United States Environmental Protection Agency
Prevention, Pesticides and Toxic Substances (7508P)
EPA 738-R-06-030
July 2006

Reregistration Eligibility Decision (RED) for Malathion

REREGISTRATION ELIGIBILITY

DECISION

for

Malathion

Case No. 0248

Approved by:

_____
Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

_____
Date

TABLE OF CONTENTS

Malathion Reregistration Eligibility Decision Team

Office of Pesticide Programs

Biological and Economic Analysis Assessment
Donald Atwood
Jin Kim
Timothy Kiely

Environmental Fate and Effects Risk Assessment
Norman Birchfield

Health Effects Risk Assessment
Jack Arthur
Anna Lowit
Sheila Piper
Louis Scarano

Registration Support
Marilyn Mautz

Risk Management
Tom Moriarty
Neil Anderson

General Counsel
Scott Garrison

Glossary of Terms and Abbreviations

ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
IDFS	Incident Data System
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, 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. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration

NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Cropped Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for malathion and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of malathion that pose risks of concern. As a result of this review, EPA has determined that malathion-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

Malathion is a broad-spectrum organophosphate (OP) insecticide first registered in 1956. It is used widely in agriculture for various food and feed crops, homeowner outdoor uses, ornamental nursery stock, building perimeters, pastures and rangeland, and regional pest eradication programs. Previous risk assessments indicated some drinking water, occupational handler and post-application, residential bystander, and ecological risks of concern. Drinking water and residential bystander risk estimates were revised based on refinements to the assessments and/or mitigation measures, such as reduced maximum application rates and number of application permitted per year for many use sites. Occupational risks have been mitigated through personal protective equipment or engineering control requirements on the labels and extending re-entry intervals for some sites, and ecological risks have been addressed through adding buffer zone and spray drift requirements to the labels, and amending use patterns for many uses.

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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility of infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Malathion belongs to a group of pesticides called organophosphates (OPs), which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. When the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, and the cumulative risks for pesticides which share a common mechanism of toxicity, such as the OPs, are below the Agency's level of concern, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. Malathion is a member of the OP class of pesticides, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate the risk from food, drinking water, residential, and other non-occupational exposures resulting from registered uses of OP pesticides, including malathion. EPA has concluded that the cumulative risks associated with OP pesticides are below the Agency's level of concern. For additional information, refer to the *OP Cumulative Assessment* (2006 Update), which is available in EPA docket EPA-HQ-OPP-2006-0618 and on EPA's website at http://www.epa.gov/pesticides/cumulative/.

This document presents EPA's revised human health and ecological risk assessments, its tolerance reassessment, and reregistration eligibility decision (RED) for malathion. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments;

Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The revised risk assessments for malathion and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (http://www.regulations.gov.) under docket number EPA-HQ-OPP-2004-0348.

II. Chemical Overview

A. Regulatory History

Malathion is a broad spectrum organophosphate insecticide and miticide first registered in 1956. Malathion has numerous commercial agricultural, industrial, governmental, and homeowner uses. In 2000, approximately 11-13 million pounds of malathion were used annually; currently, approximately 15 million pounds are used annually.

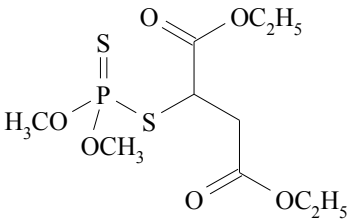
In February 1988, the Guidance for the Reregistration of Pesticide Products Containing Malathion (*Malathion Registration Standard*) was issued. The Registration Standard summarized the human health and ecological risk findings based on the data available at that time, and required other studies to complete the malathion data base. The Registration Standard also imposed label restrictions to reduce exposure resulting from indoor applications of malathion, and updated environmental hazard statements on malathion product labels. Numerous data requirements needed to complete the Agency's reassessment of malathion were imposed through Data Call-In (DCI) Notices issued as part of the reregistration process of malathion. DCIs on malathion were issued in 1992, 1993, 1994, 1995, 1999, and 2004.

In February 2000, EPA issued its *Preliminary Risk Assessment for the Reregistration Eligibility Decision Document*. The Preliminary Risk Assessment reflected the conclusion of the OPP Hazard Identification Assessment Review Committee (HIARC), and the FQPA Safety Factor Committee, as well as the OPP Cancer Assessment Review Committee. A preliminary ecological risk assessment was also issued at that time. In September 2000, EPA issued a *Revised Malathion Risk Assessment.* The revised assessment reflected comments received during the public comment period, and incorporated new data the Agency received regarding exposure to agricultural workers. The 2000 *Revised Malathion Risk Assessment* also included a revised cancer classification of malathion. The *2000 Revised Ecological Risk Assessment* changed little from the *Preliminary Ecological Risk Assessment*.

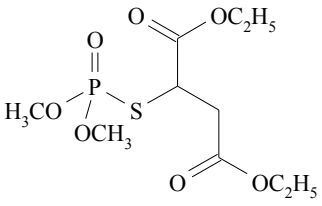
In 1999, EPA required a developmental neurotoxicity study along with a comparative cholinesterase study. These data were submitted to the Agency in 2002, and were assessed as part of the Agency's revised risk assessment, which was issued for public comment in September 2005. The *2005 Revised Human Health Risk Assessment* also contained other changes, including a toxicity adjustment factor for the primary metabolite malaoxon, and addressed the pharmaceutical use of malathion. As no new data were received with respect to ecological fate or hazard of malathion, the ecological risk assessment remained unchanged between 2000 and 2005.

B. Chemical Identification

Malathion is a colorless to amber liquid with a mercaptan odor and boiling point of 156-157^{0}C. Malathion is soluble in water and is readily soluble in most alcohols, esters, aromatic solvents, and ketones, and is only slightly soluble in aliphatic hydrocarbons. Below is a summary of the chemical compound malathion.

Malathion Test Compound Nomenclature		
Chemical Structure		
Empirical Formula	$C_{10}H_{19}O_6PS_2$	
Common name	Malathion	
IUPAC name	O,O-dimethyl dithiophosphate of diethyl mercaptosuccinate	
CAS Registry Number	121-75-5	
Chemical Class	Organophosphate	
Known Impurities of Concern	Empirical Formula:	$C_{10}H_{19}O_6PS_2$
	Common Name:	Isomalathion
	IUPAC Name:	Butanedioic acid, [[methoxy(methylthio)phosphinyl]thio]-, diethylester
	CAS Registry Number:	3344-12-5

Malaoxon is the primary metabolite of malathion and, under certain conditions, is formed as an environmental breakdown product of malathion making it available for direct human exposure. Below is a summary of the chemical compound malaoxon.

Malaoxon Test Compound Nomenclature	
Chemical Structure	
Empirical Formula	$C_{10}H_{19}O_7PS$
Common name	Malaoxon (the active ChE inhibiting metabolite of malathion)
IUPAC name	O,O-dimethyl thiophosphate of diethyl mercaptosuccinate
CAS Registry Number	1634-78-2
Chemical Class	Organophosphate

A number of impurities have been reported to be present in representative technical formulations of malathion. Isomalathion is an impurity known to be present at very low levels in both technical grade and end-use product samples of malathion. These low levels of isomalathion may be formed during the manufacturing process of malathion, and low levels of isomalathion may also be formed if malathion undergoes chemical rearrangement (isomerization) during product storage. Data provided by the registrant indicate that Fyfanon® Technical (EPA Reg. No. 4787-5) is stable for up to 1 year when stored under warehouse conditions (20-23°C), although a small amount of isomalathion accumulated (increase from <0.01% to about 0.1%). Storage of malathion at 54°C for 2 weeks resulted in an increase of isomalathion from about 0.05% to 0.2%.

C. Use Profile

Malathion is a broad-spectrum organophosphorous (OP) insecticide, used widely in agriculture and regional pest eradication programs. The following use sites and crops are being supported and were included in this risk assessment. A detailed table of the uses of malathion eligible for reregistration is available in Appendix A.

Food and Feed Crops - Alfalfa; apricot; asparagus; avocado; barley; bean (succulent and dry); beets (table); birdsfoot trefoil; blackberry; blueberry; boysenberry; broccoli; broccoli raab; Brussels sprout; cabbage (including Chinese); carrot; cauliflower; celery; chayote; cherry; chestnut; clover; collards; corn (field; sweet; and pop); cotton; cucumber; currant; dandelion; date; dewberry; eggplant; endive; escarole; potato; fig; garlic; gooseberry; grape; grapefruit; guava; hay grass; hops; horseradish; kale; kohlrabi; kumquat; leek; lemon; lespedeza; lettuce (head and leaf); lime; loganberry; lupine; macadamia nut; mango; melon; mint; mushroom; mustard greens; nectarines; oats; okra; onion; orange; papaya; parsley; parsnip; passion fruit; pea; peach; pear; pecan; pepper; pineapple; pumpkin; radish; raspberry; rice; rutabaga; rye; salsify; shallot; sorghum; spinach; spring wheat; squash; strawberry; sweet potato; Swiss chard; tangelo; tangerine; tomato (including tomatillo); turnip; vetch; walnut; watercress; watermelon; wheat (spring, and winter); wild rice; and yam; indoor stored commodity treatment and empty storage facilities for barley, corn, oats, rye, and wheat.

Other Uses - Homeowner outdoor uses: ornamental flowering plants, ornamental lawns, ornamental turf, vegetable gardens and fruit trees; ornamental flowers, shrubs, and trees; Christmas tree plantations; slash pine; ornamental nursery stock; woody plants; building perimeters (domestic dwellings as well as commercial structures); uncultivated nonagricultural areas; outdoor garbage dumps; intermittently flooded areas; irrigation systems; pastures; and rangeland.

