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

Interim Reregistration Eligibility Decision
for
Methyl Parathion

Case No. 0153

Note: This is an acrobatted copy for internet. Appendices and supporting documents are not attached. Appendices and supporting documents will be posted in EPA's eDocket system when the public comment period opens.

METHYL PARATHION TEAM

Office of Pesticide Programs:

Health Effects Risk Assessment

Jonathan Becker
Bonnie Cropp-Kohlligian
Ken Dockter
Diana Locke
Sherie Kinard (nee Mason)
Kathleen Raffaele
Renee Sandvig
Jeffrey Dawson

Environmental Fate Risk Assessment

Kevin Costello
James Hetrick
Amer Al-Mudallal
Edward Odenkirchen

Use and Usage Analysis

David Brassard
Timothy Kiely
Donald Atwood
Colwell Cook
Nicole Mosz
Nikhil Mallampalli
Jihad Alsadek
Bill Gross

Registration Support

Marilyn Mautz

Risk Management

Dennis Deziel

Jane Mitchell
Laura Parsons

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
ME	Microencapsulated Formulation
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System

NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography

TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for methyl parathion. The decisions outlined in this document do not include the final tolerance reassessment decision for methyl parathion; however, thirty tolerances have been revoked by Federal Register notice, published January 5, 2001. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for methyl parathion once the cumulative assessment is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of pre-mitigation 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 methyl parathion. After considering the revised risks, as well as mitigation proposed by Cheminova, Cerexagri, and Griffin, the technical registrants of methyl parathion, EPA developed its risk management decision for uses of methyl parathion that pose risks of concern. Comments on the risk assessment were received from several other groups such as the Consumers Union, Environmental Working Group, World Wildlife Fund, Natural Resources Defense Council, several grower organizations, and agricultural extension agents, but these groups did not propose any additional mitigation measures. The risk management decision is discussed fully in this document.

Methyl parathion is an organophosphate insecticide which was registered in 1954 as an insecticide/acaricide. Methyl parathion is used to control a wide variety of insect pests. Use data from 1987 to 1997 indicate an average domestic use of approximately 4 million lbs a.i. per year.

Overall Risk Summary

EPA's risk assessments for methyl parathion, which are available in the public docket and on the Agency's web site (http://www.epa.gov/pesticides/op), were based on a review of the required target database supporting the registered uses of methyl parathion products before the Memorandum of Agreement (MOA) signed by EPA and the registrants in August 1999. The risk of concern identified in the human health risk assessments was the potential of methyl parathion to cause cholinesterase inhibition and peripheral neuropathology. The revised human health risk assessment showed that, considering the food/feed uses registered at that time, methyl parathion did not meet the FQPA safety standard for dietary food risk for any population. Limited targeted water monitoring indicated that there also may be a drinking water dietary concern. Since the dietary food

levels alone exceeded the Agency's level of concern, the aggregated dietary food and drinking water risk assessment also showed unacceptable risk. The occupational risk assessment also indicated that handlers of methyl parathion are exposed at levels which pose risk concerns. In terms of ecological risk, methyl parathion exceeds the Agency's levels of concern for all aquatic and terrestrial species considered. The following paragraphs discuss these dietary, occupational and ecological risks as well as some of the mitigation measures which were implemented with the MOA or are proposed by this document.

The primary mitigation implemented by the MOA was the cancellation of several fruit and vegetables uses. These cancellations account for approximately 10% of all methyl parathion use, but significantly reduced dietary risk to all populations. Additionally, the use cancellations are also believed to lessen occupational risk since fruits and vegetables are often hand labor intensive. Ecological risk is also lessened since bees and beneficial insects forage on many fruit and vegetable crops. To reduce the uncertainty in the occupational risk assessment, the registrants conducted several biomonitoring studies. Additional mitigation measures to be implemented by the MOA and this interim RED are lower application rates and fewer applications for some crops.

Dietary Risk

The refined pre-MOA dietary risk assessment which is provided on the Agency's website indicated that the acute dietary risk to children one to six years of age exceeded the acute population adjusted dose (or amount that can be consumed safely in one day or less) by 881%. To mitigate the high dietary risk to children, EPA accepted voluntary cancellation of those crops that contributed most to children's diet. These canceled uses represented 90% of the acute dietary risk to children. Removing these crop uses brought the estimated dietary risk for children 1 to 6 years in age down to 75% of the acute population adjusted dose (PAD) for methyl parathion. The voluntary cancellation was accomplished through the MOA between all methyl parathion registrants and EPA, signed August 2, 1999. These use changes, along with certain mitigation measures to protect workers, such as longer re-entry intervals, have been implemented through the registration of "replacement" methyl parathion products.

Based on the post-MOA use pattern for methyl parathion, the Agency's human health risk assessment for the most sensitive populations of infants and children indicates that dietary risks do not exceed 75% of the acute PAD while chronic risks do not exceed 8% of the chronic PAD. Limited targeted surface water monitoring indicates that the Drinking Water Level of Comparison is exceeded for children 1-6 years of age and that this population may be at risk from acute exposures to methyl parathion in drinking water. This monitoring data were mostly associated with areas of cotton production; therefore, the

total allowable application rate to cotton as well as some other crops will be reduced.

Since methyl parathion has no residential uses, the Agency's aggregate risk assessment consists of dietary and drinking water risks. Aggregate risks less than 100% of the PAD do not exceed the Agency's level of concern. The aggregate risk estimates presented indicate no unreasonable risks to the general population or to infants. However, though acute exposure to methyl parathion from food sources alone does not exceed the Agency's level of concern (< 100% acute PAD), limited surface water monitoring data indicate potential exposures at unacceptable levels for children one to six years of age.

For the emulsifiable concentrate formulation, magnitude of residues/field crop data for wheat forage, and wheat hay and sunflower seed processing data are necessary. Magnitude of residues/field crop data are needed for rice straw for the microencapsulate formulation. Magnitude of residues for meat/milk/poultry/eggs data are required for both formulations.

A Developmental Neurotoxicity (DNT) Test which is needed to thoroughly evaluate neurotoxicity has been submitted and is currently in review. The DNT study has been screened and is considered unlikely to change the dietary endpoint. The screened study was considered in the safety factor decision for the organophosphate cumulative assessment.

Residential Risk

Methyl parathion is a restricted use pesticide that is only applied by certified applicators and there are no residential uses.

Occupational Risk

This document identifies risk mitigation measures necessary to provide an additional margin of protection for handlers for aerial applications of the microencapsulated formulation, closed systems for applicators, and extended re-entry intervals for some uses. The use of human flaggers is also prohibited.

With the MOA, methyl parathion registrants agreed to generate chemical-specific exposure studies to resolve outstanding potential worker exposure issues. The following worker exposure studies were conducted: dislodgeable foliar residues on cotton, sweet corn, and walnuts; monitoring during aerial mixing/loading, groundboom applications, airblast applications to walnuts, walnut harvesting, cotton scouting, and sweet corn harvesting. Additionally, the registrant has conducted a 28-day dermal toxicity study.

Ecological Risk

In addition to the human health effects, the Agency also assessed ecological risks potentially caused by the use of methyl parathion under all use scenarios. To address ecological risk, the registrants have agreed to amend label requirements to minimize ecological concerns by reducing rates and numbers of applications. Also, since there was no assessed benefit associated with use on cabbage, dried beans, dried peas, hops, lentils, pecans, and sugar beets, these uses are considered to be ineligible for reregistration. Methyl parathion may not be mixed/loaded or otherwise handled in areas prone to runoff to aquatic environments based on uncertainties in the drinking water assessment and toxicity to aquatic organisms. Anaerobic aquatic metabolism, field volatility, aquatic plant growth, vegetative vigor, and seedling emergence studies are needed to better assess the ecological risk and refine the assessment.

Based on the use cancellation on tree fruits and vegetables, and considering the implementation of mitigation measures discussed above, the Agency has determined that pesticides containing methyl parathion generally will still present risk to humans and the environment. But there are significant benefits associated with the remaining uses which balance this risk.

The Agency is issuing this Interim Reregistration Eligibility Document (IRED) for methyl parathion, as announced in a Notice of Availability published in the *Federal Register*. The Notice of Availability also announces the beginning of a 30 day public comment period. During this comment period, interested parties may submit additional information on methyl parathion's benefits, usage, risks to workers and/or the environment, etc. The Agency will review all comments and if warranted, will make amendments to the regulatory decisions contained within this document. Neither the tolerance reassessment nor the reregistration eligibility decision for methyl parathion 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 methyl parathion.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the

"no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the Federal Food, Drug, and Cosmetic Act (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. Methyl parathion 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 methyl parathion. It is intended to be only the first phase in the reregistration process for methyl parathion. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for methyl parathion.

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 published in the *Federal Register* on August 12, 1999 a draft Pesticide Registration Notice that presents EPA's proposed approach for managing risks from organophosphate pesticides to occupational users. This notice describes the Agency's baseline approach to managing risks to handlers and workers of organophosphate pesticides. 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 draft guidance 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 draft Pesticide Registration Notice.

This document consists of six sections. This section, Section I, contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page http://www.epa.gov/pesticides/op, and in the Public Docket.

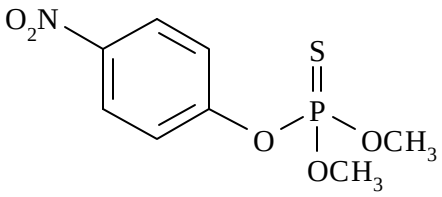
II. Chemical Overview

A. Regulatory History

This interim reregistration eligibility document is a full review of methyl parathion by the Agency. Methyl parathion was first registered in 1954 for use as an insecticide/acaricide. In December 1986, the Agency published Guidance for the Reregistration of Pesticide Products Containing Methyl Parathion. Some label changes to enhance worker safety were imposed by this document and several Data Call Ins were issued to support continued registration. In 1996, agreement was reached with the registrants producing the EC formulation to make various changes designed to end illegal home use of methyl parathion. These changes included tracking of all containers and reuseable/returnable closed containers for all EC products. On August 2, 1999, a Memorandum of Agreement was signed by methyl parathion registrants and EPA to voluntarily cancel a number of crop uses to address dietary concerns and to commit to conducting studies to refine potential occupational risk concerns.

B. Chemical Identification

Methyl parathion [O,O-dimethyl O-*p*-nitrophenyl phosphorothioate]:



- **Common Name:** methyl parathion
- **Chemical Name:** O,O-dimethyl O-*p*-nitrophenyl phosphorothioate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 298-00-0
- **OPP Chemical Code:** 053501
- **Empirical Formula:** $C_8H_{10}O_5NPS$

- **Molecular Weight:** 263.2 g/mole
- **Trade and Other Names:** Methyl Parathion 4EC, Penncap-M, Declare
- **Basic Manufacturers:** Cheminova Agro A/S, Elf Atochem North America, Griffin L.L.C

Pure methyl parathion is a white crystalline solid with a melting point of 35-36 C, bulk density of 1.358 g/mL at 25 C, vapor pressure of 9.7×10^{-6} mm Hg at 20 C, and octanol/water partition coefficient (P_{ow}) of 3300. Methyl parathion is only slightly soluble in water (55-60 mg/L at 20 C); readily soluble in dichloromethane, 2-propanol, and toluene; and practically insoluble in n-hexane. Methyl parathion is formulated with inert ingredients for manufacturing use to produce an 80% tan-colored liquid. (See "Human Health Risk Assessment, Methyl Parathion, August 2, 1999".)

C. Use Profile

The following information is based on the currently registered use of methyl parathion, consistent with the methyl parathion MOA signed August 2, 1999.

Type of Pesticide: Insecticide/miticide

Summary of Use:

Sites: Terrestrial food and feed crops;

Food/Feed: Alfalfa, almonds, barley, dried beans, cabbage, corn, cotton, grass forage/fodder/hay, hops, lentils, oats, onion, pastures, dried peas, pecans, rangeland, rape seed (canola), rice, rye, soybeans, sugar beets, sunflower, sweet potatoes, walnuts, wheat, white potatoes, and yams.

Residential: None;

Nonfood/Nonfeed: None;

Target Pests: Methyl parathion is used to control many types of pests, including mites, thrips, weevils, aphids, and leafhoppers.

Formulation Types:

Registered: Methyl parathion is formulated as a microencapsulate (ME) (20.9% a.i.) and as an emulsifiable concentrate (EC) (ranges from 27.59 to 52.7% a.i.). The EC products contain a stenching agent to deter indoor misuse. Methyl parathion is formulated with other active ingredients including malathion.

Method and Rates of Application:

Equipment: Applied by aerial equipment and with groundboom equipment. The ME formulation can also be applied by airblast equipment or by chemigation.

Method and Rate: Maximum label application rates vary from 0.25 to 3.0 lbs. a.i./acre. Currently, methyl parathion containers (EC formulation only) are designed for closed-system mixing/loading. These returnable/refillable containers are bar-coded for tracking purposes.

Use Classification: Methyl parathion is a “restricted use" chemical due to toxicity to humans, avian species and honey bees.

Proposed rates: Based on worker and ecological risks which were highlighted in the risk assessments released prior to the 1999 MOA, the methyl parathion technical registrants submitted written requests to have the risk assessments revised to lower some rates and numbers of applications even though the labels have not been revised to include these changes. The worker biomonitoring studies were conducted at these proposed lower rates. Additionally, to address ecological risks, the maximum number of applications has been lowered for several crops. The occupational and ecological risk assessments take into account these proposed rates. Any end-use product that does not conform with these revised agreed-upon rates and number of applications will not be eligible for reregistration. Table 1 provides the new rates on which the risks assessments are based and gives the pre-harvest intervals (PHI).

Table 1. Proposed rates (lb ai/A) for each formulation.

Crop	Emulsifiable Concentrate			Microenpasulated		
	max rate	max # app	PHI	max rate	max # app	PHI
alfalfa	1.0	6[a]	15	--	--	--
almonds	–[b]	--	--	2.0	4	28
barley, oats, rice, wheat	0.75	2	14	0.75	2	14
beans, dried	1.5	2	15	1.0	3	15
cabbage	1.5	2	21	--	--	--
corn	0.5	2	12	1.0	3	12
sweet corn	0.5	2	12	0.75	4	12
cotton	0.75	5	7	1.0	4	14
grass (forage, fodder, hay, range)	0.75	4[a]	15	--	--	----
lentils	--	--	--	0.5	2	14
onions	0.5	2	15	0.5	4	15
peas, dried	1.0	3	15	0.5	2	15
pecans	--	--	--	2.0	8	51
rapeseed (canola)	0.5	2	28	--	--	--
rye	0.75	2	15	--	--	--
soybeans	0.5	2	30	0.75	2	30
sugar beets	0.375	2	20	--	--	--
sunflower	1.0	2	30	--	--	--
sweet potatoes and yams	--	--	--	0.75	8	5
walnuts	--	--	--	2.0	4	14
white potatoes	0.75	3	5	1.5	4	5
hops	1.0	3	15	--	--	--

a for hay, there can be two applications per cutting.

b – indicates that the formulation is not registered for use on that crop

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of methyl parathion, based on available pesticide usage information for 1987-1997. A full listing of all uses of methyl parathion, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Usage Analysis" 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 4 million lbs a.i. on approximately 5 million acres treated are used annually, according to Agency and registrant estimates. This value includes use on crops which were canceled in August 1999. The largest uses for methyl parathion in terms of total pounds active ingredient are: cotton, corn, wheat, soybeans, and rice.

