchards.

All birds were subjected to foot washing to analyze for organophosphate residues; methidathion residues ranged from 2.7 ppb to 12 ppm. The presence of residues on the feet indicates the birds perched in treated trees within 72 hours of the time the foot wash was performed. In addition to dermal absorption through the feet, the raptors could have been exposed through ingestion of contaminated prey (the stomach contents of the harrier contained 15 ppm of methidathion) or while preening (the feathers of one red-tail contained 0.09 ppm) after being sprayed directly or from drifting aerosols. When exposed to drift or direct spray the birds would acquire additional residues via inhalation. Three of the birds showed brain cholinesterase levels less than 50% of normal. Such findings indicated that death, or severe impairment that would have lead to death, was the result of exposure to one or more cholinesterase inhibiting agents. The two remaining birds, one of which survived and was released, had their blood plasma analyzed for cholinesterase and acetylcholinesterase levels. The level in the surviving bird was below the normal range whereas the level of the euthanized bird were at the lower range of normal levels.

In light of mortality to raptors, the Agency has concern for small birds and mammals. Carcasses of small birds and mammals are extremely difficult to find or the incidents are not reported unless kills are extensive. Because other birds and small mammals are exposed to similar routes of exposure (inhalation, dermal, drinking water, dietary consumption) as raptors the Agency presumes they too are at risk from methidathion.

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 is 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 methidathion active ingredients.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient methidathion, as well as a methidathion-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 methidathion, EPA has sufficient information on the human health and ecological effects of methidathion to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that methidathion 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) cumulative risks considered 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 methidathion and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet considered its cumulative risks 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 methidathion. Based on its current evaluation of methidathion alone, the Agency has determined that methidathion 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 methidathion.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For methidathion, 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 methidathion 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 considered the cumulative risks for the organophosphates, this interim RED does not fully satisfy the reassessment of the existing methidathion food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has considered cumulative risks, methidathion tolerances will be reassessed in that light. At that time, the Agency will reassess methidathion 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 methidathion, 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 the assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

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

B. Summary of Phase 5 Comments and Responses

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

Of the eleven comments, ten were received from growers or grower groups and one comment was received from the registrant (Gowan Company). The comment from the registrant challenged many of the data and assumptions contained in the Agency risk assessment. Grower and grower groups who submitted comments include: Ed Chambers Farm Management; LoBue Brothers, Inc.; California Citrus Mutual; Claussen Family Partnership; AgriCare Production Specialists; Sun World International, Inc.; Associated Citrus Packers, Inc.; Almond Hullers & Processors Association; Mulholland Citrus Trees and Sea Mist Farms. Many of the comments from grower and grower groups expressed the need for continued use of methidathion on artichokes and other crops. Commentors emphasized that methidathion is an important tool for Integrated Pest Management and without it, resistance would develop quickly because of limited effective alternatives. Comments were also received on the safety of methidathion products to field workers. Since they are sold in water-soluble bags, used in a closed system and because of the extensive training provided to mixers, loaders and applicators, worker exposure problems have not been experienced and are not expected.

The Agency also took into account three other comments that were received after the formal comment period had closed. Dr. Robert I. Krieger, an extension toxicologist with the University of California, Riverside, submitted comments about the lack of an EPA policy concerning off-site pesticide exposures. California Citrus Mutual submitted additional information about harvesting activities and a description and data about the differences between growing practices in California and Florida. Anne Katten of the California Rural Legal Assistance Foundation submitted comments supporting the 30-day REI established by the State of California for citrus groves and challenged the Agency's policy of relying on data that has been generated by the registrants to establish REIs.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with methidathion. 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 consider 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 methidathion is within its own "risk cup." In other words, if methidathion did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for methidathion 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 methidathion "fit" within the individual risk cup. Therefore, the methidathion tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is considered.

b. Tolerance Summary

The tolerances listed in 40 CFR §180.298(a and c) are expressed in terms of methidathion (S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)-yl) methyl] O,O-dimethyl-phosphorodithioate) *per se* and its metabolites; i.e., its oxygen analog (S-[(5-methoxy-2-oxo-1,3,4-thiadiazole-3-(2H)-yl)methyl] O,O-dimethyl-phosphorothioate), its sulfoxide metabolite (2-methoxy-4-(methylsulfinylmethyl)-1,3,4-thiadiazole-5-one) and its sulfone metabolite (2-methoxy-4-(methylsulfonylmethyl)-1,3,4-thiadiazole-5-one).

Tolerances Listed Under 40 CFR §180.298(a)

Methidathion residues are generally not expected to occur in any food commodities except citrus. Methidathion is nonsystemic and is applied to pome fruits, stone fruits, tree nuts and some other crops before the edible portion of the plant has formed. Foliar treatments of citrus commodities while the fruit are on the tree do result in residues; however, these residues are almost entirely limited to the peel. Processing of these fruits result in some residues in fruit and

juice at very low levels. USDA PDP data are available for apples, apple juice, oranges, grape fruit, peaches and canned pears.

Adequate data are available to support the established tolerances for methidathion residues in/on the commodities listed in Table 15. The established tolerance for residues in/on citrus fruit should be increased from 2 ppm to 4 ppm, as residues of 3.4 and 3.5 ppm have been observed following registered use. The group commodity definitions "Almonds, hulls" and "Artichokes" should be revised to "Almond, hulls" and "Artichoke, globe," respectively. The group commodity definitions "Citrus Fruits (except mandarins)" and "Citrus Oil" should be revised to "Fruit, citrus, except mandarin" and "Citrus, oil," respectively. The group commodity definitions "Cottonseed" and "Cotton gin byproducts" should be revised to "Cotton, undelinted seed" and "Cotton, gin byproducts," respectively. The group commodity definitions "Fruits, pome" and "Fruits, stone" should be revised to "Fruit, pome, group" and "Fruit, stone, group," respectively. The tolerance for peaches is not necessary as peaches are covered by the tolerance for residues in/on "Fruits, stone;" therefore, EPA recommends reassignment of the tolerance for peaches to the Fruit, stone, group designation. The group commodity definition for "Kiwi Fruit" should be amended to reflect the correct crop group designation "Kiwifruit." The group commodity definitions "Mandarins" and "Mangos" should be revised to "Tangerine" and "Mango," respectively. The group commodity definition for "Nuts" should be amended to reflect the correct crop group designation "Nut, tree, group," and the tolerances for pecans and walnuts, which are covered by the Nut, tree, group designation, should be reassigned. The group commodity definitions "Olives" and "Safflower seeds" should be revised to "Olive" and "Safflower seed," respectively. The group commodity definitions "Sorghum, fodder," "Sorghum, forage" and "Sorghum, grain" should be revised to "Sorghum, grain, stover," "Sorghum, grain, forage" and "Sorghum, grain, grain," respectively. The group commodity definition for "Sunflower seeds" should be amended to reflect the correct crop group designation "Sunflower, seed."