Regional Pest Eradication Programs - Boll Weevil eradication (USDA sponsored program), Medfly control (USDA), and mosquito control (public health).

Pharmaceutical Malathion - There is a pharmaceutical use of malathion as a pediculicide for the treatment of head lice and their ova, which is regulated by the Food and Drug Administration (FDA).

Types/Formulations Registered - Malathion is formulated as an emulsifiable concentrate (EC), dust (D), wettable powder (WP), ready-to-use (RTU) liquid, and as a pressurized liquid (PrL). The EC

and RTU formulations may contain up to 82% and 96.8% active ingredient (ai), respectively. Several of the 96.8% ai RTU liquids are intended for ultra-low-volume (ULV) application with the use of aerial or ground equipment. Malathion is typically applied as multiple foliar treatments as needed to control various pest species.

Application Equipment - Aircraft (fixed wing, and rotary), duster, fogger, ground boom, irrigation, shaker can, sprayer, and spreader.

Target Pests - Ants, aphids, apple mealybug, armyworm, bagworm, beetle, borer, casebearer, blackheaded fireworm, blueberry maggot, cadelle, caterpillars, cattle lice, cherry fruitworm, cockroaches, corn earworm, corn rootworms, cotton fleahopper, cotton leaf perforator, cotton leafworm, cranberry fruitworm, crickets, currant cutworm, earwigs, European fruit lecanium, fall cankerworm, fleahoppers, fleas, flies, fruit flies, fungus gnats, garden webworm, grain borer, grape phylloxera, grasshoppers, green cloverworm, greenbug, groundpearls, hornets, imported cabbageworm, imported currantworm, ked, leafhoppers, leafrollers, leafminer, looper, millipedes, mites, mosquitoes (adult, larvae), moths, kermes, mushroom flies, omnivorous leaftier, onion maggot, orange tortrix, orangeworms, pear psylla, pecan phylloxera, pepper maggot, pickleworm, pillbugs, pine needle sheathminer, plant bugs, plum curculio, poultry lice, rose chafer, sawflies, scales, scorpions, silverfish, sorghum midge, sowbugs, spiders, spittlebugs, springtails, strawberry leafroller, sugarbeet root maggot, tadpole shrimp, thrips, ticks, tingids, tomato fruitworm, vetch bruchid, wasps, weevil, whiteflies, and wild rice worm.

Application Rate Ranges

General Agriculture:	0.175 – 6.25 lb ai/A
Home and Garden:	0.000085 – 0.0003 lb ai/ft^2
Boll Weevil Eradication Program:	0.3 – 1.22 lb ai/A
Fruit Fly Treatment:	0.09 – 0.18 lb ai/A
Public Health Adulticide:	0.11 – 0.23 lb ai/A

Typical Usage - An average annual estimate of total domestic usage of malathion is approximately 15 million pounds of malathion as active ingredient (ai). Approximately 10.2 million pounds ai are applied through the USDA Boll Weevil Eradication Program, 1.5 million pounds are applied to agricultural crops, and 300,000 pounds are applied as postharvest grain treatment to corn, wheat, and oats. Approximately 500,000 pounds ai are used on non-agricultural sites, such as around buildings, roads, and ditches. Approximately 1.5 million pounds are applied in quarantine programs and public health (adulticide) programs, and 1 million pounds are used in the residential/home owner market.

Percent crop treated - For the majority of the agricultural sites for which malathion is registered and the Agency has use data, less than 1% of the crop is typically treated with malathion; however on several agricultural crops, malathion is applied to 10% of the crop or more.

Percent Crop Treated Range	*Crops*
>10	blueberries, raspberries, strawberries, limes, cotton, cherries, garlic, greens,

	dates, celery.
5 – 10	okra, walnuts, lettuce, avocados, onions, carrots, squash, asparagus, cantaloupes, cabbage, collards, kale.
1 - 5	alfalfa, pecans, wheat, rice, oranges, almonds, corn, peaches, apples, pears, tomatoes, potatoes, sorghum, grapes, beets, lemons, broccoli, cucumbers, grapefruit, pumpkins, sunflowers, watermelons, peas, corn, beans, peppers, plums, prunes, spinach, apricots, cauliflower.
<1	Approximately 54 crops make up this category, but are not listed here.

III. Summary of Malathion Risk Assessment

The following is a summary of EPA's revised human health and ecological risk assessments for malathion, as presented fully in the documents *Malathion: Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED)*, dated July 31, 2006, and *Revised EFED RED Chapter for Malathion*, dated October, 2000. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decision for malathion. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2004-0348 and may also be accessed on the internet at http://www.regulations.gov

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children. The Agency's use of human studies in the malathion risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

The EPA released its revised risk assessments for malathion for public comment on September 23, 2005 for a 60-day public comment period (and additional Phase 5 of the public participation process). In response to comments received and additional data submitted during Phase 5, the risk assessments were updated. The revised risk assessments may be found in the OPP public docket at the address given above and in EPA's electronic docket under docket number EPA-HQ-OPP-2004-0348. Major revisions to the malathion human health risk assessment include the

following:

- Revised Toxicity Adjustment Factor: revision based on recalculation of the doses administered to the test animals in the original data set.
- New chronic dietary endpoint: revised chronic dietary endpoint also based on the recalculation of the doses administered to the test animals in the original data set.
- New dermal toxicity endpoint: new data were voluntarily submitted by the technical registrant, reviewed by the Agency, and incorporated into the current assessment.

For more information on the malathion revised human health risk assessment, see *Malathion: Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED)*, dated July 31, 2006.

1. Toxicity Summary

The toxicity (hazard) assessment is designed to predict whether a pesticide could cause adverse health effects in humans, including short-term (acute) effects, or lifetime (chronic) effects at the level or dose which is expected to occur through the labeled use. The Agency has reviewed all the toxicity data submitted for the reregistration of malathion and has determined that the toxicological database is sufficient to assess potential hazard to all population subgroups, including infants and children, under various exposure scenarios and time durations. The only toxicity data gaps for malathion are a special acute and repeated dose comparative cholinesterase assay with malathion and malaoxon, the environmental degradate of malathion, in juvenile rats, and an immunotoxicity study. The Agency issued a Data Call-In in October, 2004 requiring the special cholinesterase assay. The immunotoxicity study will be required as part of this RED.

Malathion (O,O-dimethyl thiophosphate of diethyl mercaptosuccinate) is an organophosphorous insecticide, which targets the nervous system and, like all members of this class, displays its mode of toxic action through inhibition of cholinesterase (ChE). Malathion is converted to its metabolite, malaoxon (via oxidation of the P=S moiety to P=O), in insects and mammals. The oxon is the active ChE inhibiting metabolite of malathion. When administered to animals directly, malaoxon is a more potent ChE inhibitor than malathion. Cholinesterase inhibition (ChEI) in the nervous system, from exposure to malathion, has been measured in various compartments and observed in multiple species (rat, mouse, rabbit, and dog), following oral, dermal, and inhalation routes of administration. Other treatment related effects of malathion include histopathologic lesions of the nasal cavity and larynx, following inhalation. For a complete discussion on the toxicological database on malathion, see *Malathion: Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED)*, dated July 31, 2006.

Data from chronic studies revealed ChEI effects at the lowest doses tested. In standard guideline prenatal developmental toxicity studies, no developmental toxicity was observed in rats. The weight of evidence from guideline studies and open literature does not support a mutagenic concern for malathion. Published literature studies have shown that malathion can affect immune function, depending on route, magnitude, and frequency of administration. This information has prompted the requirement for a guideline immunotoxicity study to better characterize the potential

effects of malathion on the immune system, which will be required as part of this RED.

a. Acute Toxicity Profile

Malathion exhibits low acute toxicity via the oral, dermal, and inhalation routes (Toxicity Category III or IV). It exhibits only slight eye and dermal irritation and is not a dermal sensitizer. Table 1 provides a summary of the toxicity categories for malathion.

Table 1. Malathion Acute Toxicity Profile

Guideline Number	Type of Study - Species	MRID (Date)	Results	Toxicity Category
870.110	Acute Oral - Rat	00159876 (1986)	LD_{50}= 5400(M)/5700(F) mg/kg	IV
870.1200	Acute Dermal - Rat	00159877 (1986)	LD_{50} >2000 mg/kg (M)(F)	III
870.1300	Acute Inhalation - Rat	00159878 (1986)	LC_{50}> 5.2 mg/L (M)(F)	IV
870.2400	Eye Irritation - Rabbit	00159880 (1985)	Slight conjunctival irritation; Clear by 7 days	III
870.2500	Skin Irritation - Rabbit	00159879 (1985)	Slight dermal irritation (PIS=1.1)	IV
870.2600	Dermal Sensitization - Guinea pig	00159881 (1986)	Not a skin sensitizer	N/A

LD_{50} or LC_{50}; Median Lethal Dose or Concentration, statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).

b. FQPA Safety Factor Considerations

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA, directs the Agency to use an additional tenfold (10x) safety factor (SF) to account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FFDCA authorizes the Agency to reduce the 10x FQPA SF only if reliable data demonstrate that the resulting margin of exposure is adequate to protect infants and children. The toxicology database for malathion is adequate although data gaps remain: a guideline immunotoxicity study and a special comparative ChEI study for acute and repeated exposures in juvenile animals with malaoxon and malathion.

The data the Agency used to address potential differences between young and adult animals are the following guideline studies: pre-natal developmental toxicity in rats and rabbits; a two-generation reproductive toxicity study in rats; an acute neurotoxicity study in rats ; a sub-chronic neurotoxicity study in rats; and a developmental neurotoxicity study in rats (with a

supplemental range-finding study). Additionally, a comparative ChE study with malathion in adult and immature rats for acute and repeated exposures is also available. Consistent with its mode of action, ChE inhibition provides the critical effect for determining the point of departure for the oral, dermal and inhalation (aggregate only) routes of exposure. The comparative ChE in the young demonstrate that juvenile animals are more sensitive than adults.