Table 2. Methyl Parathion Estimated Usage for Representative Sites.

Crop	Lbs Active Ingredient Applied (Wt. Avg.)[1]	Percent Crop Treated (Wt. Avg.)	Percent Crop Treated (Likely Maximum)
cotton	1,960,000	12	17
corn	770,000	2	3
wheat	445,000	1	2
rice	147,000	8	12
soybeans	270,000	1	1

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

Most other uses have less than or equal to 1% of the crop treated with methyl parathion.

E. Uses Deleted by the 1999 MOA

Food uses: apples, artichokes, broccoli, Brussels sprouts, carrots, cauliflower, celery, cherries, clover, collards, filberts, garden beets, grapes, kale, kohlrabi, lettuce, mustard greens, nectarines, peaches, pears, plums, rutabagas, sorghum, spinach, succulent beans, succulent peas, tomatoes, turnips, vetch

Non-Food/Feed Uses: birdsfoot trefoil, Christmas trees, chrysanthemums, daisies, field grown ornamentals, flowering plants, forest, grasses grown for seed, guayule, jojoba, marigolds, any mosquito larvicide use, nursery stock, non-agricultural land, roadside areas, and wasteland.

III. Summary of Methyl Parathion Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide methyl parathion as fully presented in the documents, "Methyl Parathion Revised Human Health Risk Assessment," dated August 2, 1999, "2nd Revised HED Risk Assessment" dated June 12, 2002, and, "Methyl Parathion Revised Environmental Fate and Effects Risk Assessment," dated July 30, 1999 (and addendums thereto). The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to enhance understanding of the conclusions reached in the assessments.

These risk assessments for methyl parathion were presented at an August 2, 1999, technical briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the

Agency's interim risk management decisions for methyl parathion only; the Agency must still consider cumulative risks of all the organophosphate pesticides before other final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for methyl parathion on December 18, 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are included in the summary below:

The Agency conducted the human health risk assessment for all registered uses of methyl parathion which were being supported under reregistration, as well as for the use changes which reflect mitigation measures. The toxicity endpoints selected for the risk assessment are based primarily on neurotoxic effects, including neuropathology and cholinesterase (ChE) inhibition in the brain, red blood cells (RBC), and plasma, as well as behavioral effects and systemic toxicity (decreased hematocrit and erythrocyte levels). In addition, a single oral exposure to methyl parathion (7.5 mg/kg or higher) in rodents resulted in peripheral nerve demyelination (tibial and sural nerves, dorsal and ventral root fibers). Additional effects of chronic exposure include retinal degeneration and sciatic nerve degeneration. No evidence of carcinogenicity was seen in any study. The endpoints selected for the methyl parathion human health dietary risk assessment are listed in Table 3 and for the occupational risk assessment in Table 9.

An uncertainty factor (UF) of 100 was applied to the doses selected for risk assessment to account for both interspecies extrapolation and intraspecies variability. An additional factor of 10X was retained in accordance with the FQPA for the dietary risk assessment. In accordance with current EPA policy, the FQPA factor is not retained for the occupational 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 adequate, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of methyl parathion can be found in the June 1, 1999 Toxicology Chapter, June 4, 1999 Human Health Risk Assessment and the June 14, 2002: 2nd Revised HED Chapter. A brief overview of the studies used for the dietary risk assessment is outlined in Table 3 in this document.

b. FQPA Safety Factor

The decision to retain the full 10X FOPA Safety Factor was based on a weight-of-evidence that included a data gap that could be filled with the submission of a Developmental Neurotoxicity Study (DNT). The DNT has been received and is under review. A reevaluation of the need to retain or reduce the FQPA factor will follow the completion of the DNT review. The data that were instrumental in the decision to retain the 10X are discussed below and in "METHYL PARATHION - Report of the FQPA Safety Factor Committee. Brenda Tarplee. July 21, 1999").

Neuropathology is reported in acceptable studies submitted by the registrant.

- Neuropathology seen in experimental animals in the guideline acute neurotoxicity study;
- Neuropathology seen in experimental animals in the guideline chronic/carcinogenicity study;
- Neuropathology seen in experimental animals in the non-guideline, but acceptable one year neurotoxicity study.

*The registrant has submitted a re-read of the neuropathology slides from several of these studies. These submissions are currently under review.

Fetal/neonate susceptibility is reported in open literature citations which were retrieved and reviewed by the Agency.

- An open literature citation which assessed postnatal functional toxicity following prenatal exposure reported the inhibition of acetyl cholinesterase and other neurochemical biomarkers in pups which persisted to day 28 and impaired behavioral parameters (Gupta *et. al.* 1985);
- Additional open literature citations reported that neonates were more sensitive to acute lethality from methyl parathion than adults and that significant compound-related and age-related differences in duration of ChEI can occur (Pope *et.al.* 1991; Pope and Chakraborti 1992);
- Possible endocrine disruption in mammals (Dhondup and Basavanneppa 1997, Lukaszewica-Hussain, Moniuszko-Jakoniuk and Pawlowska 1985).

Fetal/neonate sensitivity/susceptibility is reported in studies submitted by the registrant during the comment period.

- Decreased survival and convulsions in the surviving F_{1b} pups were reported in a non-guideline multi-generation reproduction study in rats;
- Embryotoxicity or fetotoxicity was observed at non-maternally toxic levels in an

additional supplementary developmental study in rats which had previously been submitted to the Agency.

The standard guideline studies for developmental and reproductive toxicity, which have been submitted by the registrant and are acceptable, are not required to measure ChEI, behavioral effects, neuropathology, or increased sensitivity to lethal effects in pups. Thus, these studies are silent on effects that have been reported in the open literature. Even though the open literature studies have a number of deficiencies, the fact that *several* studies have reported adverse effects on neonates raises concern. The suggestive evidence of possible endocrine disruption, although not heavily weighted, was also taken into account. If the information from these studies is considered together with the reported neuropathology seen in adult animals after a single and multiple doses of methyl parathion and the results from the supplementary developmental and reproduction studies submitted by the registrant which demonstrate fetal and neonate sensitivity, the concern for effects on the developing organism increases. Thus all of these data, taken *in toto* require that the 10X FQPA Safety Factor be retained until such time as the Agency completes the review of the submitted DNT. When the study review is completed, the final decision on the retention, reduction, or removal of the 10X FQPA Safety Factor will be made based upon the weight of the evidence.

c. Population Adjusted Dose (PAD)

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

Acute PAD

The dose and endpoint for establishing the RfD is the NOAEL = 0.11 mg/kg based on plasma, brain and RBC ChEI, and neuropathology at 0.53 mg/kg (LOAEL). A UF of 100 was applied to account for inter-species variation (10x) and for intra-species extrapolation (10x).

Acute RfD: 0.11 mg/kg ÷ 100 (UF) = 0.0011 mg/kg

Acute PAD (aPAD): 0.001 ÷ 10 (FQPA) = 0.00011 mg/kg

Chronic PAD

The dose and endpoint for establishing the RfD is the NOAEL = 0.02 mg/kg based on

RBC ChEI, neuropathology, and hematologic effects seen at 0.21 mg/kg (LOAEL). A UF of 100 was applied to account for inter-species variation (10x) and for intra-species extrapolation (10x).

Chronic RfD: 0.02 mg/kg ÷ 100 (UF) = 0.0002 mg/kg

Chronic PAD (cPAD): 0.0002 ÷ 10 (FQPA) = 0.00002 mg/kg

d. Endpoints and Doses for Dietary Risk Assessment

Table 3. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Methyl Parathion.

Assessment	Dose mg/kg/d	Endpoint	Study	UF	FQPA Safety Factor	PAD mg/kg/d
Acute Dietary	0.53	neuropathology and inhibition of brain, plasma, and RBC ChE NOAEL 0.11 mg/kg/d	41853801 44204501	100	10	0.00011
Chronic Dietary	0.21	systemic toxicity, neuropathology and inhibition of RBC ChE NOAEL 0.02 mg/kg/d	00074299	100	10	0.00002

e. Exposure Assumptions

Revised acute and chronic dietary risk analyses for methyl parathion were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-92.

The methyl parathion residues of concern for plant and animal commodities included in this risk assessment are based on ChEI, and are methyl parathion and methyl paraoxon. Although tolerances for residues of methyl parathion have been established on numerous animal feed items, no tolerances for residues of methyl parathion have been established in animal commodities of meat, milk, poultry, and eggs [Category 3, 40CFR §180.6(a)] because there is no reasonable expectation of finite residues. Residues of methyl parathion or paraoxon were not detected in ruminant tissue, milk, and egg samples collected from the ruminant and poultry metabolism studies or in USDA monitored samples (1304 samples) of milk (1996-1998). Residues of methyl parathion detected in poultry tissue samples collected from the poultry metabolism study were very low. Based on available data, estimates for residues of methyl parathion and methyl paraoxon in animal commodities were not included in the dietary risk assessment for methyl parathion. If required,

appropriate tolerances for methyl parathion residues in animal commodities will be determined once data are available from outstanding livestock feeding studies.

The dietary assessment is highly refined, using all available monitoring, processing and cooking factors. Methyl parathion residue estimates in this assessment are based primarily on three data sources: 1) field trial data, submitted by the registrant to support tolerances; 2) USDA Pesticide Data Program (PDP) food sampling data; and 3) Food and Drug Administration (FDA) Surveillance Monitoring data. Field trial data are normalized for percent crop treated and processing data. Field-trial data were used for the following commodities: sugar beets, green onions, almonds, pecans, walnuts, cottonseed, hops, canola, and sunflowers.

f. Acute Dietary Risk from Food

The Agency conducted the dietary risk assessment for methyl parathion using available data and updated methods for estimating acute dietary exposure. The uses/crops included in this assessment reflect the MOA between the Agency and the registrants (August 2, 1999) in which it was agreed that some uses/crops would be canceled. Risk estimates are provided for the general U.S. population and various population subgroups, including estimates for infants and children. This assessment concluded that the dietary risks for the post-MOA remaining uses do not exceed the aPAD for any population subgroup.

The uses for methyl parathion included in this assessment (reflecting the MOA) are: almonds, barley, dried beans, cabbage, canola oil (rape seed oil), field corn, sweet corn, cottonseed, hops, lentils, oats, onions, peanuts, dried peas, pecans, potatoes, rice, rye, soybeans, sugar beets, sunflowers, sweet potatoes, walnuts, and wheat.

Based on the acute dietary exposure analysis as described above and using an aPAD of 0.00011 mg/kg/d, acute dietary exposure to all population subgroups does not exceed the aPAD at the 99.9th exposure percentile (Table 4).

Table 4. Post-mitigation Acute Dietary Risk Estimates.

Population	(99.9th percentile)	
	Exposure	% aPAD
U.S. Population	0.000066 mg/kg/day	60
All Infants <1 year	0.000067 mg/kg/day	61
Children 1-6 years	0.000082 mg/kg/day	75

Population	(99.9th percentile) Exposure	% aPAD
Children 7-12 years	0.000085 mg/kg/day	77
Females 13-50 years	0.000058 mg/kg/day	53

2. Chronic Dietary Risk from Food

For chronic risk assessment, reported residues were averaged, whether based on PDP, FDA, or field trials. If a commodity had no reported detections by the PDP and FDA programs, and the expectation of no detection was confirmed by field trial data, the weighted average of the Limits of Detection (LOD) were used to account for possible exposure that could not be more precisely quantified (½ LOD methyl parathion + ½ LOD methyl paraoxon).

Based on the chronic dietary exposure analysis reflecting mitigation measures and using a cPAD of 0.00002 mg/kg/d, chronic dietary exposure to all population subgroups does not exceed the cPAD (See Table 5 following).

Table 5. Post-mitigation Chronic Dietary Risk Estimates

Population	Exposure (mg/kg/day)	% Chronic PAD
U.S. Population	0.000001	4
All Infants (<1 year)	0.000001	3
Children 1-6 years	0.000002	8
Children 7-12 years	0.000001	6
Females 13-50 years	0.000001	3

The mitigation measures, including the deletion of fruits and most vegetables, removed many of the substantial contributors, and therefore greatly lowers the potential dietary exposures to the US population and all population subgroups.

3. 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 monitoring data, if available, to estimate those risks.

While the Agency's Office of Water (OW) has established a lifetime Health Advisory (HA) Level of 2 ppb, methyl parathion does not have an established Maximum Contaminant Level, and is not included on the OW's Unregulated Contaminant Monitoring List. Therefore, public drinking water supply systems are not required to analyze for methyl parathion. Consequently, EPA has relied on simulation models and other surface- and ground-water monitoring data for this revised risk assessment. Drinking water concentrations for ground water were estimated after considering model estimates from the Tier 1 SCI-GROW model and ground-water monitoring data. Drinking water concentrations for surface water were estimated after considering the Tier 2 PRZM/EXAMS surface water model estimates and limited targeted surface water monitoring data. Please see the EFED Risk Assessment chapter for a complete discussion of the ground and surface water monitoring studies.

The only environmental degradate of human toxicological concern included in the assessment is the metabolite methyl paraoxon. Although there are not extensive monitoring data for methyl paraoxon in raw and finished drinking waters, methyl paraoxon was not detected (LOD =0.031 ppb) in raw or finished water samples in the United States Geological Survey (USGS)/EPA Reservoir Monitoring Program. Methyl parathion, however, was detected (0.061 ug/L) in a single raw water sample at the Lake Bruin water treatment plant. It is important to note the monitoring study was not targeted to methyl parathion use areas. The Agency does not currently have any data available with which to predict the rate of formation or the half-life of methyl paraoxon. Though there are data to show that other organophosphate pesticides such as diazinon and malathion, degrade to their oxon metabolites during drinking water treatment, it is unknown if methyl parathion would behave in a similar manner.

a. Surface Water

Methyl parathion has been included as an analyte in several national-scale surface-water (non-drinking-water) monitoring studies since the early 1970's. Methyl parathion was detected in 2% or fewer of the samples taken in these studies, with a maximum concentration of 1 ppb. However, these survey studies were not targeted specifically to methyl parathion, and therefore are not well-suited for the determination of potential acute exposure.

Limited targeted monitoring data have been collected for methyl parathion, most recently in the Mississippi Embayment NAWQA study undertaken by the USGS. Samples were taken from five rivers in this cotton-growing region, and methyl parathion was detected

in all five. The maximum concentration detected was 0.422 ppb.

Targeted monitoring has also been performed in California to evaluate the effect of management measures on the concentration of methyl parathion in surface water due to use on rice. Before these measures were instituted in the early 1990's, methyl parathion was detected at concentrations up to 6 ppb in the Colusa Basin Drain, which drains to the Sacramento River. The California Environmental Protection Agency determined that spray drift from aerial applications led to as much as 15% deposition directly to water bodies adjacent to treated rice fields. However, since the imposition of irrigation and application controls along with a reduction in the use of methyl parathion on rice, the maximum detection has been 0.12 ppb.