Tolerances Needed Under 40 CFR §180.298(a)

Field residue data are required to determine a tolerance level on methidathion in the plant byproducts from ginning cotton, consisting of burrs, leaves, stems, lint and immature seeds. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. At least three field trials for each type of harvesting (stripper and mechanical picker) are needed, for a total of six field trials. The need for additional tolerances and revisions to the exposure/risk assessments will be made upon receipt and evaluation of required data. When adequate field residue data have been submitted, a tolerance must be proposed for this commodity.

Tolerances Listed Under 40 CFR §180.298(b)

On August 2, 1999 (64 FR 41933), the Agency published its determination that there is no reasonable expectation of finite residues in or on meat, milk, poultry and egg commodities

associated with methidathion, and some other specific pesticides, based on exaggerated feeding studies (10x the dietary burden) which did not show measurable residues. On October 5, 2001 (66 FR 50829), the Agency revoked methidathion tolerances in the animal commodities [40 CFR §180.298(b)] effective January 3, 2002 for cattle, fat; cattle, mbyp; cattle, meat; eggs; goat, fat; goat mbyp; goat, meat; hog, fat; hog, mbyp; hog, meat; horse, fat; horse, mbyp; horse, meat; milk; poultry, fat; poultry, mbyp; poultry, meat; sheep, fat; sheep, mbyp; and sheep, meat. Pursuant to 40 CFR §180.6(a)(3), the Agency revoked those tolerances because they are no longer needed to cover residues of methidathion and its metabolites; i.e., its oxygen analog, the sulfoxide metabolite and the sulfone metabolite on those commodities.

Tolerances (with regional registration) Listed Under 40 CFR §180.298(c)

Adequate data are available to support the established tolerances for methidathion residues in/on carambola, kiwifruit, longan and sugar apple. The Special Local Need (SLN) label language for use on clover grown for seed contains restrictions to prevent food or feed use of treated plant parts.

The registrant has requested to maintain a regional SLN registration for the use of methidathion on alfalfa, timothy hay and timothy-alfalfa mixes (primarily timothy) in Kittitas County, WA only. Approximately 85% of this crop is exported to Japan and Taiwan. There are no other registered or potential alternatives for methidathion to control grass scale, thrips and mites on these crops. Most of the hay that is not exported is consumed by horses, not by dairy or beef cattle; therefore, the potential for dietary intake of methidathion via meat and milk consumption is negligible.

In conclusion, the tolerances on alfalfa and alfalfa hay should be lowered to 5 ppm and reassigned to tolerances with regional registration under 40 CFR §180.298(c). The tolerances on grass and grass hay (currently under 40 CFR §180.298(a)) should be reassigned to tolerances with regional registration under 40 CFR §180.298(c) for timothy and timothy hay and should also be lowered to 5 ppm. A summary of the methidathion tolerance reassessment and recommended modifications in commodity definitions are presented below in Table 15.

Table 15. Tolerance Reassessment Summary for Methidathion.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.298(a)			
Alfalfa	12.0	Reassign	Establish regional tolerances under 40 CFR §180.298(c)
Alfalfa, hay	12.0		
Almonds, hulls	6.0	6.0	*[Almond, hulls]*
Artichokes	0.05	0.05	*[Artichoke, globe]*
Citrus Fruits (except mandarins)	2.0	4.0	*[Fruit, citrus, except mandarin]* Increased residues observed in field trials
Citrus oil	None	420	*[Citrus, oil]* Residues concentrate an average of 118x in oil processed from methidathion-treated oranges.
Cottonseed	0.2	0.2	*[Cotton, undelinted seed]*
Cotton gin byproducts	None	To be determined	*[Cotton, gin byproducts]* Residue data are required to determine the appropriate tolerance level.
Fruits, pome	0.05	0.05	*[Fruit, pome, group]*
Fruits, stone	0.05	0.05	*[Fruit, stone, group]*
Grass	12.0	Reassign	Establish regional tolerances under 40 CFR §180.298(c)
Grass, hay	12.0		
Mandarins	6.0	6.0	*[Tangerine]*
Mangos	0.05	0.05	*[Mango]*
Nuts	0.05	0.05	*[Nut, tree, group]*
Olives	0.05	0.05	*[Olive]*
Peaches	0.05	Reassign	Covered by Fruit, stone, group
Pecans	0.05	Reassign	Covered by Nut, tree, group
Safflower seeds	0.5	0.5	*[Safflower seed]*
Sorghum, fodder	2.0	2.0	*[Sorghum, grain, stover]*
Sorghum, forage	2.0	2.0	*[Sorghum, grain, forage]*
Sorghum, grain	0.2	0.2	*[Sorghum, grain, grain]*
Sunflower seeds	0.5	0.5	*[Sunflower seed]*
Walnuts	0.05	Reassign	Covered by Nut, tree, group
Tolerances Listed Under 40 CFR §180.298(c)			
Alfalfa	12.0	5.0	Restricted to Kittitas County, WA; other sites are restricted to seed production.
Alfalfa, hay	12.0	5.0	
Carambola	0.1	0.1	
Kiwi Fruit	0.1	0.1	*[Kiwifruit]*
Longan	0.1	0.1	
Sugar Apple	0.2	0.2	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment *[Correct Commodity Definition]*
Timothy	12.0	5.0	Restricted to Kittitas County, WA. Other sites are restricted to seed production. Covered by Grass.
Timothy, hay	12.0	5.0	Restricted to Kittitas County, WA. Other sites are restricted to seed production. Covered by Grass, hay.

The Agency will commence proceedings to revoke, modify (lower) the existing tolerances and correct commodity definitions. The establishment of a new tolerance or raising tolerances will be deferred, pending the outcome of cumulative risks.

2. Endocrine Disruptor Effects

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

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

3. Benefits and Alternatives

In considering benefits and alternatives, EPA has focused on the dormant sprays on orchard crops which pose risk to birds and air blast applications to citrus at the maximum rate of 5 lbs a.i./A which would pose risk to applicators. Other risks discussed in this section can be mitigated to acceptable levels with standard mitigation measures; benefits have not been considered for those uses.

Dormant Sprays to Orchard Crops

Methidathion is used primarily to control San Jose scale in apples, peaches, pears and nuts and to control peach twig borer in peaches, nectarines and apricots. If heavy infestations of San Jose scale are left unchecked, trees may be seriously damaged, resulting in reduced vigor, thin foliage, cracked or dying branches and the eventual death of the tree. Young trees may be killed before fruiting. Due to the damage potential of this pest, annual dormant sprays are recommended in most areas. Some alternatives to methidathion exist, but are also organophosphates, e.g., chlorpyrifos and diazinon.