In order to account for the increased toxicity due to exposure from malaoxon, the Agency is applying a Toxicity Adjustment Factor (TAF) of 61x to malaoxon exposures. The Agency has data on malaoxon (including a 14-day and 2-year feeding study in rats) for repeated exposures which shows malaoxon to be 61x more toxic to adults than malathion. This TAF is, in the absence of data, assumed to be health protective in assessing single (acute) exposures to malaoxon in adults as well as both acute and repeated exposures to the young. The Agency will be receiving confirmatory acute and repeated dose toxicity data for the young in the near future, as discussed earlier.

The Agency has determined that there is evidence that following acute or repeated dose exposures to malathion, young animals exhibit adverse effects more readily than adults. The Agency has oral data for this most sensitive subpopulation and is using it to determine the appropriate point of departure (PoD) for use in assessing risk for acute and chronic dietary and incidental oral scenarios. In those instances where the Agency is using a PoD derived on pup data, the FQPA SF is reduced to 1x. The Agency has decided to retain the FQPA SF (10x) for those scenarios where the PoD does not already reflect the most sensitive population (i.e., the PoD is derived from adult animal studies). Consequently, for dermal exposure scenarios, where the PoD is derived from adult animals and children are expected to be exposed, the FQPA SF of 10x has been retained. Similarly, for inhalation exposure scenarios where the endpoint selected is ChE inhibition (in order to aggregate non-occupational exposures) and the PoD is based on adult animals, the FQPA SF of 10x has also been retained. Finally, the Agency has retained the FQPA SF of 10x for the bystander inhalation scenario in order to account for the lack of a NOAEL, severity of effect, as well as any differential in susceptibility in the young.

Although the immunotoxicity study is identified as a data gap, it is not considered important to the quantification of risk from malathion. Rather it will be used to further characterize the hazard from malathion in terms of its effects on the immune system, and it is not expected to have an effect on the hazard values used in the risk assessment. Therefore, no additional safety factor is necessary to account for the lack of a guideline immunotoxicity study.

FQPA also requires that the completeness of the exposure data base be considered in deciding whether to retain, reduce or remove the FQPA SF. The Agency is confident that the risk assessment for each potential exposure scenario will not underestimate dietary or non-occupational exposures to infants and children.

c. Dose-Response and Benchmark Dose Analysis

A means of refinement to the use of no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) to describe the relationship between dose and response is the use of benchmark dose (BMD) modeling. BMD modeling is a statistically more robust approach, which better incorporates all the data from the test animals at all doses, thus characterizing response (from 0% - 100% inhibition) along the dose continuum.

For malathion, BMD modeling was utilized for the malathion comparative ChE study, (used for endpoint selection for the acute and chronic dietary, and incidental oral scenarios), and 21-day dermal studies (used for endpoint selection for the dermal occupational and non-occupational exposure scenarios). In the past, the Agency has selected the point at which 10% ChEI is observed (BMD_{10}) as the point of departure (PoD) i.e, the point of biological and statistically significant response to a chemical exposure. The Agency then determines the 95% lower confidence limit associated with the PoD to select the toxicity endpoint value, which is termed the BMDL. Thus the $BMDL_{10}$ is the lower 95% confidence interval associated with the dose determined to cause 10% inhibition in the test animals. Although previous PoDs were based upon the BMD_{10}, the Agency may consider alternative benchmark response levels (greater or lower than 10% inhibition) on a chemical by chemical basis, provided there is sufficient information to ensure that the appropriate and protective response level is chosen.

The technical registrant provided comments and analysis to the Agency suggesting that the 20% response level (20% ChEI) was both statistically and biologically more appropriate than the 10% ChEI level, due to the variability associated with ChEI measurements in the red blood cell (RBC) compartment. The Agency reviewed the relevant data and concluded that a 20% RBC ChEI (BMD_{20}) in the malathion adult animal is protective of obvious clinical signs in adult animals, and an appropriate PoD for dermal exposure. Therefore, the Agency selected the $BMDL_{20}$ dose (127 mg/kg/day) from the data set as the dermal toxicity endpoint. The Agency also considered the technical registrant's analysis regarding a BMD_{20} for dietary exposure. However, after reviewing the relevant data, the Agency determined that the BMD_{20} for dietary exposure was not protective, and that the $BMDL_{10}$ is the appropriate and protective endpoint for dietary and incidental oral exposure. Further information on BMD modeling is contained in the *Malathion: Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED)*, dated July 31, 2006

d. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for malathion are listed in Table 2, below. The uncertainty factors (UF) which account for interspecies extrapolation (10x), intraspecies variability (10x), and the FQPA SF used to account for susceptibility of infants and children, are also described in Table 2.

Table 2. Summary of Toxicological Endpoints

Exposure Scenario and Population	Dose (mg/kg/day) and Uncertainty Factor or FQPA Safety Factor	Level of Concern (LOC) as either Population Adjusted Dose (PAD) or Margin of Exposure (MOE)	Study and Toxicological Effects
Dietary Exposure			
Acute Dietary Females 13-49	There is no increased susceptibility expected to females of child-bearing age. Effects observed in the rat and rabbit developmental studies showed reduced body weight gains with NOAELs of 400 and 25 mg/kg/d, respectively. The aRfD for the general population is lower and, thus, would be protective of this population group.		
Acute Dietary General population, including infants and children	Oral $BMDL_{10}$ = 13.6 mg/kg/d UF = 100^2 FQPA SF = 1x	RfD = dose/UF Acute RfD = 0.14 mg/kg/day aPAD = acute RfD/FQPA SF aPAD = 0.14 mg/kg/day	$BMDL_{10}$ = 13.6 mg/kg/day based on RBC ChEI in male pups from the comparative ChE acute oral study in the rat. FQPA SF = 1x since dose is taken from pup data, susceptibility of young is accounted for.
Chronic Dietary All populations	Oral $BMDL_{10}$ = 7.1 mg/kg/d UF = 100 FQPA SF = 1X	RfD = dose/UF Chronic RfD = 0.07 mg/kg/day cPAD = chronic RfD/FQPA cPAD = 0.07 mg/kg/day	$BMDL_{10}$ = 7.1 mg/kg/d based on RBC ChEI in offspring from the comparative ChE multiple dose oral study in the rat. FQPA SF = 1x since dose is taken from the pup data, susceptibility of young is accounted for.
Non-Dietary Exposure			
Incidental Oral Short- (1-30 days) and Intermediate-Term (1-6 months) Children	Oral $BMDL_{10}$ = 7.1 mg/kg/d UF = 100 FQPA SF = 1x	Residential LOC = UF x FQPA SF Residential (Short-term only) LOC for MOE = 100 Occupational = N/A	$BMDL_{10}$ = 7.1 mg/kg/d based on RBC ChEI in offspring from the comparative ChE multiple dose oral study in the rat. FQPA SF = 1x since dose is taken from pup data, susceptibility of young is accounted for.
Dermal Short- (1-30 days) and Intermediate-Term (1-6 months) Children	Dermal $BMDL_{20}$ = 127 mg/kg/d UF = 100 FQPA SF = 10x	Residential LOC = UF x FQPA SF Residential (Short-term only) LOC for MOE = 1000^3 Occupational = N/A	$BMDL_{20}$ = 127 mg/kg/d based on RBC ChEI (%) in two separate 21-day dermal studies in rabbits FQPA SF = 10x since dose is taken from adult data.

Exposure Scenario and Population	Dose (mg/kg/day) and Uncertainty Factor or FQPA Safety Factor	Level of Concern (LOC) as either Population Adjusted Dose (PAD) or Margin of Exposure (MOE)	Study and Toxicological Effects
Dermal Short- (1-30 days) and Intermediate-Term (1-6 months) Adults	Dermal $BMDL_{20}$ = 127 mg/kg/d UF = 100 FQPA SF = 1x[1]	Residential LOC = UF x FQPA SF Residential (Short-term only) LOC for MOE = 100 Occupational LOC for MOE = 100	$BMDL_{20}$ = 127 mg/kg/d based on RBC ChEI (%) in two separate 21-day dermal studies in rabbits FQPA SF =1x since population of concern is adults
Inhalation Short- (1-30 days) and Intermediate-Term (1-6 months) All populations	Inhalation LOAEL = 0.1 mg/L (25.8 mg/kg/day) UF = 100 FQPA SF = 10x	Residential LOC = UF x FQPA SF Residential (Short-term only) LOC for MOE = 1000	LOAEL = 0.1 mg/L (25.8 mg/kg/d) based on histopathology in respiratory epithelium 90-day inhalation study in rats. FQPA SF = 10x to account for LOAEL to NOAEL extrapolation and severity of effect (due to concern for exposure to infants and children)
	Inhalation LOAEL = 0.1 mg/L (25.8 mg/kg/day) UF = 1000[4]	Occupational LOC for MOE = 1000	LOAEL = 0.1 mg/L (25.8 mg/kg/d) based on histopathology in respiratory epithelium 90-day inhalation study in rats.
Inhalation Short- (1-30 days) and Intermediate-Term (1-6 months) Children - Aggregate Only	Inhalation NOAEL= 0.1 mg/L (25.8 mg/kg/day) based on ChEI UF = 100 FQPA SF = 10x	Residential LOC = UF x FQPA SF Residential (Short-term only) LOC for MOE = 1000[3] Occupational = N/A	LOAEL = 0.45 mg/L (115 mg/kg/day) based on plasma and RBC ChEI 90-day inhalation study in rats. FQPA SF = 10x since the dose is taken from adult animals.