The Agency cannot state with confidence that the concentrations detected in the limited targeted monitoring studies represent the highest surface-water concentrations that might occur in areas of methyl parathion use. However, given the lack of direct drinking water data, and uncertainties related to the effects of water treatment on methyl parathion, the Agency also cannot state with certainty that concentrations of methyl parathion detected in surface water correspond to the concentrations that might be detected in drinking water derived from surface water.

Surface water monitoring studies performed over the past 30 years have not shown concentrations of methyl parathion at levels predicted in the chronic modeling assessments using PRZM-EXAMS (4.2 ppb). A single study at two drinking water intakes on the Mississippi River yielded an average detection of 0.009 ppb in weekly composite samples. While the chronic monitoring data were very limited, the data from the Mississippi River study were collected closer to drinking water intake over a period of a year from a high-use area and therefore may be approaching what may be actual residues in surface source drinking water. The Agency recognizes that long-term, targeted monitoring studies would be required to more accurately quantify the spatial and temporal variability of methyl parathion concentrations in drinking water.

b. Ground Water

Methyl parathion has been detected in ground water, but these detections have been rare, and at low concentrations. Although targeted ground-water monitoring data for methyl parathion are limited, an extensive body of ground-water monitoring data is available, with a maximum reported concentration of 0.256 ppb. EPA considers the concentration of 0.6 ppb estimated with the SCI-GROW screening model to be a reasonable conservative estimate of possible acute concentrations of methyl parathion in drinking water derived from ground-water.

However, given the rarity of detections of methyl parathion in ground water, the estimate of 0.6 ppb does not seem appropriate for use in the chronic drinking water assessment. The Agency does not currently have a second-tier model with which to refine the ground-water assessment. However, EPA concludes that methyl parathion does not pose a chronic concern for drinking water derived from ground water.

c. Drinking Water Levels of Comparison (DWLOCs)

Generally, the Agency calculates Drinking Water Levels of Comparison (DWLOC) for comparison to measured or modeled drinking water concentrations for the risk analysis. The DWLOC is the concentration in drinking water, as part of the aggregate exposure, that occupies no more than 100% of the PAD. The dietary exposure from food and DWLOC together, cannot be greater than 100% of the PAD. Any measured or modeled drinking water estimates that are less than the DWLOC are not of concern.

ACUTE

An acute DWLOC ($DWLOC_{acute}$) was calculated using the following formulae:

$$DWLOC_{acute}\ (\mu g/L) = \frac{\text{acute water exposure (mg/kg/d) x body weight (kg)}}{\text{consumption (L/d) x } 10^{-3}\ \text{mg/}\mu g}$$

where acute water exposure (mg/kg/d) = [aPAD - acute food (mg/kg/d)]

The current Agency default body weight and consumption values are 10 kg and 1 liter/day, respectively, for all infants and children, 70 kg and 2 liters/day for adult males, and 60 kg and 2 liters/day for adult females. These default values and others are presently under review in the Agency (Office of Research and Development). If at a future time, the Agency decides to change the default assumptions used, the impact of the changes on the methyl parathion risk assessment will be considered.

Surface water monitoring data range between 6 ppb from methyl parathion applications to rice fields in California to 0.42 ppb from applications to cotton in Mississippi. After the monitoring data were recorded in California, the state instituted a number of its own mitigation measures to reduce contamination of surface waters and therefore, present-day concentrations would be expected to be lower. As a result of these mitigation measures, the peak surface water concentration from targeted monitoring studies in Mississippi (0.42 ppb) may represent a conservative peak concentration of methyl parathion in surface source waters. EPA has more confidence in the surface water concentrations from Mississippi (0.42 ppb). It should also be noted that cotton has the highest application rate for methyl parathion of all remaining uses.

Table 6. Acute Surface Water Reflecting Use from the 1999 MOA Mitigation Measures

Population	Monitoring Data (ug/L)	aPAD (mg/kg/d)	Acute Food Exposure (mg/kg/d)	Acute H_2O Exposure (mg/kg/d)	$DWLOC_{acute}$ (ug/L)
General U.S. Population	0.42	0.00011	0.000066	0.000044	1.54
Females 13-50 years	0.42	0.00011	0.000058	0.000052	1.56
Infants <1 year	0.42	0.00011	0.000067	0.000043	0.43
Children 1-6 years	**0.42**	0.00011	0.000082	0.000028	**0.28**

Though comparisons between the surface water monitoring data and the $DWLOC_{acute}$ for children 1-6 years of age raise some concerns, it is uncertain what the effects of water treatment have on residues in finished drinking water. Since these Mississippi monitoring data come from a high use region (cotton has the highest application rate) and represent source water concentrations only, the Agency believes that they are somewhat conservative, though recognizably limited in their ability to capture spatial and temporal variability of methyl parathion residues in drinking water.

It is uncertain whether exposures from ground water would pose a risk concern without any targeted monitoring studies. The highly conservative modeled ground water concentration of 0.6 ppb from the acute model is the estimated concentration for both the acute and chronic ground water drinking water estimates. However, EPA believes it is very **unlikely that any ground water exposures would be as high as 0.6 ppb**, based on fate information and therefore is confident that this is a reasonable conservative estimate.

CHRONIC

A chronic DWLOC ($DWLOC_{chronic}$) was calculated using the following formulae:

$$DWLOC_{chronic}\ (\mu g/L) = \frac{\text{chronic water exposure (mg/kg/d) x body weight (kg)}}{\text{consumption (L/d) x } 10^{-3}\ \text{mg/}\mu g}$$

where chronic water exposure (mg/kg/d) = [cPAD - (chronic food + residential(ADD)(mg/kg/d)], and

ADD = average daily dose

Residential exposures were not factored into the $DWLOC_{chronic}$ since there are no residential uses of methyl parathion.

Non-targeted surface water survey studies performed over the past 30 years have not

shown concentrations of methyl parathion at levels predicted in the chronic modeling assessments (4.2 ppb). Concentrations from available monitoring studies were well below the OW's 2 ppb HA. Although the available chronic monitoring data do not allow a comprehensive assessment, EPA believes that chronic concentrations of methyl parathion in surface water will be below the 2 ppb HA. The table below shows the limited monitoring concentration of 0.009 ppb does not exceed the $DWLOC_{chronic}$.

Table 7: Chronic Dietary Exposure from Food (post-MOA) and Surface Water

Population	Monitoring Data (ug/L)	cPAD (mg/kg/d)	Chronic Food Exposure (mg/kg/d)	Chronic H_2O Exposure (mg/kg/d)	$DWLOC_{chronic}$ (ug/L)
General U.S. population	0.009	0.00002	0.000001	0.000019	0.67
Females 13-50 years	0.009	0.00002	0.000001	0.000019	0.57
Infants <1 year	0.009	0.00002	0.000001	0.000019	0.19
Children 1-6 years	0.009	0.00002	0.000002	0.000018	0.18

Based on the limited chronic drinking water monitoring data, potential residues of methyl parathion in surface water are not of concern. The chronic monitoring data were collected closer to the tap (drinking water intake) over a period of a year from a high use area and therefore, are approaching what may be actual residues in "at the tap" drinking water.

Again, it is uncertain whether exposures from ground water would pose a risk concern without any targeted monitoring studies. The highly conservative modeled ground water concentration of 0.6 ppb from the acute model is the estimated concentration for both the acute and chronic ground water drinking water estimates. However, EPA believes it is very unlikely that any ground water concentrations would be as high as 0.6 ppb, based on fate and monitoring information.

d. Drinking Water Considerations

There are several things to consider when weighing the potential contribution to the total dietary risk from drinking water contaminated with methyl parathion. The monitoring data available to the Agency indicate that exposures would be expected to be lower than the modeled estimates. In addition, neither the models nor the monitoring data reflect concentrations after drinking water treatment. There are currently little data on the efficacy of other more common treatment technologies in removing methyl parathion.

When the available monitoring data were gathered, methyl parathion was measured, but methyl paraoxon usually was not. EPA does not have any data available with which to predict the rate of formation, or the half-life of, methyl paraoxon. Though there are data to show that another organophosphate, malathion, degrades to its oxon metabolite during drinking water treatment, it is unknown if methyl parathion would behave in a similar manner. Methyl paraoxon was not included in the drinking water assessment since there are no monitoring detections.

Given the fact that the monitoring data represent only a very small range of conditions (regional weather, streamflow, application rates and methods), it cannot be assumed that they represent surface water concentrations or conditions elsewhere in the United States. The data collected closest to the tap (treatment plant intake) in Louisiana do not indicate exposures that would be of concern. Though the Agency considers it unlikely that drinking water concentrations "at the tap," will make the largest, or a significant, contribution to the total dietary burden, there is sufficient information from available monitoring data and models to warrant close monitoring of potential surface and ground water sources of methyl parathion exposure.

Even though the monitoring data exceeds the DWLOC for some populations, the Agency believes that this acute drinking water risk estimate from the uses of methyl parathion may be mitigated by provisions cited in this document such as reduced application rates and numbers of applications.

4. Aggregate Risk Assessment

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources for aggregate chronic risk, specifically; food, drinking water, and residential. Methyl parathion has no registered residential uses, therefore only exposures through food and drinking water were considered in the aggregate risk assessment. Therefore, the aggregate risks are the same as those presented in Section 2 above.

Although methyl parathion is a restricted use pesticide that is only to be applied by certified applicators, residential exposures may occur from spray drift from the application of methyl parathion to agricultural fields. Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from ground application methods. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target

drift and risks associated with aerial as well as other application types where appropriate.

5. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. However, as noted above, there are no residential uses. Occupational handlers of methyl parathion 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 determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

The Agency has determined that there are potential short- and intermediate-term exposures to mixers, loaders, applicators, and other occupational handlers during the usual use-patterns associated with methyl parathion. Based on the use patterns of methyl parathion, nineteen major exposure scenarios were identified for the ME and EC formulations. See details in *"Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Methyl Parathion. By Renee Sandvig. May 29, 2002"*.

a. Current Label PPE

Current label PPE for handlers includes coveralls over long sleeved shirt and long pants, waterproof or chemical resistant gloves, chemical resistant footwear plus socks, protective eye wear, and chemical resistant headgear to protect against overhead exposure. For exposure in enclosed areas, a respirator with an organic vapor removing cartridge with a prefilter or canister approved for pesticides is required. For outdoor exposures, a dust/mist filtering respirator is required. Some labels also require a chemical resistant apron when cleaning equipment or mixing/loading the product. The 1999 MOA restricts the application of EC methyl parathion products to handlers using enclosed cabs/cockpits only and prohibits human flaggers. Most EC products are packaged Micromatic "DV" liquid transfer enclosed mixing/loading systems.

b. Toxicity

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

residential risk assessments for methyl parathion are listed below. Methyl parathion is very toxic by oral, dermal, and inhalation routes, but is not a strong eye or dermal irritant and is not a skin sensitizer.

Table 8: Acute Toxicological Categories for Methyl Parathion.

Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.1100	Acute Oral (rat)		LD_{50} = 4.5-24 mg/kg	I
870.1200	Acute Dermal (rat)		LD_{50} = 6 mg/kg	I
870.1300	Acute Inhalation (rat)	256961	LC_{50} < 0.163 mg/L (< 7 mg/kg)	I
870.2400	Primary Eye Irritation (rabbit)	256966, 40542602	Irritation clear by 7 days	III
870.2500	Primary Skin Irritation	256962	Max. score = 2.0; 72 h = 0.5	IV
870.2600	Dermal Sensitization	256963	Negative	NA
870.6100	Acute Neurotoxicity Delayed Hen	41606801	Negative	NA

A 28 day dermal toxicity study was selected for this risk assessment because it is of an appropriate duration and route of exposure, and the effects of concern (ChEI, hematological effects, and neuropathology) were assessed. Based on the effects seen in this study (MRID# 45481601), the LOAEL was 0.3 mg/kg/day (based on ChEI in RBC and brain on day 28), with no NOAEL determined. In addition to the standard application of a UF of 100 to account for inter-species variation (10x) and for intra-species extrapolation (10x), a UF of 3 was applied, to extrapolate from a LOAEL to a NOAEL (total UF=300). The choice of this study and UF are supported by the NOAEL of 0.11 from a chronic dietary neurotoxicity study with methyl parathion, based on brain, plasma, and erythrocyte ChEI and neuropathology at the LOAEL of 0.53 mg/kg/day, previously selected (March 29, 1999) for this endpoint, with a dermal absorption factor of 100%.

This chronic dietary neurotoxicity study in rats (MRID# 41853801, 44204501) was selected for the short- and intermediate-term inhalation endpoints. The dose and endpoint for risk assessment purposes is the NOAEL = 0.11 mg/kg based on plasma, brain and RBC ChEI, and neuropathology at 0.53 mg/kg (LOAEL). This study for risk assessment does not underestimate the risk for both short- (1-30 days) and intermediate-term (1-6 months) exposure, due to the longer duration of the selected study (one year) and the evaluation of the critical effects (ChEI and neuropathology). A UF of 100 was applied to account for inter-species variation (10x) and for intra-species extrapolation (10x). Due to the high

toxicity seen in the submitted acute inhalation study, 100% absorption was used.

Table 9: Methyl Parathion Endpoints.

Exposure Scenario	Dose (mg/kg/day)	Effect	Study
Short- (1-30 days) & Intermediate- (1-6 months) term Dermal	LOAEL = 0.3 UF = 300	Inhibition of brain and RBC ChE. No NOAEL identified.	28-Day dermal toxicity study in rats. MRID# 45481601
	Dermal LOC for occupational MOE = 300		
Short - & Intermediate-term Inhalation	NOAEL = 0.11 UF = 100	Neuropathology and inhibition of brain, plasma, and RBC ChE. Inhalation absorption rate estimated to be 100%.	One year dietary neurotoxicity study in rats. MRID# 41853801, 44204501
	Inhalation LOC for occupational MOE = 100		
Cancer	**Classification**: Group E or "Not Likely"		

The overall LOC for occupational MOE is 100 since for the dermal study, the LOAEL of 0.3 mg/kg/day is divided by 3 to determine an adjusted LOAEL of 0.1 mg/kg/day for use in the risk calculations. In other words, the dermal and inhalation risks were normalized by applying the 3x factor to the dose. Biomonitoring exposures may occur by both dermal and inhalation routes and, given the available data, cannot be separated into components for risk assessment.

c. Exposure

The duration of exposure for handlers of methyl parathion is assumed to be short-and intermediate-term (1-30 days; 1-6 months). Since methyl parathion is applied to several large acreage crops, it is assumed that a professional pesticide applicator could apply methyl parathion for over one month, therefore; intermediate term handler exposure was assessed; however, endpoints and doses are the same as for the short term handler exposures.

Handler exposure assessments were completed using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) in an attempt to achieve an appropriate margin of exposure. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, no respirator, and no chemical-resistant gloves. Scenarios were assessed with PHED and with chemical specific data at the median and 90th percentile study unit exposure. For simplicity, scenarios with median values, chemical specific data and engineering controls are presented here. For a complete scenario listing see the *"Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Methyl Parathion. By*

Renee Sandvig. May 29, 2002".