Peach twig borer damages crops in two ways. Larvae burrow down tender shoots and kill the tip, which causes problems in training young trees. They also feed on fruit, primarily at the stem end. Either feeding damage or the presence of larvae will cause fruit to be off grade and results in decreased revenue for growers. Dormant sprays are used in orchards with a history of infestation; monitoring and postbloom sprays can be used in orchards without a history of peach twig borer damage. Alternatives to methidathion include diazinon and pyrethroids.

Air Blast Application to Citrus at Maximum Rate

Methidathion is used to control numerous types of scale on citrus in Arizona, Florida, California and Texas. Labeled application rates range from 0.25 to 5 lbs a.i./A. Usage data available to EPA indicate that actual use rates range from 1 to just over 4 lbs a.i./A, with an average of 3 lbs a.i./A. There are registered, efficacious alternatives to methidathion on citrus. However, the most efficacious alternatives are other organophosphates (i.e., chlorpyrifos and ethion). It should be noted that as a result of reregistration review, ethion is being phased out. Based on the usage information available, it is reasonable to conclude that severe infestations requiring treatment at the maximum rate of 5 lbs a.i./A are sporadic.

D. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

The Agency has no risk concerns for any dietary (food and drinking water) exposure to methidathion (acute or chronic) when it is applied at 3.0 lbs a.i./A, which is the typical rate on citrus and the maximum rate on all other crops. Therefore, no risk mitigation is necessary when methidathion is applied at this rate.

When methidathion is applied at the maximum rate on citrus of 5.0 lbs a.i./A, the expected concentration in surface water is 28.5 ppb, which is above the DWLOC of 19.1 for infants. However, when methidathion is not applied within 50 feet of surface water, the expected concentration drops to 10.8 ppb, which is no longer of concern. Therefore, the use of methidathion at rates greater than 3.0 lbs a.i./A is eligible for reregistration, provided this buffer zone is included on the labels as specified in Table 17.

b. Occupational Risk Mitigation

1) Agricultural Uses

The Agency has concerns about workers using methidathion in several different scenarios. Each is discussed below.

Mixing/Loading Water Soluble Packs for Aerial Application

The MOEs for workers mixing/loading the water-soluble package (WSP) formulation for aerial application are 27 and 39, depending on the application rate that the worker uses and the acreage to be treated. The Agency has proposed, and the registrant has agreed, to limit the use WSP formulation to nonaerial applications. Under this proposal, the WSP formulation will only be available for air blast or groundboom applications.

EPA acknowledges the uncertainties associated with the risk assessment for mixing and loading WSP for aerial application. Because current WSP data in PHED are of lower quality, the Agency is investigating the possibility of requiring additional inhalation and passive dosimetry studies for workers using the WSP. Should the Agency call in this data, it would levy the requirement on all chemicals with this use pattern so that the cost of conducting the studies could be shared across the industry. This additional data would lessen the uncertainties involved in estimating the risks of exposure to workers using the WSP.

Air Blast Application to Citrus

To mitigate the concern for air blast applicators in citrus groves, the registrant has agreed to require a minimum of 500 gallons of water per acre be used to dilute methidathion products. This change is expected to limit the exposure to applicators as well as ensure that the methidathion covers the area more uniformly. At the typical application rate, the MOEs for mixers/loaders and applicators are all above 100. However, at the highest application rate, the MOEs for the mixers/loaders and applicators using methidathion on citrus are 85 for mixers/loaders and 53 for applicators. The Agency is not proposing that enclosed cabs be required for this use pattern because usage data indicate that the 5-lb rate is only occasionally necessary to control heavy infestations and that the acreage typically treated with methidathion is approximately one-half of the maximum assumed in the Agency risk assessment.

The following table summarizes the engineering controls and additional PPE that is needed on the label for the different agricultural use scenarios.

Table 16. PPE Summary for all Agricultural Scenarios

Scenario	PPE (in addition to long sleeved shirt, long pants, socks and shoes)	Engineering Controls
Mixing/Loading Wettable Powders - Groundboom (1c & 1d)	Chemical-resistant gloves and chemical-resistant apron	WSP
Mixing/Loading WSP - Air blast (1e)	Chemical-resistant gloves and chemical-resistant apron	WSP
Mixing/Loading Liquids - Aerial (2a & 2b)	Chemical-resistant gloves and chemical-resistant apron	Closed system
Mixing/Loading Liquids - Groundboom (2c & 2d)	Chemical-resistant gloves, chemical-resistant apron and an organic vapor-removing respirator	None
Mixing/Loading Liquids-Air blast (2e)	Chemical-resistant gloves, chemical-resistant apron	None
Applying with Aircraft (3a & 3b)	None	Closed cockpit
Applying with Groundboom (4a & 4b)	Chemical-resistant gloves and an organic vapor-removing respirator	None
Applying with Air blast Sprayer (5)	Double-layer clothing, chemical-resistant gloves, chemical-resistant apron and an organic vapor-removing respirator	None
Mixing/Loading/Applying with Low-Pressure Handwand (6)	None	None
Mixing/Loading/Applying with Backpack Sprayer (7)	None	None
Flaggers - liquid application (8)	Not applicable	Human flaggers are prohibited

2) Post-Application Risk

Based on data summarized in Section III.A, the REI for methidathion will be established at 3 days for all crops. This is based on the day at which MOEs are greater than 100 for activities other than harvesting. For tree crops and artichokes, the REI is being established on non-harvesting activities, as the label prohibits harvesting before the preharvest interval has expired. For tree crops, the preharvest interval of at least 14 days is substantially longer than 8 days, which is the day at which the harvesting activity is greater than 100. For artichokes, methidathion cannot be applied after the bud is formed, which will yield a harvest of substantially longer than 19 days, which, again is the day at which the harvesting activity is greater than 100. Therefore, the Agency believes that an REI of 3 days will sufficiently protect workers.

2. Environmental Risk Mitigation

The environmental risk assessment suggests that exposure to methidathion could result in both acute and chronic risks of concern for terrestrial and aquatic organisms.

a. Avian Species Mitigation

The Agency's risk assessment for avian species exceeds the level of concern for both acute and chronic exposure. However, based on communications with the California Department of Fish and Game, the Agency believes that these risks may not be unreasonable. Two of the major uses in California, dormant spray to orchards and foliar spray to cotton, would result in little or no exposure to breeding birds. One rare exception could occur among mourning doves in orchards if there had been limited rain fall and warm weather. Mourning doves produce multiple clutches and, like most other birds, do not breed during the dormant spray period, but rather from April through June. Foliar sprays to cotton and citrus coincide with the breeding period of many species of birds. Although cotton fields provide little suitable habitat for breeding birds, citrus orchards are attractive to birds, therefore methidathion's use should present both acute and chronic risk. The Agency assumes a similar degree of risk to breeding birds in other states.