Exposure Scenario and Population	Dose (mg/kg/day) and Uncertainty Factor or FQPA Safety Factor	Level of Concern (LOC) as either Population Adjusted Dose (PAD) or Margin of Exposure (MOE)	Study and Toxicological Effects
Inhalation Short- (1-30 days) and Intermediate-Term (1-6 months) Adults - Aggregate Only	Inhalation NOAEL = 0.1 mg/L (25.8 mg/kg/day) based on ChEI UF = 100 FQPA SF = 1x[1]	Residential LOC = UF x FQPA SF Residential (Short-term only) LOC for MOE = 100 Occupational LOC for MOE = 100	LOAEL = 0.45 mg/L (115 mg/kg/day) based on plasma and RBC ChEI 90-day inhalation study in rats. FQPA SF = 1x since population of concern is adults.
Cancer	**Classification:** Suggestive evidence of carcinogenicity		

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable, RBD = red blood cell, ChEI = cholinesterase inhibition, $BMDL_{10}$ = Benchmark Dose Lower Limit (lower 95% confidence limit on the RBC ChEI 10% effect level, $BMDL_{20}$ = Benchmark Dose Lower Limit (lower 95% confidence limit on the RBC ChEI 20% effect level)

[1]: The FQPA SF has not been retained for women of child-bearing age following dermal and/or inhalation exposure because: (i) the observed susceptibility differences between young and old are a result of postnatal exposures and ChEI data from gestational only exposures which indicate that fetuses are less sensitive than the mother at birth; (ii) the dermal toxicity endpoint is based on the more sensitive species (rabbit); (iii) in dermal and inhalation studies, females were neither more sensitive nor responded differently than males; and, (iv) oral studies indicate that there is no enhanced sensitivity of pregnant animals versus non-pregnant animals to malathion, and there is no reason to believe that this is route-specific.

[2]: UF = 100 [10x for interspecies and a 10x for intraspecies variations].

[3]: MOE = 1000 [10x for interspecies extrapolation, 10x for intraspecies variations, and 10x for known susceptibility of the young based on the malathion comparative ChE study].

[4]: UF = 1000 [10x for interspecies extrapolation, 10x for intraspecies variations, and 10x for a LOAEL to NOAEL extrapolation and for the severity of the effect.]

e. Toxicity Adjustment Factor for Malaoxon

Under certain environmental conditions, humans may be directly exposed to malaoxon following applications of malathion (i.e., when malathion undergoes oxidation and the P=S moiety is converted to a P=O moiety). As the oxon metabolite, malaoxon is a more potent ChE inhibitor. The Agency characterizes the toxicity of the metabolite in terms of its degree of potency in comparison to the parent compound. The ratio of relative toxicity between the parent and the oxon is termed the Toxicity Adjustment Factor (TAF).

To calculate the ratio of toxicity between malathion and malaoxon, the Agency utilized BMD modeling of the data. Ideally, a separate TAF for acute/short-term and chronic/long-term exposures would be determined. At the present time, the Agency does not have sufficient data to calculate an acute TAF, but sufficient data with which to estimate a chronic TAF does exist (i.e., 14-day rat study and 2-year chronic rat study). The Agency issued a Data Call-In in October,

2004 which will result in the submission of a special acute and repeat dose comparative cholinesterase assay with malaoxon and malathion in juvenile animals, which will be used to determine the acute TAF. In the absence of an acute TAF, the Agency has applied the chronic TAF to acute exposure scenarios. Based on BMD modeling, the chronic TAF is 61x, meaning malaoxon is estimated to be 61 times more toxic than malathion. Therefore, in the absence of an acute TAF, the chronic TAF of 61x calculated from oral studies is applicable to residues of malaoxon for risk assessment of all exposure durations, routes, and scenarios and is considered to be health protective.

f. Carcinogenicity

Malathion has been classified as having "suggestive evidence of carcinogenicity" in accordance with the EPA *Proposed Guidelines for Carcinogen Risk Assessment* (July 1999). A quantitative cancer dose-response assessment is not indicated for pesticides in the "suggestive" category.

The classification is based on the following evidence: 1) the occurrence of liver tumors in mice and rats only at excessive doses; 2) the presence of a few rare tumors in rats, which cannot be distinguished as either treatment related or due to random occurrence; 3) the evidence for mutagenicity is not supportive of a mutagenic concern in carcinogenicity; and 4) malaoxon, a structurally related chemical, is not carcinogenic in rats. The carcinogenic potential of malathion was also reviewed by the FIFRA Scientific Advisory Panel (SAP) on August 17-18, 2000. The Panel report, *"A Consultation on the EPA Health Effects Division's Proposed Classification of the Human Carcinogenic Potential of Malathion*," dated December 14, 2000, offers an overall equivocal recommendation on the Agency's classification of malathion as "suggestive." The Agency subsequently considered the SAP recommendations and concluded that the cancer classification should remain as "suggestive." Additionally, the CARC recently evaluated a publication by Cabello et al. (2001) and concluded that the paper provided insufficient basis for revising the cancer classification for malathion. Furthermore, the chronic dietary risk assessment is considered protective of any potential carcinogenic effects.

2. Endocrine Disruption

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 recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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 evaluation. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, malathion may be subject to further screening and/or testing to better characterize effects related to endocrine disruption.

In the available toxicity studies on malathion, there was no estrogen or androgen mediated toxicity. Thyroid effects were observed in the combined chronic/carcinogenicity study in rats, which included an increase in parathyroid hyperplasia in male and female rats, and a significant trend in thyroid follicular cell adenomas and/or carcinomas and thyroid c-cell carcinomas (all in males). However, the FIFRA SAP did not consider the thyroid effects of concern or necessarily related to malathion exposure (SAP, 2000).

3. Dietary Exposure from Malathion and Malaoxon in Food

EPA conducted highly refined acute (probabilistic) and chronic dietary (food) risk assessments for malathion using Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEM-FCID™, Version 2.03), which uses food consumption data from the U.S. Department of Agriculture's Continuing Survey of Food Intakes by Individuals (CSFII) from 1994-1996, and 1998. The acute and chronic dietary risk assessment was conducted for all supported malathion food uses.

Malathion dietary residue estimates reflect use of monitoring data, processing factors, and percent crop treated. Pesticide residue data are drawn from several sources: USDA's Pesticide Data sampling Program (PDP) between 1999-2003; FDA's surveillance program; the FOODCONTAM database (designated FODC) between 1992-1998; and field trial data for malathion and malaoxon. The four residue data sources analyzed for both malathion and malaoxon provide EPA with residue data on more than 40,000 food sample items. Residue data is combined with consumption data to estimate potential dietary exposure on an acute (one-time), and chronic basis.

As the major metabolite, malaoxon is to be regulated in plant commodities. The formation of malaoxon can occur via oxidation during water treatment processes (discussed below), or through reaction with the ambient air. Data suggest though, that the oxidation of malathion to malaoxon via ambient air does not readily occur on biologically active material (plant surfaces). Indeed, within the more than 40,000 residue samples collected between 1992-2003, only 43 detections of malaoxon were made. Although detections of malaoxon in or on food commodities are infrequent, they are accounted for in the Agency's dietary assessment by multiplying each malaoxon detection by the TAF (61x) and adding this value to the malathion dietary residue values.

a. Population Adjusted Dose

The dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic dietary assessments, the risk is expressed as a percentage of a level of concern (i.e., the dose predicted to result in no unreasonable adverse health effects to any human sub-population, including sensitive members of such sub-populations). This level of concern is referred to as the Population Adjusted Dose (PAD). Dietary risk is characterized in terms of the PAD, which reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA SF. The Agency reduced the FQPA SF to 1x where the endpoint is derived from data using juvenile animals, i.e., for both the aPAD and cPAD. Both the acute and chronic PADs for malathion are protective of all population subgroups including all infants, children, and women of child bearing age.

Estimated dietary risks less than 100% of the PAD, either acute (aPAD) or chronic (cPAD), are below the Agency's level of concern (LOC). The aPAD is the dose at which a person could be exposed at any given day with no adverse health effects expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime with no adverse health effects expected.

b. Acute and Chronic Dietary (Food) Risk

The estimated acute and chronic dietary risks from malathion and malaoxon, in food alone, are less than 100% of both the aPAD and the cPAD and, therefore, are below the Agency's LOC. Acute dietary exposure to malathion and malaoxon in food at the 99.9th percentile is 5% of the aPAD for the general U.S. population, and 11% of the aPAD for infants (<1 yr old), the most highly exposed population subgroup. The chronic dietary (food) exposure to malathion and malaoxon is less than 1% of the cPAD for all population subgroups. Tables 3 and 4 below summarize the acute and chronic dietary (food only) risks, respectively, from dietary exposure to food alone.

Table 3. Acute Dietary Exposure and Risk at the 99.9th Percentile - Food Only

Population Subgroup	aPAD (mg/kg/day)	Exposure (mg/kg/day)	Percent of the aPAD
General U.S Population	0.14	0.006975	5
All Infants < 1 year old	0.14	0.015734	11
Children 1 – 2 years old	0.14	0.013100	9
Children 3 – 5 years old	0.14	0.012432	9

Table 4. Chronic Dietary Exposure and Risk - Food Only

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	Percent of the cPAD
General U.S Population	0.07	0.000148	< 1

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	Percent of the cPAD
All Infants < 1 year old	0.07	0.000219	< 1
Children 1 – 2 years old	0.07	0.000343	< 1
Children 3 – 5 years old	0.07	0.000334	< 1

c. Drinking Water Exposure

Exposure to pesticides from drinking water can occur through surface and groundwater contamination. The Agency considers both acute (one day) and chronic (long-term) drinking water risks and uses either modeling or actual monitoring data, if available. EPA has assessed potential dietary risk from exposure to concentrations of malathion and malaoxon in surface water and groundwater sources of drinking water, using both modeling and available monitoring data.