Scenarios included in this document are:

2a) Mixing/Loading Liquids (EC formulations) for Aerial Application
2c) Mixing/Loading Liquids (EC formulations) for Groundboom Application
3a) Mixing/Loading Liquids (ME formulation) for Aerial/Chemigation Application
3c) Mixing/Loading Liquids (ME formulation) for Groundboom Application
3e) Mixing/Loading Liquids (ME formulation) for Airblast Sprayer
4) Applying Liquids with Aerial Equipment (EC and ME formulations)
5) Applying Liquids with a Groundboom Sprayer (EC formulation)
6a) Applying Liquids with a Groundboom Sprayer (ME formulation)
7) Applying Sprays with an Airblast Sprayer (ME formulation)

i. Chemical Specific Data

Chemical specific handler data were submitted by Cheminova and Cerexagri according to the requirements stated in the 1999 MOA. Cheminova submitted one biomonitoring mixer/loader study in support of the EC formulation (MRID# 455276-01). Cerexagri submitted two biomonitoring mixer/loader studies (MRID# 455130-01 & 453271-01) and two biomonitoring groundboom application studies (MRID# 454490-01 & 455024-01) in support of the ME formulation. These studies have been reviewed by the Agency for compliance with OPPTS Series 875: Occupational and Residential Exposure Test Guidelines. All workers who participated in the biomonitoring studies read and signed Informed Consent forms, which explained the purpose of the study, the procedures, and a statement of their rights.

Unit exposure values were calculated from the five submitted chemical specific handler studies. The amount of methyl parathion that a worker was exposed to was determined by the amount of the methyl parathion metabolite, 4- (or para) nitrophenol (4NP) found in the workers' urine. The raw data (which consisted of the amount of 4NP found in a 24-hour urine sample) were corrected for four parameters: 1) field recovery data, 2) creatinine content, 3) molecular weight, and 4) metabolism of methyl parathion to 4NP in the body. The corrections for these parameters are explained in *Revised "Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Methyl Parathion. Renee Sandvig. May 29, 2002*.

Both inhalation and dermal exposure may result from the handling of methyl parathion. Biomonitoring data measures in total exposure (dermal + inhalation), therefore it is difficult to determine from which route this exposure occurred. Since the dermal and

inhalation endpoints are very similar (0.11 mg/kg/day for inhalation and 0.1 mg/kg/day for dermal), there was no need to determine from which route the exposure occurred.

ii. Surrogate Data

Chemical specific handler data does not exist for several of the identified handler scenarios, including application of sprays with aerial equipment, an airblast sprayer (ME formulation only) and a groundboom sprayer (EC formulation only). It is the EPA policy to use
data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available. The exposure and risk values were also calculated using PHED unit exposure values for the scenarios that have chemical specific handler unit exposure data (mixing/loading the EC and ME formulations and applying the ME formulation with a groundboom sprayer) as a comparison, since the PHED data have more replicates.

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

iii. Data Comparison

Table 10 below, shows a comparison of the PHED unit exposure values and the unit exposure values determined from the submitted biomonitoring studies. After the unit exposure values were obtained from the study data, the doses were calculated using the standard handler exposure equations.

Table 10. Comparison of PHED and Study Unit Exposure Values.

	Mixer/Loader ME Open System (mg/lb ai)	Mixer/Loader EC Closed System (mg/lb ai)	Open Groundboom Tractor Applicator ME (mg/lb ai)
PHED unit exposure (dermal/inhalation)	0.017/ 0.00024 (liquid surrogate data)	0.0086/0.000083	0.011/0.00015 (liquid surrogate data)
PPE worn	double layer of clothes, gloves, dust/mist respirator	single layer of clothes, gloves	double layer of clothes, gloves, dust/mist respirator
# of PHED Replicates	75 to 122 dermal, 53 hand, 85 inhalation	16 to 22 dermal, 31 hand, 27 inhalation	23 to 42 dermal, 21 hand, 22 inhalation
Biomonitoring Study Unit Exposure (total)	0.000201	0.000030	0.000468
PPE worn	double layer of clothing, gloves, plastic goggles, and dust/mist filtering respirator. Some workers also wore a face shield, instead of goggles, chemical resistant apron, and Tyvek® rain type hat.	Double layer of clothing, gloves, protective eye wear, chemical-resistant apron; and dust/mist filtering respirator.	double layer of clothes, gloves, protective eyewear, chemical-headgear; and dust/mist respirator
# of Study Replicates	26	16	15
Study Distribution/ Average Used	neither lognormal or normal/ median	neither lognormal or normal/ median	lognormal/ geometric mean
90th Percentile Study Unit Exposure Value (total)	0.000882	0.000151	0.00186

The following factors should be considered when comparing the differences in the unit exposure values calculated from the study and the PHED unit exposure values. The PHED data unit exposure values for mixing/loading of the ME formulation were conducted using liquids, not an ME formulation; therefore, the study unit exposure values for this formulation should be considered more representative for the mixing/loading scenario than the PHED values. The lower ME unit exposure values may indicate that the ME formulation is not as readily absorbed into the skin as a standard liquid, since it is encased in the microcapsules. Also, as required by the 1999 MOA, the workers in the chemical specific studies were wearing more PPE than the workers did in the PHED studies. In the groundboom study, in addition to the double layer of clothing, gloves and dust/mist respirator, the workers wore plastic eyewear and headgear. In the mixer/loader studies, some workers wore eyewear or face shields, rain hats and aprons, in addition to the double layer of clothing, gloves and dust/mist respirator. In the closed mixing/loading study for the EC formulation, the workers wore double layer of clothing and a dust/mist respirator, which are not normally worn by workers operating closed systems, but which were required for the

methyl parathion EC by the 1999 MOA. This extra PPE may have lowered the study unit exposure values in comparison to the PHED data.

d. Summary of Risk Concerns for Handlers

Dermal and inhalation risks for handlers were combined into a total MOE since the effects seen at the LOAEL were the same (ChEI). Handler exposures to methyl parathion are expected to be short- and intermediate-term (1-30 days, 1-6 months, respectively). Since short- and intermediate-term exposures have the same endpoints, the following risks are for both durations of exposure. The target MOE for occupational exposures is 100 (3x assigned to the short and intermediate term dermal endpoint was already accounted for by dividing the LOAEL of 0.3 mg/kg/day by 3 to determine an adjusted LOAEL of 0.1 mg/kg/day for use in the risk calculations).

Chemical specific data do not presently exist for the following scenarios and may further refine exposure and risk calculations: applying the EC formulation with aerial equipment and groundboom equipment, and applying the ME formulation with aerial equipment and airblast sprayers. Additionally, no data exists for flagging aerial spray operations for both formulations, but the registrants have asked to prohibit the use of human flaggers for methyl parathion applications.

- For mixing/loading the EC formulation, all of the assessed scenarios have a risk of concern using PHED data. Using the chemical specific data, no scenarios are of concern at the 50th percentile.

- For mixing/loading the ME formulation, all of the assessed scenarios have a risk of concern using PHED data. Using the chemical specific data, one out of the four scenarios assessed mixing/loading for aerial applications has a risk of concern at the additional PPE level of exposure; at the 50th percentile.

- For applying the EC formulation, no chemical specific data were available and all scenarios assessed using PHED surrogate data have a risk of concern.

- For applying the ME formulation, all of the assessed scenarios have a risk of concern using PHED data. Using the chemical specific data for applying ME with a groundboom, there is a risk of concern at an application rate of 1 lb ai/acre and 200 acres per day.

The PHED data are considered at the 50th percentile and for regulatory purposes, the 50th percentile (or median) of the biomonitoring studies are presented here. Risks of concern do exist using the study data, at the 90th percentile for mixing/loading the EC

formulation for aerial applications, mixing/loading the ME formulation for groundboom, airblast, and aerial applications. The PHED surrogate data do have more replicates (53 to 122) compared with the study data (26) for mixing/loading and 39 to 47 PHED replicates compared to 15 study replicates for applying sprays with a groundboom.

The risks from mixing/loading the EC formulation in the closed micromatic "DV" liquid transfer system are lower than those assessed using closed mixing/loading PHED liquid data. This may indicate that the closed system used in this study is effective at reducing the risks from mixing/loading the ECs. However, the study conducted on closed mixing/loading using the micromatic "DV" transfer system had workers wearing more PPE than would normally be used with an engineering control, such as double layer of clothing and a dust/mist respirator. Risks of concern still exist using the study data at the higher usage amounts (1200 acres per day) and the 90th percentile. The PHED data do have more replicates (16 to 32) compared with the study data (16) for mixing/loading.

Table 11 summarizes the MOEs calculated for each mitigation level. The short and intermediate-term MOEs are identical since they have the same endpoint (dermal endpoint adjusted).

Table 11. Summary of Occupational Short- and Intermediate-Term Total Inhalation and Dermal MOEs for Methyl Parathion.

Exposure Scenario (Scenario #)	Unit Exposure Data Source[a]	Maximum Application Rate (lb ai/acre)[b]	Crop[c]	Daily Acres Treated[d]	Total MOE[e]		
					Baseline[f]	Additional PPE[g]	Engineering Controls[h]
Mixer/Loader Exposure and Dose Levels							
Mixing/Loading Liquids (EC formulations) for Aerial Application (2a)	Study (45527601) median	0.375	sugar beets	350	ND	ND	1800
		1.5	Potato[c]				440
		0.5	Corn	1200			390
		1.0	Alfalfa				190
Mixing/Loading Liquids (EC formulations) for Groundboom Application (2c)	Study (45527601) median	0.375	sugar beets	80	ND	ND	7800
		1.5	potato				1900
		0.5	Corn	200			2300
		1.0	Alfalfa				1200
Mixing/Loading Liquids (ME formulation) for Aerial/Chemigation Application (3a)	Study (45327101, 45513001) Median	0.5	Onion	350	ND	200	ND
		1.0	corn			100	
		2.0	Walnut			50	
		1	corn	1200		29	
Mixing/Loading Liquids (ME formulation) for Groundboom Application (3c)	Study (45327101, 45513001) Median	0.5	Onion	80	ND	870	ND
		1.5	Potato			290	
		1	corn	200		170	
Mixing/Loading Liquids (ME formulation) for Airblast Sprayer (3e)	Study (45327101, 45513001) Median	2	walnuts	40	ND	440	ND
Applicator Exposure							
Applying Liquids with Aerial Equipment (EC and ME formulations) (4)	PHED	0.375	sugar beets	350	See Eng. Controls	See Eng. Controls	11
		1.0	Alfalfa				4
		2.0	Walnut				2
		0.5	Corn	1200			2
		1.0	Alfalfa				1

Table 11. Summary of Occupational Short- and Intermediate-Term Total Inhalation and Dermal MOEs for Methyl Parathion.

Exposure Scenario (Scenario #)	Unit Exposure Data Source[a]	Maximum Application Rate (lb ai/acre)[b]	Crop[c]	Daily Acres Treated[d]	Total MOE[e]		
					Baseline[f]	Additional PPE[g]	Engineering Controls[h]
Applying Liquids with a Groundboom Sprayer (EC formulation) (5)	PHED	0.375	sugar beets	80	16	21	46
		1.5	Potato		4	5	12
		0.5	Corn	200	5	6	14
		1.0	Alfalfa		2	3	7
Applying Liquids with a Groundboom Sprayer (ME formulation) (6a)	Study (45449001, 45502401) geometric mean	0.5	Onions	80	ND	370	ND
		1.5	Potato			130	
		1.0	Corn	200		75	
Applying Sprays with an Airblast Sprayer (ME formulation) (7)	PHED	2.0	Walnut	40	0.24	0.40	5

Footnotes

EC = emulsifiable concentrate formulation. ME = microencapsulate formulation.
ND = No data for this scenario for this data source.

a Unit exposure data source: PHED unit exposure data shown for all scenarios, either as the sole unit exposure data source or as a comparison to the unit exposure data determined from the studies. Unit exposure data from the studies shown for the average unit exposure value. See above study summaries and description of unit exposure calculations shown previously in this document for more information.

b Application rates are a range of maximum application rates proposed by the registrant and on the labels. See list of crop specific application rates in the use section of this assessment for more information.

c Crops named are index crops which are chosen to represent all other crops at or near that application rate for that use. See the application rates listing in the use summary section of this document for further information on application rates used in this assessment. The assessment of the range of application rates that exists for a scenario is what is assessed, index crops are only for clarification. Note: the rate for use of the EC on white potatoes is 0.75 lb ai.

d Daily amount treated are based on Science Advisory Council for Exposure Policy # 9.1.[11]

e Total Short and Intermediate Term MOE =1/((1/dermal MOE)+(1/inhalation MOE)). See Appendix Tables E, F, and G for individual dermal and inhalation values.

f Baseline exposure represents long pants, long sleeved shirt, no gloves, no respirator, open mixing/loading, open cab tractor. Baseline data are not available for aerial equipment.

g Additional PPE represents long pants, long sleeved shirt, coveralls, gloves, dust/mist respirator, open mixing/loading, open cab tractor.

h Engineering controls represent long pants, long sleeved shirt, no gloves or respirator with the following equipment:

Scenario Number	2	Micromatic “DV” liquid transfer system, gloves, double layer clothing, and dust/mist respirator
	3	Closed mixing / loading, single layer clothing, chemical resistant gloves.
	4, 5, 6, 7	Enclosed cab, single layer clothing, no gloves.

6. Post-Application Occupational Risk

The postapplication occupational risk assessment considered exposures to workers entering treated agricultural sites. All of the postapplication risk calculations for handlers completed in this assessment are included in the HED chapter. Calculations were done for activities such as scouting and irrigation, sweet corn and walnut harvesting, hand weeding, and thinning.

In the Worker Protection Standard (WPS), a restricted entry interval (REI) is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in any task or activity would not result in exposures which are of concern. Typically, the activity with the highest risk will drive the selection of the appropriate REI for the crop. The REIs on currently registered methyl parathion labels were set according to the requirements stated in the 1999 MOA. The REIs set in the agreement were considered interim until methyl parathion dislodgeable foliar residue (DFR) data were reviewed and analyzed in order to determine the final requirements for the REIs. These interim REIs are 4 days, except for areas receiving less than 25 inches of average rainfall per year. In these low rainfall areas the REI is 5 days.

a. Chemical Specific Data

The Agency has determined that there are potential postapplication exposures to individuals entering treated fields. Chemical specific handler data were submitted by the Cheminova and Cerexagri according to the requirements stated in the MOA between the primary methyl parathion registrants and the Agency, dated August 2, 1999. Cheminova submitted three DFR studies on corn, cabbage and cotton in support of the EC formulation (MRID# 452837-01, 453174-01, & 452925-01). Cerexagri submitted four DFR studies on corn (2), walnuts, and cotton (MRID# 452750-1, 452697-01, 453592-01, & 452697-02) and three postapplication biomonitoring studies on walnut harvesting, sweet corn hand harvesting, and cotton scouting (MRID# 453677-01 & 453915-01 amended, 452001-01, & 452047-01), in support of the ME formulation. The postapplication ME studies were done concurrently with the DFR studies in order to determine the transferability of the ME for the activity conducted in the studies. These studies have been reviewed by the Agency for compliance with OPPTS Series 875: Occupational and Residential Exposure Test Guidelines. All workers who participated in the biomonitoring studies read and signed Informed Consent forms, which explained the purpose of the study, the procedures, and a statement of their rights. Summaries of the studies can be found in *Revised "Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Methyl Parathion. Renee Sandvig. May 29, 2002*. The level of DFR of methyl paraoxon, a degradate of methyl parathion, was also determined in the DFR studies. No toxicity data exist for methyl paraoxon, so it is assumed to have the same toxicity as methyl parathion. Therefore, the DFR values for methyl paraoxon were combined with the methyl parathion DFR values found on that day.

b. Exposure and Risk Calculations

Chemical specific DFR data exist for the EC formulation on cotton, corn and cabbage. Chemical specific DFR data exist for the ME formulation on cotton, corn and walnuts. The DFR data were extrapolated to all remaining crops. DFR data were taken at three sites for each crop tested, for both formulations. Regression analyses were run on each data set, to determine half lives and correlation coefficients (R value) in order to predict residues between sampling days or after the study was completed, if necessary. For each formulation, there was no apparent trend in the half lives of the DFR values between sites for a single crop, such as half lives being longer in arid regions. Therefore, for brevity, the Agency chose one site per crop per formulation to use in the calculation of REIs. To be protective, the site with the longest half life was chosen. The half lives of the ME formulation are longer than the EC formulation. This most likely occurred because the polymeric-type microcapsules are designed to slowly release the active ingredient over time.