To address avian risk, the Agency believes that the additional dilution of methidathion products (a minimum of 500 gallons of water per acre) intended to reduce exposure to workers may also reduce exposure to birds by eliminating concentrations of pesticide and by reducing the amount of pesticide on food items. The registrant has also agreed to additional precautionary labeling to protect avian species.

b. Aquatic Species Mitigation

Methidathion's present use in California suggests that its adverse impact on estuarine organisms is likely to be limited because very little methidathion is used near estuaries. Artichokes (principally in Monterey county) are grown along the Salinas and Pajaro Rivers, within a quarter mile of Pajaro lagoon in Monterey Bay. However, methidathion is applied to artichokes during June and July when there is little or no rainfall resulting in runoff. Most other California uses of methidathion (e.g., cotton, orchards) are in non coastal counties. The remainder are in coastal counties where the treated acreage is extremely low and some distance from estuaries. methidathion is conveyed by streams and rivers to coastal areas and diluted with salt water, residues may be below levels of concern for estuarine organisms including invertebrates. Methidathion may, however, have an impact on freshwater organisms. The following measures are expected to mitigate these risks.

For all applications applied at rates greater than 3.0 lbs a.i./A:

– Do not apply within 50 feet of lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries

For all applications applied at rates of 3.0 lbs a.i./A or less:

– Do not apply within 25 feet of lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries

For ground applications:
– Shut off sprayer when turning at end rows
– Do not apply when gusts or sustained winds exceed 12 mph

For air blast application:
– Adjust deflectors and aiming devices so that spray is only directed into the canopy
– Block off upward pointed nozzles when there is no overhanging canopy
– Use only enough air volume to penetrate the canopy and provide good coverage
– Do not allow spray to go beyond the edge of the cultivated area. Spray the outside row only from outside the planting

For aerial application:
– Do not apply within 150 feet of water
– Do not apply when gusts or sustained winds exceed 8 mph

The Agency believes labels should be amended to include a surface water advisory statement, which is outlined in the Environmental Hazards portion of Table 17 in Section V. This statement will encourage users to apply methidathion in a way that will minimize exposure to freshwater fish and invertebrates.

c. Nontarget Insect Mitigation

The Agency is concerned about the risk to beneficial insects from the use of methidathion. To reduce the likelihood for significant mortality to bees, precautionary labeling is required.

E. Other Labeling

1. Endangered Species Statement

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

The Endangered Species Protection Program as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The pamphlets are available for voluntary use by pesticide applicators on EPA's website at *http://www.epa.gov/espp*. A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the *Federal Register* before the end of 2001.

2. Spray Drift Management

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

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

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

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

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

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

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

"Do not allow this product to drift."

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

V. What Registrants Need to Do

In order to 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 methidathion 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 Carmen Rodia at (703) 306-0327 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)
ATTN: Mr. Carmen Rodia
US EPA (7504C)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk (DCI/SRRD)
ATTN: Mr. Carmen Rodia
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

B. For products containing the active ingredient methidathion, 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 17 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 Jane Mitchell at (703) 308-8061 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (PDCI/PRB)
ATTN: Ms. Jane Mitchell
US EPA (7504C)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service only:
Document Processing Desk (PDCI/PRB)
ATTN: Ms. Jane Mitchell
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

860.1500 (171-4K)	Field Trial Data on Cotton Gin Byproducts[3]
201-4-SS	Background for Pesticide Aerial Drift Evaluation[4]
850.1400 (72-4A)	Fish Early Life Stage Freshwater Fish: Note that the current study on Fathead minnow is supplemental due to the absence of raw data necessary to corroborate the reported results. Even if the raw data was provided, the Agency still has concern that reported results suggest fathead minnow are not as sensitive as other freshwater fish. If an LC_{50} study was conducted by the same laboratory around the time of the test in question, then an Application Factor could be computed and chronic values for the other fish tested could be computed. If no such LC_{50} study exists, than there is high value in conducting another FEL study (and an accompanying LC_{50} study) on the fathead minnow. Preferably, the study would be conducted on the rainbow trout. The value added for this study is high in order to better assess the chronic risk of methidathion to fresh water fish.
72-4-SS	Fish Early Life Stage Estuarine Fish: Note that there is no study to address this requirement. The label permits methidathion to be used on at least two crops, citrus and cotton, that the Agency uses to trigger the requirement. Although methidathion's current usage appears to be of relatively low volume and, in California where the degree of estuarine contamination may be low, the present chronic risk assessment for estuarine fish is still highly uncertain This is especially true in light of the discussion in the preceding comment for Guideline 72-4A. The value added for this study is high.

Additionally, a Data Call-In Notice (DCI) was sent to registrants of organophosphate pesticides, including methidathion, currently registered under FIFRA (August 6, 1999

[3] Data depicting the magnitude of methidathion residues of concern in/on cotton gin byproducts following application(s) of a representative formulation according to the maximum registered use patterns are required. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. At least three field trials for each type of harvesting (stripper and mechanical picker) are needed, for a total of six field trials. The need for additional tolerances and revisions to the exposure/risk assessments will be made upon receipt and evaluation of required data.

[4] Guideline 201-4-SS may be satisfied by participating in the Spray Drift Taskforce.

64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic and developmental neurotoxicity studies.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 17 at the end of this section.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling for End-Use Products

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

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 24 months from the date of the issuance of this interim RED. Persons other than the registrant may generally distribute or sell such products for 50 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 methidathion products bearing old labels/labeling for 24 months from the date of issuance of this interim RED. Persons other than the registrant may distribute or sell such products for 50 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. Labeling Changes Summary Table

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

Table 17: Summary of Labeling Changes for Methidathion

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the Interim RED and Agency Label Policies	"This pesticide is toxic to fish, aquatic invertebrates, mammals and extremely toxic to birds. 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."	Directions for Use
End-Use Products Intended for Occupational Use (WPS)		
Handler PPE Considerations (all formulations)	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain methidathion, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. For **multiple-active-ingredient** end-use products that contain methidathion, the handler PPE/engineering	Handler PPE