Although malathion has some mobility characteristics which suggest it may leach into groundwater, its short soil persistence in conjunction with its relatively quick degradation reduces this potential exposure. EPA's groundwater database (EPA Pesticides in Ground Water Data Base 1971-1991, National Summary) identified very few wells with positive detections of malathion (12 of 990 sampled). Based upon its review of the monitoring data, EPA selected 3.17 ppb to be used for dietary exposure for malathion and malaoxon via groundwater in earlier assessments. The selected value of 3.17 ppb is considered to be a much more conservative value than concentrations predicted through EPA's Tier I SCI-GROW model (0.142 ppb).

Malathion's solubility gives it the potential to dissolve in rainwater and be transported in runoff from the application site. Surface water monitoring data on malathion has been collected in connection with the Boll Weevil Eradication Program and the Mediterranean fruit fly (Medfly) control programs, and is consistent with the fate data. These monitoring data indicate that malathion is mobile, but also that concentrations of malathion in surface water runoff decrease as distance from the application site increases. This result was expected since a greater distance (from the application site) allowed malathion to penetrate soil, adsorb to soil particles, or break/down via hydrolysis and/or aquatic metabolism. Both the fate and the monitoring data indicate that potential runoff of malathion in agricultural settings is affected by numerous variables, including soil type, soil half-life, the amount of time between rainfall events, the amount of rainfall, and the vegetation.

To model potential runoff concentrations from agricultural uses of malathion, EPA used the Tier II Pesticide Root Zone Model (PRZM), and Exposure Analysis Modeling System (EXAMS). EPA selected 16 separate crop scenarios for PRZM-EXMS in order to represent the 100+ commercial agricultural sites for which malathion is registered. EPA selected the 16 crop surrogates based upon: geographic location, use information, percent crop treated, and crop type. The modeling reflected the "Index Reservoir" (IR), a modeled water body with physical

dimensions drawn from an actual reservoir, and Percent Cropped Area (PCA) refinements. PCA factors are used in pesticide drinking water assessments to account for the fact that the entire area of an individual watershed is not devoted to growing crops. In addition, other refinements were also considered in the models, including a refined aerobic soil half-life and an adjusted first application date. In addition, mitigated application values were modeled. Mitigated application values reflect a lower application rate (lb ai/A), and/or a reduction in the number of applications per year. Table 5 below summarizes selected input parameters used in estimating EDWCs. The Agency generated estimated drinking water concentrations (EDWCs) using both default and refined model inputs. Since the estimated residues of malathion in surface water are greater than those predicted or measured in groundwater, the Agency is only presenting dietary exposure to malathion/malaoxon via the surface water route, as this will be protective of any potential groundwater exposure to malathion.

Table 5. Selected Input Parameters for Drinking Water Modeling

	Soil Half-Life	**Percent Cropped Area (PCA)**	**Application Method**	**First Application Date**	**Use Pattern (app. rate and no. of appls./year)**
Default	3 day	National default (0.87)	Ground and Aerial	Rainiest part of the year, depending upon scenario modeled[3]	Maximum supported
Refined	1 day[1]	Regional PCAs[2]	Ground and Aerial	Typical first application date[4]	Proposed (reduced) application values

[1]: Under certain soil conditions, malathion aerobic half-life may be 24 hours.
[2]: Regional PCAs used: Southeast (0.38); Central (0.80); Western (0.56); and, North West (0.63).
[3]: Default *first application date* is intended to reflect month with heaviest rainfall in the modeled area: southeast (May 1); central (Jan. 1); northwest (Jan. 1).
[4]: "*First application date*" was needed only to refine the model scenario for strawberry grown in CA (May 1).

Refined Input Parameters

The drinking water models used in this analysis require the input of a single aerobic soil metabolism half-life for the entire modeled period. A 1-day aerobic soil metabolism half-life was modeled along with the 3-day half-life to evaluate the effect of a shorter soil half-life. Malathion has a wide range of measured soil half-lives which roughly correlate with soil microbial activity and moisture. On moist, microbially active soils, malathion is expected to degrade faster than on dryer, less microbially active soils. The drinking water modeling using a 1-day half-life may represent more typical water concentrations than the default 3-day half-life, because agricultural soils would be expected to commonly be moist and microbially active in order to support crop growth. For all but one scenario (WA cherry), estimated acute dietary risks were below the Agency's LOC, when the mitigated application values and the Regional PCAs were used to model EDWCs. For the WA cherry scenario, the Agency used the refined 1-day soil half-life, because it appropriately represents the northwest region where rainfall and soil moisture is higher.

PCA factors are used in pesticide drinking water assessments to account for the fact that the entire area of an individual watershed is not devoted to growing crops. The default national PCA of 0.87 is based on the most heavily-cropped watershed in the entire United States, which is located in the Midwest. However, many crops to which malathion is applied are grown in less extensively cropped areas. For this reason, regional PCAs, which represent a refinement of national PCAs, were also used in this assessment. Even when considered on a regional scale, regional PCA factors are still likely to be conservative, as they represent the percentage of the most heavily-cropped watershed that is planted to any crop, not just the crop considered in a particular drinking water scenario. PCAs also do not take into account the percentage of a particular crop that is actually treated with malathion. State-level usage data indicate that malathion is generally used on a relatively small portion of any given crop (<5%); thus, the probability that malathion is applied to a large portion of a watershed is decreased.

In the absence of information on the time of year when malathion is used for pest control on a particular crop, the rainiest season for a site was chosen to reflect high-end runoff and exposure values. The Agency can also consider alternate application timings if information is available that indicates the rainiest season for a particular site does not coincide with malathion use. In this instance, a refined first application date for malathion was used for strawberries grown in California, because specific information about its use pattern and timing of application was available to the Agency.

Malathion Conversion to Malaoxon in Drinking Water

As mentioned above, malaoxon is formed during the water treatment process. The rate of conversion during water treatment is efficient, but may vary depending on the type of water process used in disinfection. Limited monitoring information indicates that conversion from malathion to malaoxon may be as high as 100%; data collected by the FL Dept. of Agriculture and Consumer Services Bureau of Pesticides (1997) showed only concentrations of malathion entering the Hillsboro Water Treatment Plant and, following the treatment process, only concentrations of malaoxon exiting the plant. Once converted, malaoxon may remain stable in treated water long enough to be available at the tap for direct consumption. Recently received hydrolysis data indicates that malaoxon may remain stable for 72 hours, which is within delivery times for some publicly owned treatment works (POTWs).

Therefore, in assessing dietary risk to malathion from drinking water, the Agency conservatively assumes that all estimated concentrations of malathion which enter surface water from agricultural runoff are converted to malaoxon and are available for dietary exposure via drinking water. EPA incorporated malathion/malaoxon EDWCs into the acute and chronic dietary assessments by applying the TAF (61x) to the concentrations and including this exposure with the malathion (and malaoxon) food residue values in the DEEM model.

The drinking water assessment contains various refined and conservative assumptions. Overall though, the Agency believes that estimated dietary risk via drinking water is not

underestimated. The Agency notes that certain assumptions in its assessment potentially overestimate the dietary exposure to malathion/malaoxon. First, both environmental fate data and monitoring data indicate the malathion breaks down as it moves farther from the application source; however, the Agency has assumed that 100% of the predicted concentration value at the "edge of the field" reaches the POTW. Second, the Agency has little data to fully characterize the conversion of malathion to malaoxon in the water treatment process. While the Agency has data to support the upper-bound conversion of malathion to malaoxon as 100%, it lacks data to characterize a lower-bound rate of conversion which, under certain conditions, the Agency believes would be less than the assumed 100% conversion. Thirdly, the Agency's drinking water model is designed to predict surface water runoff from large portions of a watershed treated with a compound at the same time. However, State level malathion usage data indicates that malathion is generally used on a relatively small portion of any given crop. Therefore, even EDWCs generated with a refined regional PCA may be an overestimate. Finally, the Agency's TAF (61x), derived from chronic toxicity data could be an overestimate since acute toxicity data on malaoxon is outstanding. Table 6 presents the acute EDWCs and the types of refinements used for the malathion drinking water assessment. For more information on EDWCs refer to *Drinking Water Exposure Modeling Evaluating the Effect of Varying Crop Scenarios, Application Rate, Application Interval, Spray Drift Levels, Soil Half Life* (June 15, 2006).

Table 6. Summary of Acute EDWCs for Selected[1] Malathion Model Scenarios

Site	EDWCs (ppb): Default Input Parameters and Maximum Use Patterns	EDWCs (ppb): Refined Input Parameters and Mitigated Use Patterns	Refinements Applied to Default EDWC
Lettuce, CA	141	12.5	Default estimate was refined with: - proposed application values, - regional PCA, and, - 1 day half-life.
Peach, TX	185	25.4	Default estimate was refined with: - proposed application values, - regional PCA[2]
Citrus, FL	154	14	Default estimate was refined with: - proposed application values
Strawberry, CA	107	3.9	Default estimate was refined with: - first application date, and, - regional PCA
Cherry, WA	44	19.5	Default estimate was refined with: - regional PCA - 1 day soil half life
Asparagus, WA	23	17.1	Default estimate was refined with: - regional PCA

[1]: EPA modeled 16 crop scenarios to assess drinking water exposure. Only those which exceeded the Agency's LOC when default input parameters were used are shown here, and refinements implemented.
[2]: An adequate Peach, TX modeling scenario was unavailable; therefore, EPA combined southcentral PCA with GA Peach modeling scenario.

Chronic EDWCs for Malathion

The chronic EDWC used to assess malathion/malaoxon in surface water sources of drinking water was also estimated using the PRZM/EXAMS screening-level model. Based on the CA lettuce scenario, with a 3-day default half-life at the current maximum application rate, the 1-in-10 year annual concentration of 3.62 ppb was used in the chronic dietary exposure assessment.