Transfer coefficients were calculated from the three submitted chemical specific postapplication biomonitoring studies and four microencapsulate DFR studies. The amount of methyl parathion that a worker was exposed to was determined by the amount of the methyl parathion metabolite, 4NP found in the workers' urine. The raw data (which consisted of the amount of 4NP found in a 24 hour urine sample) were corrected for four parameters: 1) field recovery data, 2) creatinine content, 3) molecular weight, and 4) metabolism of methyl parathion to 4NP in the body.

A dose and an MOE were determined from the declining predicted DFR values until the target MOE of 100 was reached for every crop for both formulations. Re-entry workers are expected to have both short term and intermediate exposures, but, since the short- and intermediate-term dermal endpoints are the same, the calculated REIs are for both short- and intermediate-term exposures. The adjusted dermal LOAEL used in the short- and intermediate-term assessment is 0.1 mg/kg/day and the target MOE is 100.

c. Occupational Postapplication Worker Summary

Occupational postapplication risks from dermal exposure are of concern. For short- and intermediate-term exposure to the EC formulation, the day after treatment when the calculated MOE equals or exceeds the target MOE of 100 (REI) ranges from 4 to 27 days. For short- and intermediate-term exposures to the ME formulation, the day after treatment when the calculated MOE equals or exceeds the target MOE of 100 (REI) ranges from 8 to 52 days. See Table 9 for a summary. The half lives and subsequent REI calculations of the ME formulation are longer than those for the EC formulation. As mentioned above, this most likely occurred because the polymeric-type microcapsules are designed to slowly release the active ingredient over time.

Worker exposure from entering the treated fields in the three biomonitoring postapplication ME studies results in a risk of concern for hand harvesting sweet corn when exposures were extrapolated to an eight hour work day.

Table 12. Summary of Calculated Short- and Intermediate-term Days Until MOEs Are 100.

	Application Rate (lb ai/acre)	Activity	Transfer Coefficient[a] (cm^2/hr)	Day after treatment when MOE =100
	Emulsifiable Concentrate			
alfalfa	1	irrigating and scouting	1,500	4
barley	0.75	irrigating and scouting	1,500	4
beans, dried	1.5	Hand harvest	2,500	27
		irrigating and scouting	1,500	19
cabbage	1.5	Hand harvesting, irrigating, pruning, and thinning	5,000	13
		hand weeding and scouting	2,000	11
corn	0.5	Hand harvesting and detasseling	17,000	5
		irrigating and scouting	1,000	3
cotton	0.75	irrigating and scouting	1,500	6
hops	1	hand and mechanical harvesting, training, hand weeding, and stripping	2,000	16
		scouting	1,300	9
oats	0.75	irrigating and scouting	1,500	4
onions	0.5	Hand harvesting and thinning	2,500	10
		irrigating, scouting, hand weeding, and pruning	300	7
peas, dried	1	hand harvest	2,500	20
		irrigating and scouting	1,500	11
canola	0.5	irrigating and scouting	1,500	4
rice	0.75	irrigating and scouting	1,500	4
rye	0.75	irrigating and scouting	1,500	4
soybeans	0.5	irrigating and scouting	1,500	4
sugar beets	0.375	irrigating and scouting	1,500	9
			100	4
sunflower	1	irrigating and scouting	1,500	4
wheat	1.5	irrigating and scouting	1,500	4
white potato	0.75	irrigating and scouting	1,500	6
		hand weeding	300	4
Crop	Microencapsulate			

	Application Rate (lb ai/acre)	Activity	Transfer Coefficient[a] (cm^2/hr)	Day after treatment when MOE =100
almonds, pecans, walnuts	2	hand harvest (exposure to foliage) shaking trees, hand raking nuts, mechanically blowing and sweeping nuts into windrows	**49[b]**	25
		hand harvest (exposure to soil) shaking trees, hand raking nuts, mechanically blowing and sweeping nuts into windrows	3[c] (g dry soil/hour)	14 (soil)
barley, oats, rice and wheat	0.75	Irrigating and scouting	640[c]	31
beans, dried	1	hand harvesting	2,500	14
		irrigating and scouting	640[c]	11
corn	1	hand harvesting and de-tasseling	12,000[d]	52
		irrigating and scouting	640[c]	31
sweet corn	1	hand harvesting and de-tasseling Florida half-life data	12,000[d]	9
cotton	1	scouting	640[c]	11
lentils and dried peas	0.5	Hand harvesting	1,500	13
		irrigating and scouting	640[c]	10
onions	0.5	Hand harvesting	1,500	13
		irrigating and scouting	300	8
soybeans	0.75	Irrigating and scouting	640[c]	11
sweet potato	0.75	Hand harvesting	2,500	14
		irrigating and scouting	640[c]	11
white potato	1.5	Irrigating and scouting	640[c]	12
		hand weeding	300	10

Footnotes:

a Transfer Coefficients from chemical specific studies, when noted, otherwise are from Science Advisory Council on Exposure Policy 3.1.[16]

b Transfer coefficient from microencapsulate walnut harvesting study MRID # 45391501.

c Transfer coefficient from microencapsulate cotton scouting study MRID # 45204701.

d Transfer coefficient form microencapsulate sweet corn hand harvesting study MRID # 45800101.

7. Human Incident Summary

The Agency has reviewed the Incident Data System, the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide

Telecommunications Network databases for reported incident information for methyl parathion *(Review of Methyl Parathion Incident Reports. Jerome Blondell & Monica Spann. February 5, 1998*). A number of accidental human poisonings from exposure to methyl parathion in both occupational and residential settings have been reported. The data from these sources often lacked specific information on the extent of exposure and the circumstances of exposure. Collectively, however, the incidence information indicate definite poisoning risks from misuse of products that contain methyl parathion, or from not wearing personal protective equipment, or from spray drift.

Exposure to methyl parathion can lead to systemic illness. In outdoor agricultural situations, the primary activities associated with poisoning are application and spray drift. Compared to other OP and carbamate insecticides, methyl parathion is associated with less poisoning when adjusted for amount of use. To some extent the similarity between the methyl parathion and the far more toxic ethyl parathion (in terms of poisonings and deaths even after adjusting for use), may have resulted in workers handling any product with the 'parathion' name with greater care. More recently, ethyl parathion uses have been cancelled.

Interior home misuse of methyl parathion has resulted in deaths in two separate incidents in Mississippi. Food or water contamination and an unusually high concentration used in the application probably contributed to these deaths which occurred in the 1970s and early 1980s. The more recent cases exposed primarily in Ohio, Mississippi, and Louisiana have been summarized in Environmental Health Perspectives and the articles can be found at: "http://ehpnet1.niehs.nih.gov/docs/2002/suppl-6/toc.html".

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 revised Environmental Fate and Effects Division chapter, dated July 30, 1999, available in the public docket. This document was revised to account for use reductions in the number of applications and maximum application rate.

In general, ecological risk assessment indicates that methyl parathion may pose an acute and chronic risk of adverse effects to birds. Toxicity studies indicate that a series of effects occur with short exposure to methyl parathion. These effects include direct mortality, as well as sub-lethal effects such as reproduction effects, changes in maternal care and viability of young birds, anorexia, increased susceptibility to predation, and greater sensitivity to environmental stress. Estimated environmental concentrations suggest that levels of concern for acute risk to freshwater fish are exceeded only at the highest use rate, although there is high uncertainty in this analysis. Other data suggest the potential for indirect effects to freshwater fish from methyl parathion exposure. Methyl parathion use appears to pose acute risk to estuarine and marine fish, although there is uncertainty associated with the exposure component of this analysis (e.g., use of a static pond to represent water bodies that may be influenced by tides).

Extensive field incident data over 20 years indicate that methyl parathion poses risks to honey bees, and that bee kill incidents continue to occur. Currently, warning language is on labels for the ME

formulation, because the microencapsules are inadvertently collected by honey bees along with pollen. Studies suggest that the emulsifiable concentrate formulation of methyl parathion is also hazardous to bees.

Further, evidence exists in the open literature that methyl parathion may hinder successful reproduction and sexual development in non-target organisms, such as birds, mammals, and fish.

1. Environmental Fate and Transport

The major routes of dissipation for methyl parathion are microbial degradation, aqueous photolysis, hydrolysis, and incorporation into soil organic matter. Methyl parathion degrades rapidly ($t_{1/2}$< 5 days) in soil and water. It also is expected to photodegrade ($t_{1/2}$=49 hours) in aquatic environments. Other degradation processes appear to be less important routes of methyl parathion dissipation. Methyl parathion slowly hydrolyzed ($t_{1/2}$=68 days at pH 5, $t_{1/2}$=40 days at pH 7, $t_{1/2}$=33 days at pH 9) in sterile buffer solutions and slowly photodegraded ($t_{1/2}$=61 days) on soil surfaces.

The major (>10% of applied) degradation product of methyl parathion is 4-nitrophenol which is formed by the cleavage of the P-O bond in methyl parathion. Several minor degradates (<10% of applied) that have been found in laboratory studies including methyl paraoxon, which is the only degradate included in the dietary risk assessment and tolerance expression for methyl parathion. Methyl paraoxon is formed through desulfonation (P=S to P=O) of methyl parathion.

Methyl parathion is mobile to relatively mobile in soil and thus runoff and leaching could be potential routes of dissipation. However, the low persistence of methyl parathion is expected to limit the extent of off-site movement. Another route of dissipation is the secondary movement through volatilization of methyl parathion from soil and leaf surfaces. Although laboratory studies indicate that methyl parathion volatilization is not a major route of dissipation, methyl parathion has been detected in air and rain samples across the United States. These detections appear to be correlated to use on cotton, soybeans, and wheat.

2. Toxicity (Hazard) Assessment

a. Avian/Mammalian Toxicity

Methyl parathion is highly toxic to very highly toxic to birds on a acute basis from single oral doses, dermal exposures and from short term dietary exposure. Toxicity values are given in Table 13.

Table 13. Acute Toxicity to Birds

Species	LD_{50} (mg/kg)	Toxicity Category
Acute Oral (Single dose by gavage)		
Mallard duck (MRID 00160000)	6.6	Very highly toxic
Northern bobwhite quail (MRID 00160000)	7.6	Very highly toxic
Acute Dermal		
Northern bobwhite quail Emulsifiable concentrate (MRID 71200) Micro-encapsulate (MRID 83103)	 2.9 9.1	Very highly toxic
Subacute dietary[1] (five days of treated feed)		
Northern bobwhite quail (MRID 102329)	28	Very highly toxic
[1] Test organisms observed an additional three days while on untreated feed.		

Chronic effects to birds measured by avian reproduction studies show reproductive effects at low levels as seen in Table 14.

Table 14. Reproductive Toxicity to Birds

Species/ Study Duration	NOEC (ppm ai)	LOEC (ppm ai)	LOEC Endpoints
Northern bobwhite (MRID 41179302)	6.27	15.5	Egg production, egg set per hen and adult female bodyweight

Mammalian toxicity Wild mammal testing is not available for methyl parathion; therefore, rat toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. Acute and chronic rat toxicity data relevant to ecological effects show that methyl parathion is very highly toxic to small mammals on an acute oral basis. Methyl parathion affects mammalian reproduction at dietary concentrations above 5 ppm and causes significant decreased pup survival and reduced maternal bodyweight during lactation.

Non-target Insect toxicity: Honey bee toxicity tests show that methyl parathion is very highly toxic to honey bees.

Table 15. Nontarget Insect Toxicity

Species	Results	MRID No. Author/Year	Study Classification
Honey bee (Apis mellifera)	LD50 0.111 µg/bee	44038201 Atkins, 1981	Core

Species	Results	MRID No. Author/Year	Study Classification
Honey bee *(Apis mellifera)* Penncap-M	LD50 0.214 µg/bee	44038201 Atkins, 1981	Core

b. Toxicity to Aquatic Animals

Freshwater Fish and Amphibians: Methyl parathion has been shown to be moderately to highly toxic to freshwater fish and amphibians; toxicity values are listed in the table below. Methyl parathion is also moderately toxic to larval stages of developing frogs and possibly other amphibian species.

Table 16: Freshwater Fish and Amphibian Acute Toxicity

Species/	% ai	96-hour LC50 (ppm) (95% CI)	Toxicity Category	MRID No. Author/Year	Study Classification
Bluegill sunfish *(Lepomis macrochirus)*	77	1.0(0.6-1.6)	highly toxic	40098001 Mayer/1986	Core
Chorus frog (*Pseudacris triseriata*)	90	3.7(N.R.)	moderately toxic	40098001 Mayer/1986	Supplemental

Freshwater Fish, Chronic

Methyl parathion causes chronic effects in fish at concentrations less than 80 ppb. The endpoints measured are based on growth.

Table 17. Freshwater Fish Early Life-Stage Toxicity Under Flow-through Conditions

Species/ Study Duration	% ai	NOEC/LOEC (ppm) (95% CI)	Endpoints Affected	MRID No. Author/Year	Study Classification
Fathead Minnow (*Pimephales promelas*)	80	0.31/0.38	Weight	233438 Jarvinen/1988	Core
Rainbow trout (*Oncorhynchus mykiss*)	Technical 75.1	<0.08	Length and weight	250628 Bailey/1983	Supplemental

Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test showed methyl parathion to be very highly toxic to aquatic invertebrates.

Table 18: Freshwater Invertebrate Acute Toxicity

Species	% ai	48-hour LC50/ EC50 (ppb) (95% CI)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	90	0.14(0.09-0.2)	very highly toxic	40094602 Johnson/1980	Core

Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test shows that methyl parathion affects aquatic invertebrates at less than 0.25 ppb. From other studies, endpoints affected are number of young produced and survival and growth.

Table 19. Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species/ Flow-through)	% ai	21-day NOEC/LOEC (ppb)	Endpoints Affected	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	80%	0.02/0.25	Neonates produced, survival, growth (length)	44371716 Fernandez-Casalderrey	Supplemental

Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish shows that methyl parathion is very highly toxic to estuarine fish.