Description	Amended Labeling Language	Placement on Label
Handler PPE Considerations (all formulations) (continued)	control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which PPE requirements are considered to be more protective, see PR Notice 93-7. PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this interim RED does not require protective eyewear which may be required by the Acute Toxicity testing for the end-use product. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Handler PPE
PPE Requirements Established by the Interim RED for liquid products	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A, B, C, D, E, F, G or H*] on an EPA chemical-resistance category selection chart." Applicators using air blast equipment must wear: - Coveralls over long-sleeved shirt and long pants, - Chemical resistant footwear plus socks, - Chemical resistant gloves, - Chemical resistant headgear, and - A respirator with an organic-vapor (OV) removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH-approved respirator with an OV removing cartridge or canister with an `, R-, P- or HE-series prefilter." "Mixers, loaders and all other applicators and other handlers must wear: - Long-sleeved shirt and long pants, - Shoes, plus socks, - Chemical-resistant gloves for mixers and loaders and for applicators using groundboom equipment, - Chemical resistant apron for mixers and loaders, and	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the Interim RED for liquid products (continued)	- A respirator with an organic-vapor (OV) removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH-approved respirator with an OV removing cartridge or canister with an `, R-, P- or HE-series prefilter for applicators making groundboom applications." "See engineering controls for additional requirements." *Note: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation in the above respirator statement must be dropped.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the Interim RED for products in water-soluble packaging [wettable powders must be in water-soluble packaging to be eligible for reregistration]	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A, B, C, D, E, F, G or H*] on an EPA chemical-resistance category selection chart." Applicators using air blast equipment must wear: - Coveralls over long-sleeved shirt and long pants, - Chemical resistant footwear plus socks, - Chemical resistant gloves, - Chemical resistant headgear, and - A respirator with an organic-vapor (OV) removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH-approved respirator with an OV removing cartridge or canister with an `, R-, P- or HE-series prefilter." "Mixers, loaders and all other applicators and other handlers must wear: - Long-sleeved shirt and long pants, - Shoes, plus socks, - Chemical-resistant gloves for mixers and loaders and for applicators using groundboom equipment, - Chemical resistant apron for mixers and loaders, and	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the Interim RED for products in water-soluble packaging [wettable powders must be in water-soluble packaging to be eligible for reregistration] (continued)	- A respirator with an organic-vapor (OV) removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH-approved respirator with an OV removing cartridge or canister with an `, R-, P- or HE-series prefilter for applicators making groundboom applications." "See engineering controls for additional requirements." *Note: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation in the above respirator statement must be dropped.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for liquid products	"Engineering Controls Mixers and loaders supporting aerial applications must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR §170.240(d)(4)], and is designed to prevent both dermal and inhalation exposure to any person to the pesticide concentrate, use dilution, or rinse solution. The system must be designed by the manufacturer to remove a liquid pesticide from its shipping container and transfer it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 mL per disconnect point. When using the closed system, handlers must: - Wear the personal protective equipment required above for mixers/loaders, - Wear protective eyewear if the system operates under pressure, and - Be provided and have immediately available for use in an emergency (such as a broken package, spill, or equipment breakdown) additional PPE, including coveralls, chemical-resistant footwear and the type of respirator specified in the PPE section of this labeling." "Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker protection Standard for agricultural pesticides [40 CFR §170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements).

Description	Amended Labeling Language	Placement on Label
Engineering Controls for liquid products (continued)	"The use of human flaggers is prohibited." "When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR §170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements).
Engineering Controls for wettable powder products marketed in water-soluble packaging	"Engineering Controls Water-soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR §170.240(d)(4)]. Mixers and loaders using water-soluble packets must: wear the personal protective equipment required above for mixers/loaders; and be provided and have immediately available for use in an emergency (such as a broken package, spill or equipment breakdown) additional PPE. These PPE include coveralls and chemical-resistant footwear and the type of respirator specified in the PPE section of this labeling. "When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR §170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements).
User Safety Recommendations	**"User Safety Recommendations"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"This pesticide is toxic to fish, aquatic invertebrates, oysters, shrimp, mammals and extremely toxic to birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash water or rinsate.	Precautionary Statements immediately following the User Safety Recommendations

Description	Amended Labeling Language	Placement on Label
Environmental Hazards (continued)	This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination. This product may contaminate water through drift of spray in wind. This product has a high potential for runoff (primarily via dissolution in runoff water), several weeks after application. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas upon which this product is applied and surface water features such as ponds, streams and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 3 days."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment established by the Interim RED.	"PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and involves contact with anything that has been treated, such as plants, soil, or water, is: - Coveralls over short sleeved shirt and short pants, - Chemical-resistant gloves made out of any waterproof material, - Chemical-resistant footwear plus socks, and - Chemical-resistant headgear for over head exposures."	Directions for Use, Agricultural Use Requirements Box
Double Notification	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
Aerial Application Restrictions (Soluble Powder Products only)	"This product may not be applied by aerial application methods."	Directions for Use

Description	Amended Labeling Language	Placement on Label
Spray Drift and Buffer Zone Application Restrictions (all formulations except as indicated)	Registrants (and applicants) may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling. "When applying a rate greater than 3.0 lbs a.i./A, do not apply within 50 feet of lakes, reservoirs, permanent streams, natural ponds, marshes or estuaries. When applying a rate of 3.0 lbs a.i./A or less, do not apply within 25 feet of lakes, reservoirs, permanent streams, natural ponds, marshes or estuaries. Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands or animals." "For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 12 mph or less at the application site as measured by an anemometer. Use ____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. Shut off sprayer when turning at end rows." "For orchard/vineyard air blast applications, do not direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows. Block off upward pointed nozzles when there is no overhanging canopy. Use only enough air volume to penetrate the edge of the cultivated area. Spray the outside row only from outside the planting. Apply only when wind speed is 3 –10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side. A minimum of 500 gallons of spray volume per acre must be used." "When applying with aerial equipment, do not apply within 150 feet of lakes, reservoirs, permanent streams, natural ponds, marshes or estuaries. For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3 –10 mph as measured by an anemometer. Use ____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy." "The applicator also must use all other measures necessary to control drift." *Note: The above paragraph regarding aerial applications does not apply to Wettable Powder formulations since aerial applications for those formulations are prohibited.*	Directions for Use

Description	Amended Labeling Language	Placement on Label
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation."	Directions for Use, Agricultural Use Requirements Box

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 A.M. to 4:00 P.M..

The docket initially contained preliminary risk assessments and related documents as of December 8, 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.