4. Residential Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure, other than exposure due to residues in foods or in drinking water. Exposures to malathion may result from outdoor residential uses on vegetable gardens, home orchards, ornamentals and perimeter residential treatments. Residential exposure also may occur from use of malathion in wide-area treatments for adult mosquito control, spray drift from agricultural uses and fruit fly (Medfly) control.

The Agency has determined that there is a potential for exposure to malathion in residential settings for homeowners who handle (mix, load, and apply) products containing malathion. The Agency has also determined that there are potential post-application exposures to residents contacting residues while performing work associated with treating home vegetable gardens and fruit/nut trees, harvesting strawberries in commercial "pick-your-own" fields, and following outdoor fogger use.

Because of the unique circumstances regarding the special uses of malathion in public health mosquito abatement programs, the USDA's Boll Weevil Eradication Program, and fruit fly (Medfly) control, potential residential bystander exposure from these uses are assessed in separate sections later in this document. The greatest potential for malaoxon formation occurs when malathion residues deposit on hard, dry surfaces which can be inadvertently contaminated during wide area applications. For these reasons, the Agency believes that residential contact with outdoor hard surfaces following wide area aerial application of malathion presents the most relevant and worst-case scenario for assessing the risk from malaoxon exposure. Specifically, the Agency has estimated toddler post-application exposures from potential contact with malaoxon residues on wood decks and playground equipment following aerial ULV sprays for public health mosquito treatment, boll weevil eradication, and fruit fly treatment.

To estimate residential dermal and inhalation risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the point of departure (PoD) selected for risk assessment to the exposure. The MOE is compared to a level of concern which is the same value as the uncertainty and safety factors (UF) applied to a particular toxicity study. For a summary of doses, UFs and FQPA SFs used to assess residential exposures, please refer to Table 2.

Residential Use Patterns

The technical registrant (Cheminova) has indicated the following residential use sites will not be supported for reregistration and are therefore not assessed: all pet uses for all formulations; all indoor uses; all greenhouse uses; all pressurized can formulations; all broadcast turf uses; and all residential dust formulation uses.

Potential residential and non-occupational uses where exposure may occur include home gardens (flower and vegetables), home orchards, building perimeters, and back yard foggers. Additional non-occupational exposure may occur from exposure to wood decks and playground equipment following aerial ULV sprays for public health mosquito treatment, boll weevil eradication, and fruit fly treatment. For ease and brevity, the residential use sites have been grouped as shown in Table 7.

Table 7. Residential Use Sites

Use Site	Target Crops or Pests	Maximum Rates	Application Equipment
Homeowner Fruit Trees	Includes apples, cherries, grapes, peaches, plums, oranges and tangerines	0.034 lb ai/gallon	Low pressure hand wand, hose end sprayer, and backpack sprayer.
Homeowner Ornamentals	Includes shade trees, evergreens, and roses	0.034 lb ai/gallon	Low pressure hand wand, hose end sprayer and backpack sprayer.
Homeowner Vegetables/Small Fruits	Includes beans, beets, broccoli, cabbage, collards, cucumbers, melons, tomatoes, peas, peppers and strawberries	0.023 lb ai/gal	Low pressure hand wand, hose end sprayer and backpack sprayer.
Homeowner Outdoor Building Perimeter Treatments	Treatment for outdoor household pests (i.e., roaches, ants, clover mites, spiders, silverfish, crickets, earwigs)	0.1547 lb ai/gal (0.011 lb ai/gal for hose end sprayer)	Low pressure hand wand, hose end sprayer, backpack sprayer.
Outdoor Yard	Mosquito and flying insect pests	0.1 lb ai/acre	Handheld fogger

a. Residential Handler Risks

The Agency determined that exposure to homeowners handling (mixing/loading/applying) a malathion product is likely to occur via dermal (skin) and inhalation routes during the residential use of malathion on the use sites shown in Table 7 above. The risk assessment considered 5 major residential exposure scenarios, based on use patterns and current labeling, types of equipment, formulations, and techniques that can potentially be used to make applications of malathion around residential settings. The use patterns assessed are intended to be representative of the vast majority of the residential uses of malathion. These scenarios include:

(1a) mixing/loading/applying liquid with a low pressure hand wand;
(1b) mixing/loading/applying wettable powder with a low pressure hand wand;
(2) loading/applying liquid with a hose-end sprayer;
(3) mixing/loading/applying liquid with a backpack sprayer; and
(4) mixing/loading liquid for fogger.

The Agency considered residential handler exposure scenarios to be short-term (1-30 days), as homeowner applications are not expected to result in continuous exposure duration greater than 30 days. The residential risk assessment is also based on standard estimates of what and how much homeowners would typically treat, such as the size of a garden. For more information on assumptions about the daily volume handled and the area treated used in each residential handler scenarios, please refer to *Malathion: Residential Exposure and Risk Assessment for the Interim Reregistration Eligibility Decision Document*, dated July 6, 2006.

Estimated dermal and inhalation risks for homeowners handling malathion products are below the Agency's LOC for all handling scenarios. The combined (dermal and inhalation) MOEs for all scenarios assessed are greater than 100 (ranging from 250 to 13000) based on a ChE endpoint. All inhalation MOEs based on histopathologic lesions exceed 1000. Although not tabulated in this document, details on these risk estimates are available in the document referenced above.

b. Residential Post-Application Risks

The Agency refers to the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Malathion can be used in areas that can be frequented by the general population including residential outdoor areas. The Agency has determined that there are potential post-application exposures to individuals while performing work with treated home vegetable gardens and fruit/nut trees, and while harvesting strawberries in commercial "pick-your-own" fields. While the inhalation component of post-application exposure is usually considered to be negligible and, therefore, not included in most determinations, the potential inhalation exposure following use of an outdoor fogger is a primary route of exposure and, therefore, has been assessed.

Because of the unique circumstances regarding the special uses of malathion in public health mosquito abatement control, the USDA's Boll Weevil Eradication Program, and fruit fly (Medfly) control, potential residential bystander exposure from these uses is assessed in separate sections later in this document.

Unlike residential handler exposure, where the EPA assumed only adults will be handling and applying malathion products, individuals of varying ages can potentially be exposed to malathion when reentering or performing activities in areas that have been previously treated. The exposure pathway, residential population, and use patterns that were considered in the risk assessment include:

- Dermal exposure from residues on vegetable/small fruit gardens (adult);
- Dermal exposure from residues on fruit trees (adult);
- Dermal exposure from "pick your own" strawberries (adult);
- Dermal and inhalation (adults and toddlers) and incidental oral (toddlers only) exposure following handheld fogger use at residential, park and school settings.

Post-application exposure following building perimeter treatment is considered to be negligible, and was not assessed. However, existing label language (e.g., EPA Reg. 239-739) for outdoor household pest control gives a range of directions for perimeter house applications which includes directions for application to building foundations and wood piles, and application to the ground surrounding the perimeter of the house in a swath up to 10 feet wide.

EPA considers application of a 10-foot wide swath around most residential structures to be equivalent to a broadcast turf treatment, a use for which the technical registrant has requested voluntary cancellation (letter dated July 25, 2006). In addition, data indicates that application of malathion at the rate intended for residential pest control (0.1547 lb ai/gallon) may be phytotoxic to some ornamental species. Therefore, final label directions for perimeter house treatment will be required which permit application only to structural foundations and to wood piles, and the 2-foot wide path surrounding them.

For all post-application scenarios listed above, estimated dermal and inhalation risks from post-application exposure to malathion are below the Agency's LOC (MOEs ranged from 270 - 7800 for adults and 4000 for toddlers) at the residential setting and, therefore, are not tabulated in this document. A full discussion of assumptions and estimates of residential post-application exposure is available in *Malathion: Residential Exposure and Risk Assessment for the Interim Reregistration Eligibility Decision Document*, dated July 6, 2006.

Residential Post-Application Co-Exposure

The Agency also combines risk values from separate handler and post-application exposure scenarios when it is likely that they can occur simultaneously, and the toxicity endpoint is the same. Simultaneous exposure may refer to scenarios where the same individual handles (mixes/loads) malathion, treats a residential site, and performs post-application activities at that site on the same day. Table 8 below presents combined residential handler and post-application risks based on several malathion use patterns.

Table 8. Combined Handling and Post-Application Risks from Residential Malathion Uses (Adults)

Scenario	Total Dermal Daily Dose (mg/kg/day)	Total Dermal MOE[1]	Total Inhal. Daily Dose (mg/kg/day)	Total Inhal. MOE[1]	Total Combined MOE[2]
Mixing, loading and applying **wettable powder**	0.47	270	0.0014	18,000	260

Scenario	Total Dermal Daily Dose (mg/kg/day)	Total Dermal MOE[1]	Total Inhal. Daily Dose (mg/kg/day)	Total Inhal. MOE[1]	Total Combined MOE[2]
with low-pressure handwand **on vegetable gardens** plus post-application activities **with home fruit trees.**					
Mixing, loading and applying **wettable powder** with low-pressure handwand **on vegetable gardens** plus post-application activities **with vegetable gardens.**	0.37	340	0.0014	18,000	330
Mixing, loading and applying **liquids** with low-pressure handwand **on fruit trees** plus post-application activities **with home fruit trees**.	0.29	440	0.00001	2,600,000	440
Mixing, loading and applying **liquids** with low-pressure handwand **on vegetable gardens** plus post-application activities **with fruit trees**.	0.24	530	0.00001	2,600,000	530
Mixing, loading and applying **liquids** with low-pressure handwand **on fruit trees** plus post-application activities **with vegetable gardens**.	0.19	670	0.00001	2,600,000	670