Table 20: Estuarine/Marine Fish Acute Toxicity

Species	% ai	96-hour LC50 ppm (95% CI)	Toxicity Category	MRID No. Author/Year	Study Classification
Spot (*Leiostmous xanthurus*)	99	0.059 (0.045-0.074)	" very highly toxic"	40228401 Mayer/1986	Supplemental

No data are available to assess the chronic affect of methyl parathion on estuarine and marine fish.

Estuarine and Marine Invertebrates, Acute and Chronic

Methyl parathion was shown to be very highly toxic to estuarine/marine invertebrates on acute basis and to cause chronic effects at low concentrations.

Table 21(a): Estuarine/Marine Invertebrate Acute Toxicity

Species/Static or Flow-through	% ai.	96-hour LC50/EC50 (ppb) (measured) (95% CI)	Toxicity Category	MRID No. Author/Year	Study Classification
Mysid *(Americamysis bahia)*	43.2	0.35 (0.31-0.39) a.i., not product	very highly toxic	40932104	Core

Table 21(b). Estuarine/Marine Invertebrate Life-Cycle Toxicity

Species/(Static Renewal or Flow-through)	21-day NOEC/LOEC (ppb)	MATC (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Mysid *(Americamysis bahia)*	0.11/0.37	0.20	Survival and Number of offspring/&	66341 Lowe/1981	Core

c. Toxicity to Plants

Environmental Health Criteria 145 from the World Health Organization (WHO) 1993 reports that phytotoxic effects of methyl parathion have been observed in cotton and lettuce and that methyl parathion has been shown to cause a reduction of growth in sorghum. No terrestrial plant data have been reviewed for this assessment.

Aquatic plant testing shows that methyl parathion is ‘‘moderately toxic” to marine diatoms.

Table 22: Nontarget Aquatic Plant Toxicity (Tier II)

Species Nonvascular Plants	% ai	EC50/ (ppm) (95% CI)	MRID No. Author/Year	Study Classification
Marine diatom *(Skeletonema costatum*)	99	5.3 (4.3-5.7)	Lowe 66341/1981	Supplemental

3. Exposure and Risk Calculations

a. Levels of Concern

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The Agency calculates risk quotients (RQs) by dividing exposure estimates by acute and chronic ecotoxicity values:

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. Risk presumptions, along with the corresponding LOCs, are given in the table below:

Table 23. Risk Presumptions for Terrestrial and Aquatic Animals

Risk Presumption	LOC terrestrial animals	LOC aquatic animals
Acute High Risk there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification,	0.5	0.5
Acute Restricted Use -there is potential for acute risk, but may be mitigated through restricted use classification,	0.2	0.1
Acute Endangered Species -endangered species may be adversely affected; regulatory action may be warranted,	0.1	0.05
Chronic Risk -there is potential for chronic risk; regulatory action may be warranted.	1	1

b. Exposure and Risk to Nontarget Terrestrial Animals

For pesticides applied as liquids, the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk with a Risk Quotient (RQ) method. Estimates of maximum and average residue levels of methyl parathion on wildlife food was based on the model of Hoerger and Kenega (1972), as modified by Fletcher et al. (1994). EECs resulting from multiple applications are calculated from the maximum number of applications, minimum application interval, and foliar half-life data. Willis and McDowell (1987) reported a number of methyl parathion foliar half-lives ranging from 0.1 to 13.5 days, with most values being <2 days. This assessment uses a foliar half-life of 2.4 days which is the upper 90th percentile confidence limit of the mean value. The foliar half-life adjustment does not account for the formation of toxic degradates. Methyl paraoxon, which is highly toxic, may form on plant foliage after the parent degrades which would cause this analysis to underestimate avian risk because it does not consider potential avian exposure to methyl paraoxon.

Avian: The table below lists the avian acute and chronic risk quotients for several major crops for methyl parathion use. Short grass represents the food items with the highest residue concentration and therefore, the highest RQ, conversely, seeds represent the foodstuffs with the lowest RQs. Other food items fall within this range. For birds, RQs greatly exceed all levels of concern even for single applications.

Table 24: Avian Acute and Reproduction Risk Quotients for Single and Multiple Applications Based on Maximum Residues (LC50 =28.2 ppm, Reproduction NOEC =6.27 ppm)

Crop (# Apps, App. Interval in days)	Rate (lbs ai/A)	Food Items	Single Application		Multiple Applications	
			Acute RQ*	Reproduction** RQ	Acute RQ*	Reproduction RQ**
Cotton (5,7)	1.5	Short grass	12.77	57.42	14.71	66.18
		Seeds	0.80	3.59	0.92	4.14
Corn (3,5)	1.0	Short grass	8.51	38.28	10.99	49.44
		Seeds	0.53	2.39	0.69	3.09
Alfalfa (6,4)	1.0	Short grass	8.51	38.28	12.41	55.82
		Seeds	0.53	2.39	0.78	3.49
Pecan (8,14)	2.0	Short grass	17.02	76.56	17.33	77.92
		Seeds	1.06	4.78	1.08	4.87
Potato (4,7)	1.5	Short grass	12.77	57.42	14.71	66.16
		Seeds	0.80	3.59	0.92	4.14

* acute RQ (EEC/LC50)

** Reproduction** RQ (EEC/NOEC)

For mammals, risk quotients are calculated on a body weight basis based on an LD50 on a body weight basis. Even though risk quotients are provided on a single application only, most single application uses exceed LOC criteria. Multiple applications will result in quantitatively higher exceedances of the LOC criteria.

Table 25: Mammalian Acute and Chronic Risk Quotients for a Single Application Based on Average Residues (LD50 = 3.6 ppm, Reproduction NOEC = 5 ppm)

Crop (# Apps, App. Interval in days)	App.Rate (lbs ai/A)	Food Items	15 g mammal Acute RQ	35 g mammal Acute RQ	1000 g mammal Acute RQ	Rat Chronic Dietary RQ
Cotton (5,7)	1.5	Short grass	95.00	66.00	15.00	72.00
Potato (4,7)		Seeds	1.31	0.94	0.19	4.50
Corn (3,5)	1.0	Short grass	63.33	44.00	10.00	48.00
Alfalfa (6,4)		Seeds	0.88	0.63	0.13	3.00
Pecan (8,14)	2.0	Short grass	126.67	88.00	20.00	96.00
		Seeds	1.75	1.25	0.25	6.00

Risk quotients are generally not calculated for **non-target insects**. Tests with Penn-cap M showed that the average mortality of the adult honey bees was from 29 to 72 times higher than normal the first 48 hours after pollen containing Penncap -M, stored 13.5 and 14.5 months in the cells of wax combs, was introduced into nucleus colonies. After 1 week adult mortality was still 4 to 10 times higher than normal. After 4 weeks, mortality was nearly normal. Chemical analysis of the stored pollen showed 26 ppm methyl parathion. (MRID 160948). Methyl parathion is very highly toxic to bees on an acute contact basis and suggest strongly that mortality will occur under fields conditions. Additional evidence from the open literature is cited in the risk assessment. Field reports of bee kills are provided Appendix 2. Also, several studies have shown that methyl parathion is toxic to bees exposed to foliar residues (Atkins and Kellum, 1980, MRID 00074486, Waller, 1983 MRID 138663). Atkins and Kellum (1980) reported that residues of methyl parathion on alfalfa foliage were highly toxic to honeybees at application rates ranging from 0.03125 to 0.5 lb ai/acre. At the higher rates (0.25 and 0.5 lb ai/acre), the toxicity persisted from 4 to 6 days.

c. Exposure and Risk to Nontarget Aquatic Animals

i. Surface water resource assessment

PRZM-EXAMS water modeling was conducted to determine potential exposure to aquatic animals in surface water. The modeling results are summarized here. Refer to the EFED chapter for an in-depth discussion of the water models.

Non-targeted monitoring data for methyl parathion in surface waters is fairly robust and the drinking water assessment is based on monitoring data. However, most of the monitoring information gathered is from large water bodies and ecological impacts are often greatest in low order streams,

ponds and potholes. PRZM-EXAMS is an edge of field model and is appropriate to estimate concentrations for exposures to fish and aquatic invertebrates.

The tables below cite a variety of estimated concentrations from particular modeling scenarios and provides risk quotients for aquatic animals. Generally, freshwater fish are not likely to be at direct risk from uses of methyl parathion, but estuarine/marine fish may potentially be at risk from some uses of methyl parathion (e.g., cotton and pecans uses near these environments). Freshwater and estuarine/marine invertebrates may potentially be at risk based on exceedance of acute and chronic LOCs from all uses of methyl parathion.

ii. Risk Quotients for Aquatic Animals

Table 26: Risk Quotients for Freshwater fish and Amphibians (LC50 = 1.0 ppm and NOEC < 80 ppb)

Crop/Site	Rate (lbs. ai/A)	No. of applications /interval	EEC (Peak) ppb	EEC (60 day) ppb	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC)
MS Cotton	1.5	5,7	106.76	12.33	0.11	0.15
IL Corn	1.0	3,5	19.26	3.82	0.02	0.05
PA Alfalfa	1.0	6,4	22.01	5.96	0.02	0.08
GA Pecan	2.0	8,14	123.5	15.83	0.12	0.20
ID Potato	1.5	4,7	41.70	6.75	0.04	0.08

Table 27: Risk Quotients for Freshwater Invertebrates (EC50 = 0.14 ppb and NOEC = 0.02 ppb)

Crop/Site	Rate(lbs. ai/A)	No. of applications /interval	EEC (Peak) ppb	EEC (21 day) ppb	Acute RQ (EEC/EC50)	Chronic RQ (EEC/NOEC)
MS Cotton	1.5	5,7	106.76	29.51	762.6	1475.5
IL Corn	1.0	3,5	19.26	8.60	137.6	430
PA Alfalfa	1.0	6,4	22.01	11.55	157.2	577.5
GA Pecan	2.0	8,14	123.5	35.39	882.1	1769.5
ID Potato	1.5	4,7	41.70	15.81	297.9	790.5

Table 28: Risk Quotients for Estuarine/Marine Fish (EC50 =59 ppb)

Crop/Site	Rate(lbs. ai/A)	No. of applications /interval	EEC (Peak) ppb	EEC (60 day) ppb	Acute RQ (EEC/EC50)
MS Cotton	1.5	5,7	106.76	12.33	1.81
IL Corn	1.0	3,5	19.26	3.82	0.33
PA Alfalfa	1.0	6,4	22.01	5.96	0.37
GA Pecan	2.0	8,14	123.5	15.83	2.09
ID Potato	1.5	4,7	41.70	6.75	0.71

No acceptable fish early-life stage study is available for estuarine /marine fish. Therefore, chronic risk to estuarine/marine fish cannot be evaluated at this time.

Table 29: Risk Quotients for Estuarine/Marine Invertebrates (EC50 = 0.35 ppb and NOEC = 0.11 ppb).

Crop/Site	Rate(lbs. ai/A)	No. of applications /interval	EEC (Peak) ppb	EEC (21 day) ppb	Acute RQ (EEC/EC50)	Chronic RQ (EEC/NOEC)
MS Cotton (New)	1.5	5,7	106.76	29.51	305.03	268.27
IL Corn (New)	1.0	3,5	19.26	8.60	55.03	78.18
PA Alfalfa (New)	1.0	6,4	22.01	11.55	62.89	105.0
GA Pecan (New)	2.0	8,14	123.5	35.39	352.86	321.73
ID Potato (New)	1.5	4,7	41.70	15.81	119.14	143.73

d. Exposure and Risk to Nontarget Plants

Exposure to terrestrial plants will occur through foliar sprays. Risk to terrestrial plants cannot be assessed due to lack of phytotoxicity data. Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites. Since methyl parathion was shown to be of moderate toxicity to *Skeletonema costatum*, there are no major concerns to highlighted at this time. However, data are lacking on other aquatic plants.

4. Ecological Incidents

The majority of methyl parathion ecological incidents are honey bee kills. The risk to honeybees is well illustrated by over two decades of bee kills since Penncap-M was first marketed in the 1970's. Both formulations can cause bee kills, but the microencapsulated formulation extends the life of the product in the hive. A detailed summary of bee kills is included in the July, 1999 EFED risk assessment. It is significant that the great majority of the incidents included in the table are related to

orchard uses of methyl parathion. The removal of tree fruit uses should significantly reduce the number of bee kills caused by methyl parathion.

There are relatively few bird and fish kill incidents which are strongly linked to methyl parathion use. The absence of additional documented incidents involving non-targeted terrestrial organisms does not necessarily mean that such incidents do not exist. Mortality incidents must be seen, reported, investigated, and submitted to the Agency in order to be recorded in the database. Incidents may not be noted because the carcasses decayed in the field, were removed by scavengers, or were in out-of-the-way or hard-to-see locations. Poisoned birds may fly off-site to less conspicuous areas before dying. An incident also may not be reported to appropriate authorities capable of investigating it.

5. Endangered Species

Endangered species LOCs are exceeded for acute and chronic risks to birds, mammals and freshwater and estuarine/marine invertebrates, fish, amphibians, reptiles and terrestrial invertebrates (including insects). At this time there are no federally listed estuarine invertebrates.

When the regulatory changes recommended in this IRED are implemented and the ecological effects and environmental fate data are submitted and accepted by the Agency, the Reasonable and Prudent Alternatives and Reasonable and Prudent Measures in the Biological Opinion(s) may need to be reassessed and modified based on the new information.

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

6. Risk Characterization

a. Terrestrial Organisms

i. Avian Risk

EPA concludes that methyl parathion may pose significant acute and chronic risk to birds in the wild based on the exceedance of the levels of concern.

Pen studies using northern bobwhite quail and incident reports document methyl parathion's acute toxicity to birds (see table below). Shellenberger (1970) reported 40% mortality (8 birds) of

caged, 12-week-old northern bobwhite quail exposed to eight weekly sprays of 1 lb ai/A methyl parathion EC. Another study reported mortality rates of 8 to 67% and increases in stress in bobwhite quail exposed to microencapsulated (Penncap-M) and EC formulations of methyl parathion (Pennwalt 1980; MRID 00061213). Edwards (1968; MRID 00090488) observed mortality rates of 5 and 20% for caged quail and pheasants, respectively, in an alfalfa hayfield treated with 0.5 lb/acre methyl parathion. Another study of 42 penned pheasants reported 11 deaths and sickness in half of birds treated with three applications of methyl parathion at 3 lb ai/A (Smith, 1987). Another study with caged bobwhites showed potentially lethal levels of acetylcholinesterase (AChE) inhibition (55.3% and 59.9%), respectively for both Penncap-M and Technical methyl parathion when sprayed at 1 lb ai/A (Knittle, 1973; MRID 093632). ACHE inhibition of $50% may cause death (Ludke et al. 1975). The relevance of pen studies is supported by White, et al. (1990; MRID 44357806) who reported that free bobwhites spent 60% of the time they were observed in or within 100 m of a Georgia sorghum and cotton fields treated with methyl parathion.

Additionally studies indicate that a suite of effects occur with short exposure to methyl parathion. These effects include direct mortality, as well as acute sublethal and chronic effects such as: reproduction effects, changes in maternal care and viability of young birds, anorexia, increased susceptibility to predation, and greater sensitivity to environmental stress.