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. METHIDATHION (Case No. 0034): Table of Use Patterns Eligible for Interim Reregistration

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Food/feed uses						
Alfalfa and Timothy						
Foliar Ground	25% WP [WA940020]	1.0	Not Specified (NS)	Not Specified (NS)	21 days	Restricted to Kittitas County, WA; other sites are restricted to seed production.
Foliar Aircraft, ground	2 lb/gal EC [WA940019]	1.0	NS	NS	21 days	Restricted to Kittitas County, WA; other sites are restricted to seed production.
Almonds						
Delayed dormant, dormant, foliar or cover spray Ground	25% WP [100-754]	3.0	2.0	14 days	80 days	Do not graze or feed treated crop to livestock. Do not apply more than one dormant/delayed dormant application nor more than one cover spray per season.
Delayed dormant, dormant, foliar or cover spray High volume spray Low volume spray Aircraft, ground	2 lb/gal EC [100-501] [100-719]	3.0	2.0	14 days	80 days	Do not graze or feed treated crop to livestock. Do not apply more than one dormant/delayed dormant application nor more than one cover spray per season.
Apples, Pears						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Delayed dormant, dormant, foliar Ground	25% WP [100-754]	3.0	1.0	14 days	Not Required (NR)	Apply before any blossoms open, or injury may occur. Do not graze livestock in treated areas or cut treated crops for feed.
Delayed dormant, dormant, foliar High volume spray Low volume spray Aircraft, ground	2 lb/gal EC [100-501] [100-719]	3.0	1.0	14 days	NR	Apply before any blossoms open, or injury may occur. Do not graze livestock in treated areas or cut treated crops for feed.
Apricots, Cherries, Nectarines, Peaches, Plums and Prunes						
Delayed dormant, dormant, foliar High volume spray Low volume spray Ground	25% WP [100-754]	3.0	1.0	14 days	NR	Apply before any blossoms open, or injury may occur. Do not graze livestock in treated areas or cut treated crops for feed.
Delayed dormant, dormant, foliar High volume spray Low volume spray Aircraft, ground	2 lb/gal EC [100-501] [100-719]	3.0	1.0	14 days	NR	Apply before any blossoms open, or injury may occur. Do not graze livestock in treated areas or cut treated crops for feed.
Artichokes						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Foliar Ground	25% WP [100-754]	1.0	8.0	14 days	NR	Do not apply after buds begin to form. Avoid application under conditions which favor drift to adjacent artichoke fields where buds are present.
Foliar Aircraft, ground	2 lb/gal EC [100-501] [100-719]	1.0	8.0	14 days	NR	Do not apply after buds begin to form. Avoid application under conditions which favor drift to adjacent artichoke fields where buds are present.
Carambola						
Foliar Ground	2 lb/gal EC [FL920005]	0.375	3.0	30 days	21 days	Do not graze livestock in treated areas or cut treated crops for feed.
Cotton						
Foliar Ground	25% WP [100-754]	1.0	4.0	5 days	14 days	Do not graze or feed gin trash or treated foliage to livestock.
Foliar Aircraft, Ground	2 lb/gal EC [100-501] [100-719]	1.0 (0.5 after bolls open)	4.0	5 days	14 days	Do not graze or feed gin trash or treated foliage to livestock.
Grapefruit, Oranges						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Foliar Ground	25% WP [100-754]	5.0	2.0	45 days	14 days	Apply the recommended rates anytime except during the full bloom period. In coastal areas of CA and other areas with no distinct bloom period, notify beekeepers prior to application. There is a 60 day PHI if used with oil. Do not graze treated areas.
Foliar Ground	2 lb/gal EC [100-501] [100-719]	5.0	2.0	45 days	14 days	Apply the recommended rates anytime except during the full bloom period. In coastal areas of CA and other areas with no distinct bloom period, notify beekeepers prior to application. There is a 60 day PHI if used with oil. Do not graze treated areas.
Kiwifruit						
Dormant, foliar Ground	2 lb/gal EC [CA900002]	2.0	1.0	NS	NR	Do not apply after buds break.
Lemons						
Foliar Ground	25% WP [100-754]	5.0	2.0	45 days	14 days	Apply the recommended rates anytime except during the full bloom period. In coastal areas of CA and other areas with no distinct bloom period, notify beekeepers prior to application.
Lemons, continued						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
						Do not exceed 2.5 lbs a.i./A or apply more than once per season when tank mixed with oil. There is a 60 day PHI if applied with oil.
Foliar Ground	2 lb/gal EC [100-501] [100-719]	5.0	2.0	45 days	14 days	Apply the recommended rates anytime except during the full bloom period. In coastal areas of CA and other areas with no distinct bloom period, notify beekeepers prior to application. Do not exceed 2.5 lbs a.i./A or apply more than once per season when tank mixed with oil. There is a 60 day PHI if applied with oil.
Longan						
Foliar Ground	2 lb/gal EC [FL920005]	0.25	2.0	45 days	21 days	Do not graze treated areas.
Mangos						
Dormant to bloom, foliar Ground	2 lb/gal EC [100-501] [100-719]	0.25	5.0	NS	NR	Apply between postharvest and bloom stage. Do not graze livestock in treated areas or cut treated crops for feed.
Olives						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Foliar, postharvest or prebloom Ground	25% WP [100-754]	3.0	1.0	2 days	NR	Do not apply after buds break. Do not graze livestock in treated areas or cut treated crops for feed.
Foliar, postharvest or prebloom Ground	2 lb/gal EC [100-501] [100-719]	3.0	1.0	2 days	NR	Do not apply after buds break. Do not graze livestock in treated areas or cut treated crops for feed.
Pecans (Southern U.S. only)						
Foliar Ground	25% WP [100-754]	4.0	2.0	14 days	60 days	Do not graze livestock in treated areas or cut treated crops for feed.
Foliar Ground	2 lb/gal EC [100-501] [100-719]	4.0	2.0	14 days	60 days	Do not graze livestock in treated areas or cut treated crops for feed.
Safflower						
Foliar Ground	25% WP [100-754]	0.5	3.0	7 days	28 days	Do not graze treated areas.
Foliar Aircraft, ground	2 lb/gal EC [100-501] [100-719]	0.5	3.0	7 days	28 days	Do not graze treated areas.
Sorghum						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Foliar Aircraft, ground	2 lb/gal EC [100-501] [100-719]	0.5	3.0	10 days	30 days	Use in CO, KS, OK and TX only.
Sugar Apple (including sweetsop, anon, atemoya and true custard apple)						
Foliar Ground	2 lb/gal EC [FL920005]	0.5	2.0	14 days	14 days	Do not graze treated areas.
Sunflower						
Foliar Aircraft, ground	2 lb/gal EC [100-501] [100-719]	0.5	3.0	7 days	50 days	Do not feed treated forage to livestock. Do not graze treated areas.
Walnuts						
Delayed dormant, dormant, foliar or cover spray Ground	25% WP [100-754]	3.0	3.0	NS	2 days	Do not add oil to sprays in southern or central CA or to trees that may be subject to stress due to drought, drying winds, disease or severe insect infestations. Do not graze livestock in treated areas or cut treated crops for feed. Make no more than one application during the dormant/delayed dormant period, no more than one cover spray each season.
Walnuts, continued						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Delayed dormant, dormant, foliar or cover spray Aircraft, ground	2 lb/gal EC [100-501] [100-719]	2.0	3.0	2 days	7 days	Do not add oil to sprays in southern or central CA or to trees that may be subject to stress due to drought, drying winds, disease or severe insect infestations. Do not graze livestock in treated areas or cut treated crops for feed. Make no more than one application during the dormant/delayed dormant period, no more than one cover spray each season.
Non-food/feed uses						
Alfalfa (Grown for Seed)						
Foliar Aircraft, ground	2 lb/gal EC [ID930003] [OR930007]	1.0	NS	NS	NR	Do not apply through any type of irrigation system. Do not graze or feed treated crop to livestock. Seeds from treated fields may not be used for sprouts. No portion of the treated field, including seed, seed screenings, hay, forage or stubble may be used for human or animal consumption. In AZ, MT and NV, processed feed must be labeled "Not for human or animal consumption" at the processing plant. The processor must dispose of all seed screenings in such a way that they cannot be distributed or used for food or feed.
Clover (Grown for Seed)						