[1] Total MOE = NOAEL/Total Daily Dose, where:
BMDL = 127 mg/kg/day, for dermal, with an LOC of 100 (cholinesterase effects)
NOAEL = 25.8 mg/kg/day, for inhalation, with an LOC of 100 (cholinesterase effects)

[2] Total Combined MOE = 1/[(1/MOEdermal) + (1/MOEinhalation)]

The total combined MOEs for all assessed residential handler and post-application scenarios assumed to potentially occur the same day are all greater than 100 and, therefore, do not exceed the Agency's LOC.

c. Residential Bystander Assessment

The Agency has determined that there is potential for post-application exposures to adults and children contacting residues of malathion on turf resulting from wide area ULV applications (public health mosquito control, USDA's Boll Weevil Eradication Program, and fruit fly uses). Inhalation exposure usually does not factor significantly into post-application risk for home and garden uses. However, due to the use of malathion in ULV aerial and truck fogger applications to control mosquitoes (adulticide), its wide use in USDA's Boll Weevil Eradication Program, and fruit fly (Medfly) control, potential risk from the inhalation route of exposure has been assessed for both the aerial ULV and ground-based applications. In addition, potential dermal and non-dietary oral (hand-to-mouth) exposures have been estimated because of the concern for the residues that may be deposited during the ultra low volume (ULV) aerial and ground-based fogger applications in the vicinity of residential dwellings and other recreational areas (e.g., school playgrounds, parks, athletic fields). The dermal, inhalation, and hand-to-mouth components of post-application exposure to adults and toddlers have been included for public health mosquito control, boll weevil eradication, and fruit fly (Medfly) uses.

For a more detailed review of the assumptions and underlying data used to assess the residential bystander exposures and risks from these uses see the *Malathion: Residential Exposure and Risk Assessment for the Interim Reregistration Eligibility Decision (RED) Document*, dated July 6, 2006.

Public Health Mosquito Control - Malathion

EPA has determined that there are potential post-application exposures to adults and children from the ULV aerial and ground-based fogger applications for public health mosquito control uses in the vicinity of residential dwellings. The assessment was developed to ensure that the potential exposures are not underestimated, and to represent a conservative model that encompasses potential exposures received in recreational settings, such as schools, playgrounds, parks, or athletic fields. The scenarios likely to result in post-application exposures are:

- dermal exposure from residues deposited on turf at residential, park, and school sites (adult and toddler);
- incidental non-dietary ingestion of residues deposited on turf at residential, park, and school sites from hand-to-mouth transfer (toddler);
- incidental non-dietary ingestion of residues deposited on turf at residential, park, and school sites from object-to-mouth transfer (toddler);
- incidental ingestion of soil from treated areas (toddler); and
- inhalation exposure (adult and toddler).

Adult combined risks based on RBC ChEI as the endpoint are calculated using the Total MOE approach where 100 is the target MOE. For toddlers, however, combined risk was estimated by calculating an aggregate risk index (ARI) because, while oral, dermal and inhalation endpoint effects are the same (ChEI), they have different associated target MOEs or levels of concern (i.e., for dermal and inhalation exposure, the LOC = 1000; for incidental oral exposure, the LOC = 100). Calculated ARIs equal to or greater than 1 are below the Agency's LOC. Combined inhalation and dermal short-term risk estimates for adults resulted in MOEs ranging from 22,000 to 74,000. In addition, the combined dermal, inhalation and incidental oral risk estimates for toddlers from post-application exposure to malathion following public health mosquito treatment resulted in ARIs ranging from 9-20. Therefore, estimated combined short-term risks to adults and toddlers, from all routes of exposure to malathion following both ground and aerial malathion public health mosquito control treatments, do not exceed the Agency's LOC. Additionally, inhalation risks based on histopathological lesions exceeded the Agency's target MOE of 1000 for all scenarios for adults and toddlers (23,000 to 500,000).

Boll Weevil Eradication Program - Malathion

The Boll Weevil Eradication Program (BWEP) is a special project under the direction of the United States Department of Agriculture designed to systematically eradicate the boll weevil pest in cotton-growing regions of the US. The Agency has determined that there is potential for non-occupational post-application exposure to malathion residues from spray drift associated

with the use of malathion in the BWEP. Potential exposure may result from off target drift resulting from aerial applications in the vicinity of residential dwellings. The assessment has been developed to ensure that the potential exposures are not underestimated and to represent a conservative model that encompasses potential exposures received in residential and other recreational settings such as schools, playgrounds, parks, and athletic fields.

The Agency's assessment of the BWEP considers the potential for inhalation exposure (adults and children), dermal contact with residues (adults and children), and incidental ingestion (children only) of residues deposited on turf and soil. The Agency believes it is reasonable to expect that the BWEP application scenario may result in dermal, inhalation, and incidental oral exposure to a single individual within a single day.

The scenarios likely to result in dermal and inhalation (adult and child), and incidental ingestion (child) post-application exposures resulting from boll weevil control uses are as follows:

- dermal exposure from residues deposited on turf at residential, park, and school sites (adult and toddler);
- incidental non-dietary ingestion of residues deposited on turf at residential, park, and school sites from hand-to-mouth transfer (toddler);
- incidental non-dietary ingestion of residues deposited on turf at residential, park, and school sites from object-to-mouth transfer (toddler);
- incidental non-dietary ingestion of residues deposited on soil at residential, park, and school sites from treated areas (toddler);
- inhalation (adult and toddler); and
- inhalation exposure from airborne spray drift (adult and toddler).

Combined risk based on RBC ChEI endpoint for adults were estimated using the Total MOE approach, while combined risk for toddlers used the ARI methodology previously described. Combined adult dermal and inhalation exposures from malathion only result in a risk (total MOE = 3000) that does not exceed the LOC. Likewise, combined toddler exposures from malathion only result in a risk (total ARI = 1.3) that does not exceed the LOC for post-application residential (bystander) exposure in areas nearby fields being treated for boll weevil. Inhalation risks based on histopathological lesions exceeded the Agency's target MOE of 1000 for all scenarios for adults and toddlers (20,000 to 99,000)

Fruit Fly (Medfly) Eradication Treatment - Malathion

Various fruit fly species exist, which when found in areas of fruit and vegetable production trigger eradication efforts because of the potential economic damage they can inflict. Malathion, mixed with a protein-hydrolase bait which attracts the flies and applied by air or ground equipment as a ULV, has been used as part of the fruit fly eradication efforts. Treatment programs to control fruit fly pests have been undertaken in California, Florida and Texas.

As with the ULV uses of malathion for public health mosquito control and the BWEP, fruit fly treatments lead to a potential for non-occupational (residential bystander) post-application exposures. Potential exposures occur as a result from (i) direct deposition to residential areas when applications are made in residential areas; and, (ii) from off target drift in residential areas from applications made to nearby agricultural fields and orchards. The assessment has been developed to ensure that potential exposures are not underestimated and to represent a conservative model that encompasses potential exposures received in residential and public places (e.g., school playgrounds, parks, athletic fields).

This assessment considers the potential for inhalation (adults and children), dermal contact with residues on residential turf (adults and children), and incidental ingestion (children only) of malathion residues on residential turf and soil, following application of malathion to control fruit flies. The Agency believes it is reasonable to expect that the fruit fly application scenario may result in dermal, inhalation, and incidental oral exposure to a single individual within a single day.

The scenarios likely to result in dermal and inhalation (adult and child), and incidental non-dietary ingestion (child) exposures resulting from fruit fly control uses are as follows:

- dermal exposure from residues deposited on turf at residential, park, and school sites (adult and toddler);
- incidental non-dietary ingestion of residues deposited on turf at residential, park, and school sites from hand-to-mouth transfer (toddler);
- incidental non-dietary ingestion of residues deposited on turf at residential, park, and school sites from object-to-mouth transfer (toddler);
- incidental non-dietary ingestion of residues deposited on soil at residential, park, and school sites from treated areas (toddler); and
- inhalation exposure from airborne spray drift (adult and toddler).

Combined risk for adults based on RBC ChEI endpoint were estimated using the Total MOE approach, while combined risk for toddlers is expressed using the ARI methodology previously described. The Agency expects potential exposures and risks associated with aerial application to be greater than those associated with ground application. Therefore, the Agency did not assess ground application of fruit fly treatments with malathion. Based on the most conservative exposure estimates drawn from monitoring data, combined adult dermal and inhalation exposures following aerial fruit fly treatment result in a risk (total MOE = 5500) that does not exceed the LOC. Likewise, combined exposure to toddlers from dermal, inhalation, and incidental oral routes result in a risk (total ARI = 1.7) that does not exceed the LOC. Inhalation risks based on histopathological lesions exceeded the Agency's target MOE of 1000 for all scenarios for adults and toddlers (4.5×10^7 to 1.7×10^8)

Combined Residues of Malathion and Malaoxon

In vivo, malaoxon is the active ChEI, of malathion. Under certain conditions, malaoxon is formed as an environmental breakdown product of malathion and is available for direct human exposure. Monitoring data gathered following aerial application of malathion data indicated malaoxon presence in air, soil, sand and hard surfaces, but minimal to no presence on foliage. These data further indicated that the greatest potential for malaoxon formation occurs when malathion residues deposit on hard, dry (anthropogenic) surfaces such as pavement, metal or wood. For these reasons, the Agency believes that residential contact with outdoor hard surfaces following aerial application of malathion presents the most relevant and worst case scenario for assessing the risk from potential malaoxon exposure.

The Agency has estimated toddler exposures from potential contact with malaoxon residues on wood decks and playground equipment following wide area applications of (ULV) malathion. The full risk from these scenarios must include not only potential malaoxon exposure, but also the exposure to the residues of malathion that remain untransformed (to malaoxon). Therefore, the Agency estimated potential risks to toddlers from the combined exposure to malathion and malaoxon. Because toddler risks from this scenario are believed to represent the worst case for all residential populations engaged in any activity on outdoor hard surfaces, adult exposures and risks were not assessed.