For several reasons, most of the uncertainty in this risk analysis is associated with the terrestrial exposure component. First, there were no direct field measurements of methyl parathion residues used in the avian risk assessment. Furthermore, while the application method and timing are such that one can reasonably assume exposure of birds each time methyl parathion is applied, there are little direct data (e.g. incidents) showing avian adverse effects.

Finally, the uncertainty in the environmental fate database for the highly toxic metabolite, methyl paraoxon, may lead to an *underestimation* of avian and mammalian exposure to biologically active methyl parathion residues. The quantities of methyl paraoxon produced from parent on animal food items are not known. This point is particularly important because degradation of parent to methyl paraoxon in leaves and avian food items may result in a prolonged exposure to toxic residues which can result in acute and/or chronic effects to birds, mammals, and reptiles.

The use of methyl parathion is expected to coincide with the timing of waterfowl breeding. The major breeding grounds for waterfowl are in the prairie-pothole region of North America, where important crops include spring wheat, barley and sunflowers; methyl parathion is used on each of these crops.

Cotton and rice use in Mississippi River watersheds and in California are expected to affect resident bird populations (non-migratory birds) with nests near treated fields. In addition to waterfowl, a large number of shorebirds such as gulls, cranes, herons, plovers, sandpipers, egrets, stilts, terns and others are found in and around aquatic resources that could be contaminated with methyl parathion.

Further avian exposure to methyl parathion is likely in the 80 million acres in the United States planted to corn which accounts for more than 19% of methyl parathion applied annually. At least 200

bird species are found in and around corn, the majority of which is produced in three regions (the Corn Belt - Iowa, Missouri, Illinois, Indiana, Ohio; the Great Lakes states - Minnesota, Michigan, Wisconsin; and the northern plain states - North and South Dakota, Nebraska, Kansas, and Colorado). Methyl parathion applied to corn planted near prairie-potholes in the Great Lakes and northern plains regions would be expected to affect waterfowl using these areas. Application of methyl parathion to corn in states that border the Gulf of Mexico and the Atlantic and Pacific Oceans is also expected to result in exposure to waterfowl and water birds.

Mortality and reproductive impairment of survivors pose important risk to the maintenance of viable populations of avian species. The potential for adverse population impacts to many avian species from methyl parathion exposure is greatest with the cotton, grain and sunflower uses. Data showing population effects do not establish causality for these population declines since a variety of factors are likely to contribute to population decline. However, the data do suggest that local populations of many bird species could be sensitive to the subacute or reproductive effects from exposure to methyl parathion detailed in the risk assessment.

ii. Risks to Mammals

Acute and chronic toxicity studies indicate that methyl parathion is very highly toxic to mammals. Mammals are expected to be adversely affected by methyl parathion through oral, dermal, and inhalation exposure pathways.

Herbivores and insectivores are more likely than granivores to be adversely affected by *oral* methyl parathion exposure, because they must consume a greater amount of food in proportion to their body weight each day. Estimates show that mammals may experience adverse effects at a single application of the lowest use rate for any crop. And the risk posed by exposure to methyl parathion is expected to increase with the number of applications. The minimum number of applications agreed upon for this assessment is 2 and the maximum is 8.

Dermal exposure to methyl parathion is also highly likely for mammals. Small mammals, such as meadow voles or field mice, live in and around the treated fields and find it difficult to impossible to escape the treated area.

Young mammals are expected to be at greater risk than adults. The young of almost any species eat more than adults per kilogram of body weight. In addition, very young mammals are hairless and may be susceptible to dermal exposure from a variety of sources including residue on the fur of the mother.

iii. Risk to Insects

Currently the Agency does not conduct quantitative risk assessments for nontarget insects. However, acute toxicity testing shows that methyl parathion is highly toxic to honeybees (LD_{50}= 0.11-0.21 µg/bee, MRID 44038201). Additionally, Penncap-M capsules are small and durable enough to be carried to the beehive with pollen grains and may adversely affect honeybees in the hive. The

cancellation of methyl parathion fruit and vegetable crops should reduce the effect on honeybees.

b. Aquatic Organisms

i. Risk to Fish

The uncertainty in the assessment of potential concentrations of methyl parathion in surface water (see above) has ramifications for risk assessments for aquatic organisms.

For freshwater fish, modeled concentrations indicate that only use at the highest label rates may result in exceedance of risk presumption categories for freshwater fish. Published literature indicates that methyl parathion exposure has detrimental effects on freshwater fish, including behavioral changes, growth reduction from damage to the food supply, and indirect mortality. Given that the cotton use area extends in the southern United States from California to Virginia, a large number of freshwater species could be affected by methyl parathion exposure. Therefore, although there is uncertainty in the magnitude of the exposure calculated using simulation models for the large diversity of water body types throughout the methyl parathion use area, sublethal or indirect effects from exposure in the cotton use area seem likely.

ii. Risk to Aquatic Invertebrates

For freshwater aquatic invertebrates, laboratory studies submitted to EPA indicate that methyl parathion is likely to cause adverse effects in freshwater invertebrates under all labeled methyl parathion use scenarios.

Impacts to populations of freshwater aquatic invertebrates may cause additional indirect effects to the ecosystem, as discussed above. For instance, large decreases in populations due to toxic effects to freshwater invertebrates can lead to algae blooms and subsequently may cause fish kills by depleting dissolved oxygen in treated ponds as both invertebrates and algae decay.

For estuarine and marine fish, EPA concludes that methyl parathion poses acute risk. This assessment is founded on consistent toxicological data submitted by the registrants and in the open literature and the widespread use of the compound on many crops that may result in transport of methyl parathion to estuarine/marine surface-water bodies.

Open literature studies report adverse affects of methyl parathion exposure to estuarine and marine fish. Published studies have also reported acute sublethal effects on estuarine and marine fish, such as behavioral changes, cholinesterase inhibition, and ovarian damage. Chronic effects of methyl parathion use on estuarine species cannot be assessed due to lack of chronic estuarine data.

For estuarine and marine invertebrates, as reported in the toxicity portion of this document, estuarine/marine invertebrates are extremely sensitive to methyl parathion. Open literature studies show that use of methyl parathion under normal use conditions has contaminated the estuarine/marine environment and had an effect on estuarine invertebrate species. However, the California EPA Department of Pesticide Regulation has performed *Ceriodaphnia dubia* bioassays concurrently with

their surface water sampling, and reported no observable effects connected with methyl parathion concentrations since mitigation measures were instituted in response to a decline in striped bass populations. In light of supporting open literature data, and the evidence of adverse effects in California before mitigation was instituted, the certainty in the overall risk to estuarine/marine invertebrates is high.

In addition to California, where effects on estuarine species has been observed in connection with methyl parathion use on rice, the coastal areas of the Gulf States include a vast areas of tidal flats, salt and freshwater marshes which provide habitat for estuarine species. Therefore, runoff of methyl parathion into shallow aquatic areas is likely to cause exposure to many important estuarine species.

IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient methyl parathion, as well as a methyl parathion-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 methyl parathion, EPA has sufficient information on the human health and ecological effects of methyl parathion 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 certain uses of methyl parathion are eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risk assessment for the organophosphates support a final reregistration eligibility decision. Label changes are described in Section IV. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of methyl parathion, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet considered cumulative risks for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of methyl parathion. Based on its current evaluation of methyl parathion alone, the Agency has determined that methyl parathion 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 methyl parathion.

At the time that cumulative risks are considered, the Agency will address any outstanding risk

concerns. For methyl parathion, if all changes outlined in this document are incorporated into the labels, then pesticides containing methyl parathion generally will not cause unreasonable risk to humans and the environment. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for methyl parathion after considering 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 reregistration eligibility decision does not fully satisfy the reassessment of the existing methyl parathion food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, methyl parathion tolerances will be reassessed in that light. At that time, the Agency will reassess methyl parathion 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 methyl parathion, 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 consideration of the cumulative risks. 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 planned to take into account all comments received during Phase 5 of the OP Pilot Process; however, no comments were received which impacted the regulatory decision.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates, i.e., cholinesterase inhibition. The

Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the policy concerning cumulative assessments is resolved.

EPA has determined that after the use cancellations in the 1999 MOA, dietary risk (food plus water) from exposure to methyl parathion will be within its own "risk cup" **with the mitigation measure of reducing the application rate and total number of allowable applications.** In other words, if methyl parathion did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for methyl parathion meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food and drinking water. 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 methyl parathion "fit" within the individual risk cup. Therefore, the methyl parathion tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is completed.

b. Interim Tolerance Reassessment Summary

In the individual assessment, tolerances for residues of methyl parathion in/on plant commodities [40 CFR §180.241] are presently expressed in terms of ethyl parathion and/or methyl parathion. Since there were use cancellations which were brought about by FQPA safety findings, according to FFDCA 408 (l)(2) the tolerances from the canceled uses are to be revoked within 180 days after the last lawful use. There was a Federal Register notice published June 2, 2000 which listed the tolerances which are being proposed for revocation. The comment period for this proposal closed on August 2, 2000. The following tolerances were revoked upon publication of the final rule on January 5, 2001: apples, artichokes, beets (greens alone), beets (with or without tops), birdsfoot trefoil forage, birdsfoot trefoil hay, broccoli, Brussels sprouts, carrots, cauliflower, celery, cherries, collards, grapes, kale, kohlrabi, lettuce, mustard green, nectarines, peaches, pears, plums (fresh prunes), rutabagas (with or without tops), rutabaga tops, spinach, tomatoes, turnips (with or without tops), turnips greens, vegetables leafy *Brassica* (cole), and vetch. Methyl parathion applications are allowed for lentils, but the tolerance for lentils is removed since lentils are included under the dried peas tolerance. Residues resulting from legal applications of methyl parathion may be found in frozen commodities after the tolerances were revoked. The FDA developed a "channels of trade" guidance policy which specifies types of documentation necessary to prove legal applications of methyl parathion.

At this time no changes are being made to the tolerance residue levels for the remaining methyl parathion tolerances. The residue chemistry portion of the HED risk assessment provided a complete listing of recommended tolerance level changes which will be considered during the cumulative assessment for all the organophosphates.

Until September 3, 2002, the tolerances for methyl parathion and ethyl parathion were combined under 40 CFR §180.121. A final rule was published in the Federal Register on June 5, 2002 to separate the tolerances into ethyl parathion tolerances in §180.121 and the methyl parathion tolerances under §180.122. This notice also revokes the tolerances for which there are no domestic

uses and provides dates for expiration for all ethyl parathion tolerances.

Table 30. Summary of Methyl Parathion Tolerances Listed Under 40 CFR §180.122

Commodity	Current Tolerance, (ppm)
Alfalfa (fresh)	1.25
Alfalfa (hay)	5
Almonds, sugar Beets, sugar Beet (tops), Filberts, Pecans, Potatoes, Safflower Seed, Sorghum, Soybeans, Sweet potatoes, Walnuts	0.1
Almond hulls	3
Barley, Beans (dried), Cabbage, Clover, Corn, Corn (forage), Grass (forage), Hops, Oats, Onions, Peanuts, Peas (dried), Peas (forage), Rice, Soybean hay, Wheat,	1
Cotton (seed),	0.75
Guar beans, Mustard Seed, Rapeseed, Sunflower seed,	0.2

The tolerances associated with cabbage, dried beans, dried peas, hops, lentils, pecans, and sugar beets will be proposed for revocation.

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

3. Labels

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

Provided the following risk mitigation measures are incorporated in their entirety into labels for methyl parathion-containing products, the Agency finds that some of the currently registered uses of methyl parathion would be eligible for reregistration, pending a cumulative assessment of the organophosphates. The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of required mitigation measures.

The following uses are eligible for reregistration: Alfalfa, barley, corn, cotton, grass forage/ fodder/hay, oats, onion, pastures, rangeland, rape seed (canola), rice, rye, soybeans, sunflower, sweet corn, sweet potatoes, walnuts, wheat, white potatoes, and yams.

4. Mitigation for Agricultural Uses

- Deletion of use on cabbage, dried beans, dried peas, hops, lentils, pecans, and sugar beets.
- Label changes to include reduction of application rates and numbers of applications as proposed by registrants (see Table 1).

- To lower potential exposures to aquatic organisms: methyl parathion may not be mixed/loaded or otherwise handled in areas prone to runoff or movement into aquatic environments or wetlands. This does not apply to aquatic applications to rice.

- Closed delivery (mixing/loading/handling) systems are required for aerial applications of the microencapsulated formulation.

- Engineering controls such as a closed cab and closed cockpit are required for applications of both the microencapsulated formulation and the EC formulation.

- Use on sweet corn is limited to control of silk fly only. This restricts use to the southern US.

- Use of human flaggers is prohibited.

- REIs for EC applications are as follows:

Table 31: Re-entry intervals for various crops following application of emulsifiable concentrate methyl parathion.

Use site	REI (days)
alfalfa, barley, cotton[a], oats, canola, rice, rye, soybeans, sunflowers, wheat, white potatoes	4
sweet corn[b] (for use against silk fly), field corn	3
onions[c]*	6

a For cotton, a MOE of 90 was used at request of growers who needed to get into fields earlier than a 6 day REI which was necessary for a MOE of 100.

b For sweet corn, the REI was recalculated using the DFR data from Florida since silk fly is a pest that primarily occurs in Florida.

c For onions, the REI is based on the activities of hand-weeding and pruning with an MOE of 92.

- REIs for microencapsulated formulation applications are as follows:

Table 32: Re-entry intervals for various crops following application of microencapsulated methyl parathion.

Use site	REI (days)
barley, field corn, oats, rice, wheat	31
sweet corn** (for use against silk fly)	9
walnuts	25
onions	13
white potatoes	12
sweet potatoes, cotton, soybeans	11

**For sweet corn, the REI was recalculated using the DFR data from Florida since silk fly is a pest that primarily occurs in Florida.

D. Benefits Assessment Summary

Benefit assessments were conducted for methyl parathion use on: field and sweet corn, walnuts, cotton, soybeans, sweet potatoes, sunflowers, and rice. For these crops, clear high benefits were shown for soybeans, sweet potatoes and rice; moderate benefits were shown for sunflowers, but this benefit may increase when ethyl parathion may no longer be used on sunflowers. For sweet corn, high benefits were shown in control of silk fly, and therefore, use is retained for this pest only. For field corn, walnuts, and cotton benefits are considered to be low because several alternative pesticides remain for these crops including the organophosphates: azinphos methyl, acephate, dicrotophos and terbufos. However, for the most part, these organophosphate alternatives have different, but still serious ecological risks and little if any risk reduction would be attained by promoting a shift to these alternative pesticides.

Benefit assessments are available on the EPA website and in the docket for methyl parathion.

Reported methyl parathion use was very low for alfalfa, barley, cabbage, dried beans, dried peas, grass, hops, lentils, oats, onions, pecans, rape seed (canola), rye, sugar beets, and white potatoes. Therefore, benefits for these crops were assumed to be low and formal benefits assessments were not conducted. Consultations with USDA indicated benefit for use on alfalfa, barley, grass, oats, onions, rape seed, rye, and potatoes. These crops have very low amounts of use primarily focused on certain pests in isolated areas of the country, but could be considered to be high benefit for those areas and therefore use is retained.