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb a.i./A)	Max. No. of Applications	Minimum Retreatment Interval	Preharvest Interval (PHI)	Restrictions/Comments
Foliar Aircraft, ground	2 lb/gal EC [CA770039]	1.0	NS	NS	NR	None.
Nursery Stock, Woody Ornamentals or Herbaceous Plants Commercially Grown for Transplanting (Except CA and NY)						
Foliar Ground	25% WP [100-754]	0.5	1.0	NS	NR	None.
Foliar Ground	2 lb/gal EC [100-501] [100-719]	0.5	1.0	NS	NR	None.
Tobacco						
Foliar Ground	2 lb/gal EC [100-501] [100-719]	1.0	3.0	NS	3 days	None.

EC = Emulsifiable Concentrate
WP = Wettable Powder

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Methidathion

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the chemical case covered by this interim RED. It contains generic data requirements that apply in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Columns 1, 2 & 3). The data requirements are listed in the order of New Guideline Number and appear in 40 CFR §158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002, (703) 487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

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

3. Bibliographical Citation (Column 5). If the Agency has acceptable data in its files, this column lists the identification number of each of the studies. Normally, this is the Master Record Identification (MRID) Number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography (Appendix D) for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Methidathion

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
PRODUCT USE CHEMISTRY				
830.1550	61-1	Product Identity and Composition	**All**	41863501, 41863504, 42789701
830.1600	61-2A	Starting Materials and Manufacturing Process	**All**	42789701
830.1670	61-2B	Discussion of Impurities	**All**	42789701
830.1700	62-1	Preliminary Analysis	**All**	42789701
830.1750	62-2	Certification of Limits	**All**	00131026, 00142590, 40079802, 41863502, 41863505, 42789702
830.1800	62-3	Enforcement Analytical Method	**All**	00131026, 40079802, 41863502, 41863505, 42789702, 43733304
830.6302	63-2	Color	A, B, C	00011347, 00131026, 40079802, 41863503, 41863506, 42789703
830.6303	63-3	Physical State	A, B, C	00131026, 40079802, 41863503, 41863506, 42789703
830.6304	63-4	Odor	A, B, C	00011347, 00131026, 41863503, 41863506, 42789703
830.7200	63-5	Melting Point/Melting Range	A, B, C	00011347, 41863503, 42789703
830.7300	63-7	Density	**All**	41863503, 42789701
830.7840 830.7860	63-8	Solubility	**All**	00011347, 00131026, 41863503, 42789703
830.7950	63-9	Vapor Pressure	**All**	41863503, 42789701
830.7370	63-10	Dissociation Constant in Water	**All**	41863503, 42789701
830.7550	63-11	Octanol/Water Partition Coefficient	**All**	41863503, 42789703
830.7000	63-12	pH of Water Solutions or Suspensions	**All**	41863503, 42789701
830.6313	63-13	Stability	**All**	41863503, 42789701
830.6314	63-14	Oxidizing/Reducing Action	**All**	42789701
830.6315	63-15	Flammability	**All**	00131026, 41863506, 42789703
830.6316	63-16	Explodability	**All**	00131026, 41863506, 42789703, 43733305
830.6317	63-17	Storage Stability	**All**	00131026, 41863506, 42789703
830.7100	63-18	Viscosity	**All**	00131026, 41863506
830.6319	63-19	Miscibility	**All**	00131026, 41863506, 43733305
830.6320	63-20	Corrosion Characteristics	**All**	00131026, 41863506, 42789703, 43733305

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
ECOLOGICAL EFFECTS				
850.2200	71-2A	Avian Subacute Dietary Toxicity - Bobwhite Quail	A, B, C	42081701, 44806601
850.2200	71-2B	Avian Subacute Dietary Toxicity - Mallard Duck	A, B, C	00157347, 00159201, 42081701, 44381602
850.2300	71-4B	Avian Reproduction - Mallard Duck	A, B, C	44381602
850.2500	71-5A	Simulated Field Study	A, B, C	Reserved
850.2500	71-5B	Actual Field Study	A, B, C	Reserved
850.1075	72-1A	Fish Toxicity Bluegill Sunfish	A, B, C	42081702
850.1075	72-1C	Fish Toxicity Rainbow Trout	A, B, C	42081703
850.1010	72-2A	Invertebrate Toxicity	A, B, C	42081704
None	72-3A	Estuarine/Marine Fish Acute Toxicity	A, B, C	42081705, 43738501
850.1025	72-3B	Estuarine/Marine Mollusk Acute Toxicity	A, B, C	42185201-02, 42181705
850.1035	72-3C	Estuarine/Marine Invertebrate Acute Toxicity	A, B, C	42081706, 42207902
850.1300	72-4A	Fish - Early Life Stage	A, B, C	Data Gap
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A, B, C	42081707
850.1950	72-7A	Simulated Field Testing for Aquatic Organisms	A, B, C	Reserved
850.1950	72-7B	Actual Field Testing for Aquatic Organisms	A, B, C	Reserved
850.3020	141-1	Honey Bee Acute Contact Toxicity	A, B, C	00036935
850-3030	141-2	Honey Bee Toxicity of Residues on Foliage	A, B, C	42081708
TOXICOLOGY				
870.1100	81-1	30-Day Acute Oral Toxicity - Rat	A, B, C	00139328, 44434501
870.1200	81-2	Acute Dermal Toxicity - Rabbit/Rat	A, B, C	00139326
870.1300	81-3	Acute Inhalation Toxicity - Rat	A, B, C	00011449
870.2400	81-4	Primary Eye Irritation - Rabbit	A, B, C	00159199
870.2500	81-5	Primary Skin Irritation	A, B, C	00159200
870.2600	81-6	Dermal Sensitization	A, B, C	00252433
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	A, B, C	00011704
870.6200	81-8	Acute Neurotoxicity Screening Battery	A	43145903-04
870.3100	82-1A	90-Day Subchronic Feeding - Rodent	A, B, C	43582501

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A, B, C	40079806
870.6100	82-5B	90-Day Neurotoxicity, Mammal	A	43582501
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	A, B, C	00160260
870.4100	83-1B	Chronic Feeding Toxicity - Nonrodent	A, B, C	41945001
870.4200	83-2A	Chronic Carcinogenicity (Feeding) - Rat	A, B, C	00160260
870.4200	83-2B	Chronic Carcinogenicity (Feeding) - Mouse	A, B, C	00157457
870.3700	83-3A	Prenatal Developmental Toxicity - Rat	A, B, C	00139326, 40079807
870.3700	83-3B	Prenatal Developmental Toxicity - Rabbit	A, B, C	40079809-10
870.3800	83-4	2-Generation Reproduction - Rat	A, B, C	40079811-12
870.5140	84-2A	Gene Mutation (Ames Test)	A, B, C	00070213, 00078329-30, 00070832, 00084010
870.5375	84-2B	Structural Chromosomal Aberration	A, B, C	00078335
870.5500	84-4	Other Genotoxic Effects	A, B, C	00078334
870.7485	85-1	General Metabolism	A, B, C	40127818
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	A, B, C	44680501-02
875.1100	231	Estimation of Dermal Exposure at Outdoor Sites	A, B, C	Reserved
875.1300	232	Estimation of Inhalation Exposure at Outdoor Sites	A, B, C	Reserved
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B, C	42037701, 44545101
835.2240	161-2	Photodegradation - Water	A, B, C	42081709
835.2410	161-3	Photodegradation - Soil	A, B, C	42081710
835.2370	161-4	Photodegradation - Air	A, B, C	42647301
835.4100	162-1	Aerobic Soil Metabolism	A, B, C	42262501, 42647301, 42799601, 44545101
835.1410	163-2	Laboratory Volatilization from Soil	A, B	42098801, 42647301
835.8100	163-3	Field Volatility from Soil	A, B	Reserved
835.6500	164-5	Long-term Terrestrial Field Dissipation	A, B, C	Reserved
835.1850	165-1	Confined Accumulation in Rotational Crops	A, B, C	41902201
835.1900	165-2	Field Accumulation in Rotational Crops	A, B, C	Reserved
835.1950	165-4	Bioaccumulation in Fish	A, B, C	Reserved

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of the Residue - Plants	A, B, C	42708901-03, 43399701
860.1300	171-4B	Nature of the Residue - Livestock	A, B, C	43170001-05, 43399702
860.1340	171-4D	Residue Analytical Method - Animals	B, C	43296401-02
860.1480	171-4J	Magnitude of Residues in Meat, Milk, Poultry and Eggs	A, B, C	Waived
860.1500	171-4K	Crop Field Trials (Cereal Grains Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Cotton Gin Byproducts)	A, B	Data Gap
860.1500	171-4K	Crop Field Trials (Citrus Foods Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Grass Forage and Hay Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Miscellaneous Commodities Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Nongrass Animal Feeds Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Pome Fruits Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Root and Tuber Vegetables Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Stone Fruits Group)	A, B, C	Reserved
860.1500	171-4K	Crop Field Trials (Tree Nuts Group)	A, B, C	Reserved
OTHER				
72-4-SS	None	Early Life Stage Estuarine Fish	A, B, C	Data Gap
81-8-SS	None	Acute Neurotoxicity - Rats	A, B	43145901-04
201-4-SS	None	Background for Pesticide Aerial Drift (Evaluation)	A, B, C	Data Gap

Appendix C. Technical Support Documents

Additional documentation in support of this interim 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 legal holidays, from 8:30 A.M. to 4 P.M..

The docket initially contained preliminary risk assessments and related documents as of August 10, 1998. 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 June 16, 1999.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Agency's website at *http://www.epa.gov/pesticides/op*.

These documents include:

HED Documents:

1. Human Health Risk Assessment Methidathion, dated August 9, 2000.

EFED Documents:

1. Methidathion - Environmental Fate and Effects Chapter, dated November 30, 1999 and its addendum, dated April 4, 2001, (including drinking water assessment addenda, dated March 22, 2001 and dietary exposure assessment addenda, dated April 27, 2001).

Appendix D. Citations Considered to Be Part of the Data Base Supporting the Interim Reregistration Eligibility 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 Interim 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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42081709	Saxena, A. (1989) Artificial Sunlight Photodegradation of [Carbon 14]-Methidathion in a Buffered Aqueous Solution: Lab Project Number: 6117-137. Unpublished study prepared by Hazleton Laboratory America, Inc. 96 p.
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Appendix E. Generic Data Call-In

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

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.

Appendix G. EPA's Batching of Methidathion 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 methidathion as the 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 (e.g., identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular) and labeling (e.g., signal word, use classification, precautionary labeling). Note that the Agency is not describing batched products as "substantially similar" since some products within 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 the 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, only their own products within a batch or to generate all the required acute toxicological studies for each of their own products. If a 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 a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the database is complete and valid by today's 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, registrants must clearly identify the test material by the 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 (DCI) and its attachments appended to the interim 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 a registrant supplies the data to support a batch of products, he/she must select 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 6). 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.

Seven products were found which contain methidathion as the active ingredient. These products have been placed into three batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. The following bridging strategies may be employed:

- Batch 2 may cite Batch 1 with the exception of eye and skin irritation data
- Batch 5 may rely on Batch 4 data
- Batches 6 and 7 may use the policy for granular pesticide products. However, due to the differences in inerts in Batch 6, products within Batch 6 may not share eye irritation data.

Batch 1	EPA Reg. No.	Percent Dimethoate	Formulation Type
	100-530	95.0	Liquid
	10163-245	95.0	Liquid

Batch 2	EPA Reg. No.	Percent Dimethoate	Formulation Type
	10163-237	50.0	Liquid

Batch 3	EPA Reg. No.	Percent Dimethoate	Formulation Type
	100-754	25.0	Solid
	10163-244	25.0	Solid

No Batch	EPA Reg. No.	Percent Dimethoate	Formulation Type
	10163-236	25.0	Liquid
	10163-238	25.0	Liquid

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

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

Pesticide Registration Forms are available via the Agency's website at *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@epa.gov*.

The following Agency Pesticide Registration 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 Special 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 (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*

8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit http://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
   B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   C. Antimicrobials Division Organizational Structure/Contact List

D. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
E. 40 CFR §156, Labeling Requirements for Pesticides and Devices (PDF format)
F. 40 CFR §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' website.

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.

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 website.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website at http://www.ncis.orst.edu.

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; and
- 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 chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this interim RED

The following documents are part of the Administrative Record for this interim RED document and may be 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 Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.

2. Detailed Label Usage Information System (LUIS) Report