Several growers expressed desire to retain use on pecans to control stink bug even though there are alternative pyrethroid compounds which control stink bugs. There is an issue of resistance management with the use of pyrethroids, but EPA believes that resistance management of stink bugs can be managed in the crops surrounding the pecan groves. Based on what would

be the required re-entry interval, spray drift issues and ecological risk, the benefits for use on pecans does not outweigh the risks for this use.

E. Regulatory Rationale

1. Human Health Risk Mitigation

a. Dietary Mitigation

i. Dietary (Food)

Based on recent use changes and thus current labels, at the 99.9th percentile, the dietary risk, food only, is below levels of concern for all population subgroups, including the most exposed population subgroups, children 1-6 and children 6-12, at 75% and 77% of the aPAD, respectively. No additional mitigation for acute dietary food risks is required.

The chronic dietary risk estimate is below the Agency's level of concern and is estimated to be less than 8% of the cPAD for all population subgroups including the most exposed population subgroups, infants and children (1-6 years). No additional mitigation for chronic dietary food risks is required.

There are some residue and feeding studies which have not been submitted and a DNT study which is currently in review; these studies may affect the dietary risk assessment and the FQPA safety factor. The full 10x FQPA safety factor has been applied to the current assessment and this decision will be revisited when the DNT study review is complete. The DNT study has been screened and is considered unlikely to change the dietary endpoint. The screened study was considered in the safety factor decision for the organophosphate cumulative assessment. The dietary assessment for methyl parathion will be revised when these studies are submitted and the review is complete.

ii. Drinking Water

Though acute exposure to methyl parathion from food sources alone does not exceed the Agency's level of concern (< 100% acute PAD), limited targeted ground- and surface water monitoring data indicate potential exposures at unacceptable levels. Based on this uncertainty, and on the risks posed to aquatic organisms from methyl parathion, the registrants have proposed reducing the application rate and number of applications for several crops. Additionally, the Agency is requiring that methyl parathion not be mixed/loaded or otherwise handled in areas prone to runoff to aquatic areas.

As stated in the dietary (food) section, the dietary assessment will be revised when the dietary review is completed. The drinking water assessment will be updated at that time including a review of any additional monitoring which may reflect mitigation from the 1999 MOA and this reregistration eligibility review. While the Agency presumes that the risk from combined food and drinking water will be acceptable in the revised dietary assessment, the Agency reserves the option of requiring targeted water monitoring studies pending the results of this dietary (food and water) revised assessment.

b. Occupational Risk Mitigation

i. Handler Risk

The highest occupational risk assessed from biomonitoring data is to mixer and loaders handling the microencapsulated formulation. The biomonitoring study was conducted using 2.5 gallon containers to handle all applications including those for large acreage. In reality, bulk containers are used when mixing and loading for large acreages. The use of bulk tanks with closed couplings should reduce the exposure below the amount measured in the biomonitoring study. Based on the biomonitoring MOEs for mixer and loaders, **closed delivery systems are required for aerial applications of the microencapsulated formulation.**

Biomonitoring data for groundboom applicators using the microencapsulated formulation show risk from applications of 200 acres at the median and at applications at rates above 0.5 lb ai/A for 80 acres. No biomonitoring was conducted for other application methods or for any applications with the EC formulation. Engineering controls such as a **closed cab and cockpit are required for applications of both the microencapsulated formulation and the EC formulation.**

ii. Post-Application Risk

EPA has determined that post application exposures of methyl parathion can occur in occupational settings. Current REIs required by the 1999 MOA are 4 and 5 days. In order to reduce re-entry worker risk, REIs are as noted in Tables 31 and 32. Please note that longer REIs were assessed for some uses, but those uses are proposed for cancellation.

Additionally in order to manage such long REIs, EPA notes that some activities may occur during the REI as long as certain conditions are met, including protective clothing, no reentry during first 4 hours after application, 8 hour per day maximum, notification of reliance on exception, etc., as set forth for the exception for limited-contact activities and irrigation published in the Federal Register on May 3, 1995 (65 FR 21955).

These activities may include the following:

> Work performed by workers driving or riding on tractors or other power equipment (e.g., self-propelled harvesters) affording substantial protection against contact with treated soil or foliage. Examples of this kind of in-field work would include cultivation and ground application of fertilizer products.
>
> Emergency repairs of tractors or implements.
>
> Irrigation operations and work on irrigation equipment, including needed repairs or adjustments of equipment.

Hand labor activities, including but not limited hand cultivation or hand harvesting, specifically would <u>not</u> be allowed during the REI.

2. Environmental Risk Mitigation

To address the high potential ecological risk to aquatic invertebrates from methyl parathion, and the general uncertainty related to methyl parathion effects on aquatic organisms, EPA is requiring the following mitigation measures:

Cancellation of uses which do not have high benefits including: cabbage, dried beans, dried peas, hops, lentils, pecans, and sugar beets.

Label changes to include reduction of application rate and numbers of applications as proposed by registrants (see Table 1).

To lower potential exposures to aquatic organisms, methyl parathion may not be mixed/loaded or otherwise handled in areas prone to runoff to water bodies, aquatic areas or wetlands. This restriction does not apply to aquatic applications to rice. Aquatic applications are allowed based on high benefits.

Although risks are expected to still exist for birds, small mammals, aquatic invertebrates and nontarget insects, no additional mitigation options are recommended at this time. The use changes as captured in the Methyl Parathion MOA, specifically the deletion of the orchard uses of methyl parathion, are expected to significantly reduce ecological risks posed by methyl parathion to honey bees and birds.

F. Other Labeling

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing methyl parathion. For the specific labeling statements, refer to Section V of this document.

1. Endangered Species Statement

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

The Endangered Species Protection Program as described in a Federal Register notice

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

2. Spray Drift Management

The Agency is currently working with stakeholders to develop appropriate generic label statements to address spray drift risk. Once this process has been completed, methyl parathion product labels will need to be revised to include this additional language.

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 methyl parathion 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 Laura Parsons at 703-305-5776 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)
Laura Parsons
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

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

B. For products containing the active ingredient methyl parathion, 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 [insert table number] 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 703-3087-8061 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

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

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

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of methyl parathion for the above eligible uses has been reviewed and determined to be substantially complete. Based on a need to further refine the human health and the ecological risk, the following additional data are necessary.

Applicator Biomonitoring Studies for EC and Microencapsulated Formulation for each Application Method. (Guideline OPPTS 875.1500)

Residue Analytical Method (Guideline OPPTS 860.1340)

Magnitude of Residues Crop Field Trial Data for the EC Formulation -- wheat forage, wheat hay (Guideline OPPTS 860.1500)

Magnitude of Residues Crop Field Trial Data for the Microencapsulated Formulation – rice straw (Guideline OPPTS 860.1500)

Magnitude of Residues, meat/milk/poultry/eggs (Guideline OPPTS 860.1480)

Anaerobic Aquatic Metabolism. (Guideline OPPTS 835.4400)

Field Volatility (Guideline OPPTS 835.8100)

Terrestrial Field Dissipation for the Microencapsulated Formulation (Guideline OPPTS 835.6100)

Estuarine and Marine Fish Early Life Stage Test (Guideline OPPTS 850.1400)

Vegetative Vigor (Guideline OPPTS 850.4150)

Seedling Emergence (Guideline OPPTS 850.4100)

Also, one study Aquatic Plant Growth (Guideline OPPTS 850.4400) is reserved pending the results of the terrestrial plant test studies.

The above studies will be used as confirmatory data. If the Agency finds that new studies identify additional risks of concern, the Agency will reconsider the measures established in this Interim RED.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18, 1999 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies. The methyl parathion developmental neurotoxicity study has been submitted and is currently in

review.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in Table 20 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 20 at the end of this section.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Interim Reregistration Eligibility Decision document. 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 methyl parathion products bearing old labels/labeling for 26 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 20: Summary of Required Labeling Changes for Methyl parathion

Description	Required Labeling	Placement on Label
Manufacturing Use Products		
Formulation Instructions required on all MUP's	"Only for formulation into an insecticide for use on (*registrant inserts correct use site(s)*)."	Directions for Use
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	"This product may be used to formulate products for specific use(s) not listed on the MUP 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 MUP 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

Description	Required Labeling	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	**"Environmental Hazards"** "This chemical is highly toxic to aquatic invertebrates and wildlife and toxic to fish. 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		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE" The Emulsifiable Concentrate Formulation "Due to very high toxicity to humans and birds." The Microencapsulated Formulation "Due to residual effects to avian species and bees." "For retail sale to, and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification."	Top of front panel
Handler PPE considerations	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain methyl parathion 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. 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 guidance on which PPE is considered more protective, see PR Notice 93-7.	Precautionary Statements Under PPE Requirements

Description	Required Labeling	Placement on Label
Handler PPE requirements (all formulations)	"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." "Mixers, loaders, and applicators using engineering controls must wear: Long-sleeved shirt and long pants Shoes plus socks In addition, mixers and loaders must wear chemical-resistant gloves and a chemical resistant apron." "See engineering controls for additional requirements. Handlers performing tasks, such as spill clean-up, for which engineering controls are not feasible must wear: "Coveralls over long-sleeved shirt and long pants, Chemical-resistant gloves, Chemical resistant shoes footwear plus socks, Chemical-resistant headgear if overhead exposure, Chemical-resistant apron if exposed to the concentrate "A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any R or P or HE prefilter."	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 and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Required Labeling	Placement on Label
Engineering controls for Mixers and Loaders using the Emulsifiable Concentrate Formulation for all applications and for aerial applications of the Microencapsulated Formulation. Products for these uses are marketed in a closed loading system that meets the specifications of the WPS	**"Engineering Controls"** "Mixers and loaders 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)], for dermal protection and 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 the following: coveralls and chemical-resistant footwear and a respirator specified in the PPE section above)."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the User Safety Requirements
Engineering controls for all applicators.	**"Engineering Controls"** "Use of human flaggers is prohibited." "Applicators must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must: -- wear the personal protective equipment required above, -- *either* wear the type of respirator specified in the PPE section of this labeling *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, a respirator specified in the PPE section above, and chemical-resistant headgear, if overhead exposure, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." "Pilots must use an enclosed cockpit 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 the User Safety Requirements

Description	Required Labeling	Placement on Label
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	**"Environmental Hazards***"* "This pesticide is highly toxic to birds and mammals. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not mix, load or otherwise handle in areas prone to runoff or movement into aquatic environments. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Keep out of lakes, ponds, and streams. Do not contaminate water when disposing of equipment wastewater or rinsate". "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."	Precautionary Statements immediately following the User Safety Recommendations

Description	Required Labeling	Placement on Label
Restricted-Entry Interval fpr the Emulsifiable Concentrate Formulation.	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). The Directions for Use must be amended to reflect the following REI: **The REI for the following crops is 3 days:** sweet corn. field corn **The REI for the following crops is 4 days:** alfalfa, barley, cotton, oats, canola, rice, rye, soybeans, sunflowers, wheat, white potatoes, grass **The REI for the following crops is 6 days:** onions	Directions for Use, Agricultural Use Requirements Box or Next to the Crop or Use for which it applies.

Description	Required Labeling	Placement on Label
Restricted-Entry Interval fpr the Microencapsulated Formulation.	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). The Directions for Use must be amended to reflect the following REI: **The REI for the following crop is 9 days:** sweet corn **The REI for the following crops is11 days:** sweet potatoes, cotton, soybeans **The REI for the following crops is 12 days:** white potatoes **The REI for the following crop is 13 days:** onions **The REI for use of the microencapsulated formulation on the following crop is 25 days:** walnuts **The REI for use of the microencapsulated formulation on the following crops is 31 days:** barley, field corn, oats, rice, wheat	Directions for Use, Agricultural Use Requirements Box or Next to the Crop or Use for which it applies.
Early Re-entry Personal Protective Equipment established by the RED.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: - coveralls worn over long-sleeve shirt and long pants, - chemical-resistant gloves made of any waterproof material, - chemical-resistant footwear plus socks, and - chemical-resistant headgear for overhead exposures."	Directions for Use, Agricultural Use Requirements Box
Notification Statement	"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

Description	Required Labeling	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."	Place in the Direction for Use directly above the Agricultural Use Box.
Application Restrictions	The following risk mitigation measures must be reflected in the directions for use: **New maximum application rates for the Emulsifiable Concentrate formulation:** Alfalfa: 1.0 lbs ai/A/application 6.0 lbs ai/A/year Do not make more than 2 applications per cutting or 6 applications per year. Barley, oats, rice, rye, wheat: 0.75 lbs ai/A/application 1.5 lbs ai/A/year Do not make more than 2 applications per year. Field corn, sweet corn, onions, rapeseed (canola), soybeans: 0.5 lbs ai/A/application 1.0 lbs ai/A/year Do not make more than 2 applications per year. Cotton: 0.75 lbs ai/A/application 3.75 lbs ai/A/year Do not make more than 5 applications per year. Grass: 0.75 lbs ai/A/application 3.0 lbs ai/A/year Do not make more than 2 applications per cutting or 4 applications per year. Sunflower: 1.0 lbs ai/A/application 2.0 lbs ai/A/year	Place in the Direction for Use under Application Instructions for Each Crop

Description	Required Labeling	Placement on Label
	Do not make more than 2 applications per year White potatoes: 0.75 lbs ai/A/application 2.25 lbs ai/A/year Do not make more than 3 applications per year	
Application Restrictions	The following risk mitigation measures must be reflected in the directions for use: **New maximum application rates for the Microencapsulated formulation:** Barley, oats, rice, soybeans, wheat: 0.75 lbs ai/A/application 1.5 lbs ai/A/year Do not make more than 2 applications per year. Field Corn: 1.0 lbs ai/A/application 3.0 lbs ai/A/year Do not make more than 3 applications per year. Sweet corn: 0.75 lbs ai/A/application 3.0 lbs ai/A/year Do not make more than 4 applications per year. Cotton: 1.0 lbs ai/A/application 4.0 lbs ai/A/year Do not make more than 4 applications per year. Onions: 0.5 lbs ai/A/application 2.0 lbs ai/A/year Do not make more than 4 applications per year. Sweet potatoes and yams: 0.75 lbs ai/A/application	Place in the Direction for Use under Application Instructions for Each Crop

Description	Required Labeling	Placement on Label
	6.0 lbs ai/A/year Do not make more than 8 applications per year. Walnuts: 2.0 lbs ai/A/application 8.0 lbs ai/A/year Do not make more than 4 applications per year White potatoes: 1.5 lbs ai/A/application 6.0 lbs ai/A/year Do not make more than 4 applications per year	
Application Restrictions	Sweet Corn: "For use to control silk fly only". Remove references to all other pests.	Place in the Direction for Use under Application Instructions for Each Crop
Application Restrictions	Delete the following uses from all labels: cabbage, dried beans, dried peas, hops, lentils, pecans, sugar beets	Place in the Direction for Use under Application Instructions for Each Crop
Spray Drift Requirements	The Agency is currently working with stakeholders to develop appropriate generic label statements to address spray drift risk. Once this process has been completed, methyl parathion product labels will need to be revised to include this additional language.	Place in the Direction for Use where appropriate

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