Only limited data exists on the rate of transformation from malathion to malaoxon on hard surfaces. The data which the Agency does have indicates a range of potential transformation rates (1%, 5% or 10%), and the Agency has decided to estimate the risk using the full range. Data on the transformation of malathion to malaoxon will be required as part of the RED. Further, the Agency received information on the dissipation and breakdown of malathion to malaoxon, such that when 5% malaoxon is formed, only 40% of untransformed malathion is present, as opposed to 95% untransformed malathion.

To account for and assess the greater toxicity of malaoxon in residential bystander settings, the Agency applied the TAF (61x) to estimated residues of malaoxon and combined this estimated dose with the estimated dose of malathion. Because both chemicals present the same toxic effect (i.e., cholinesterase inhibition), exposure to both malaoxon and untransformed malathion residues can be directly added together.

Post-application exposures of toddlers to malathion/malaoxon residues on hard surfaces following public health mosquitocide, boll weevil eradication treatment, and fruit fly treatment have been calculated and the details of these can be found in the *Malathion: Residential Exposure and Risk Assessment for the Interim Reregistration Eligibility Decision (RED) Document*, dated July 31, 2006. The calculated exposures in this assessment are not considered to underestimate risk because they include conservative assumptions, maximum application rates and conservative deposition estimates.

Risks from individual routes of exposure (dermal and incidental oral) are combined using an aggregate risk index (ARI) and are presented in Table 9 below. The ARI approach is used

because, while dermal and incidental oral toxicity endpoint effects are the same, they occur at different dose levels and have different associated levels of concern (i.e., for dermal, the LOC = 1000; for incidental oral, the LOC = 100). Calculated ARIs of greater than or equal to 1 are not of concern to the Agency.

Table 9. Aggregate Risk Index (ARI) for Residential Toddler Bystanders from Combined Residues of Malathion and Malaoxon

Use Pattern	Appl. Method	ARIs Based on Malathion-to-Malaoxon Transformation Rates		
		1% Rate	5% Rate	10% Rate
Public Health, adulticide	Aerial	20	12	6
	Ground	340	150	90
Fruit Fly Treatment	Aerial	12	9	5
Boll Weevil Eradication Program	Aerial at 1.2 lb ai/A	2.6	1.2	0.8
	Aerial at 0.9 lb ai/A	3.6	1.6	1.0

5. Aggregate Risk Assessment for Malathion

The FQPA amends the FFDCA (FFDCA, Section 408(b)(2)(A)(ii)) to require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

For malathion, EPA conducted a highly refined aggregate risk assessment that combines exposures across all pathways including food, drinking water, and residential exposure, where appropriate, resulting from agricultural and non-agricultural uses of malathion. When aggregating risk from various sources, the Agency considers both the route and duration of exposure. For malathion, aggregate risk assessments were conducted for acute, chronic and short-term exposures. The Agency's aggregate assessment accounts for exposure to both malathion and the oxygen analogue, malaoxon. Results of the aggregate assessment are summarized here, and are discussed more extensively in the *Malathion: Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED)*, dated July 31, 2006

a. Acute Aggregate Risk

The acute aggregate risk assessment for malathion considers exposures from food and drinking water only, as there are no other pathways of acute exposure. Dietary estimates to all population subgroups were based on a highly refined (probabilistic) assessment using DEEM software. Drinking water exposure was assessed using the full distribution of estimated residues

in surface water generated by the PRZM-EXAMS model. All estimated malathion residues in drinking water were converted to malaoxon residues, multiplied by the TAF (61x), and combined with the estimated food residues. Total dietary exposure from food and drinking water was then compared to the aPAD for malathion.

Acute aggregate risk estimates, based on various default input parameters and maximum registered use patterns (rates and number of applications) from food and drinking water were above the Agency's LOC (>100% aPAD) at the 99.9th percentile of exposure. The CA lettuce maximum aerial scenario resulted in the highest drinking water concentration estimates, and consequently the highest dietary (food + drinking water) exposure estimates. Acute aggregate (food and drinking water) exposure to malathion, based on the CA lettuce scenario at the maximum aerial application rate, at the 99.9th percentile was estimated at 144% of the aPAD for the U.S. population and 520% of the aPAD for all infants (<1 yr old), the most highly exposed population subgroup.

Based on exposure estimates using refined input parameters (e.g., regional PCAs and 1-day half-lives) and mitigated use patterns, all acute aggregate (food + drinking water) risk estimates are below the Agency's LOC (< 100% of the aPAD) for all population subgroups including all infants. Because total dietary exposure from malathion/malaoxon is less than 100% aPAD, acute aggregate exposure from malathion is below the Agency's LOC. Table 10 below summarizes those acute aggregate (food + drinking water) risk estimates for malathion which were refined; other acute aggregate (food + drinking water) risk estimates for malathion which were below the Agency's LOC when default inputs were used, are not presented.

Table 10. Selected[1] Acute Aggregate Exposure and Risk Estimates (Food and Drinking Water)

Site	Population	% aPAD (Default Inputs and Maximum Use Patterns)	% aPAD (Refined Inputs and Mitigated Use Patterns)	Comments
Acute Aggregate Dietary Estimate at the 99.9th Percentile				
Lettuce, CA	U.S Population	144	19	Default estimates were refined with: - proposed application values - regional PCA - 1 day half-life
	All Infants (< 1 yr)	520	63	
	Children 1-2 yrs	218	29	
	Children 3-5 yrs	200	27	
Peach, TX	U.S Population	146	22	Used GA Peach as surrogate model Default estimate was refined with: - proposed application values - regional PCA[1]
	All Infants (< 1 yr)	485	73	
	Children 1–2 yrs	222	34	
	Children 3-5 yrs	201	30	
Citrus, FL	U.S Population	123	11	Default estimate was refined with: - proposed application values
	All Infants (< 1 yr)	430	37	
	Children 1–2 yrs	184	20	

Site	Population	% aPAD (Default Inputs and Maximum Use Patterns)	% aPAD (Refined Inputs and Mitigated Use Patterns)	Comments
Acute Aggregate Dietary Estimate at the 99.9th Percentile				
	Children 3-5 yrs	166	17	
Tomato, FL	U.S Population	115	-	Default exposure estimates refined with: - proposed revised application rates - regional PCA All population subgroups have lower estimated exposure than all infants, therefore other populations were not modeled
	All Infants (< 1 yr)	410	72	
	Children 1–2 yrs	177	-	
	Children 3-5 yrs	162	-	
Strawberry, CA	U.S Population	102	20	Default estimate was refined with: - first application date - regional PCA This scenario was also run with the more conservative 3 day half-life, which resulted in aPAD for all children of 99%.
	All Infants (< 1 yr)	370	59	
	Children 1–2 yrs	153	30	
	Children 3-5 yrs	140	28	
Cotton, MS	U.S Population	73	7	Default estimates refined with - proposed revised application rates
	All Infants (< 1 yr)	262	19	
	Children 1–2 yrs	111	13	
	Children 3-5 yrs	101	11	
Cherry, WA	U.S Population	62	29	Default estimate was refined with: - proposed application values - regional PCA - 1 day soil half-life
	All Infants (< 1 yr)	207	94	
	Children 1–2 yrs	91	43	
	Children 3-5 yrs	81	39	
Cabbage, FL	U.S Population	57	13	Default estimates refined with: - proposed revised application rates
	All Infants (< 1 yr)	195	46	
	Children 1–2 yrs	83	22	
	Children 3-5 yrs	76	20	
Sorghum, TX	U.S Population	39	5	Default estimates refined with: - proposed revised application rates
	All Infants (< 1 yr)	128	12	
	Children 1–2 yrs	58	9	
	Children 3-5 yrs	53	9	
Asparagus, WA	U.S Population	38	-	Default estimate was refined with: - proposed application values - regional PCA All population subgroups have lower estimated exposure than all infants
	All Infants (< 1 yr)	123	94	
	Children 1–2 yrs	55	-	

Site	Population	% aPAD (Default Inputs and Maximum Use Patterns)	% aPAD (Refined Inputs and Mitigated Use Patterns)	Comments
Acute Aggregate Dietary Estimate at the 99.9th Percentile				
	Children 3-5 yrs	51	-	(<1), therefore, other populations were not modeled

[1]: EPA modeled 16 crop scenarios to assess drinking water exposure. Only those which exceeded the Agency's LOC when default input parameters were used are shown here, and refinements implemented.
[2]: An adequate Peach, TX modeling scenario was unavailable; therefore, EPA combined south central PCA with GA peach modeling scenario.

b. Chronic Aggregate Risk

The chronic aggregate exposure to malathion from food and drinking water is below the Agency's LOC for the U.S. general population and all population subgroups. For all drinking water scenarios assessed, including the worst-case aerial CA lettuce scenario with maximum application rates, all chronic aggregate dietary exposure from food and drinking water for the U.S. population and all infants <1 yr, the most highly exposed population subgroup, was <1% of the cPAD. Table 11 provides a summary of chronic aggregate exposure estimates and risk estimates for food and drinking water.

Table 11. Chronic Aggregate Dietary Exposure and Risk (Food + Drinking Water)

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	Percent of the cPAD
General U.S Population	0.07	0.000224	< 1
All Infants < 1 year old	0.07	0.000469	< 1
Children 1 – 2 years old	0.07	0.000456	< 1
Children 3 – 5 years old	0.07	0.000441	< 1

c. Short-Term Aggregate Risk

Aggregate short-term (1-30 days) risk estimates include the contribution from chronic (average) dietary sources (food + drinking water) and short-term residential sources. Several short-term residential exposure scenarios exist that could be aggregated with the chronic dietary exposure sources. Short-term residential exposure (dermal + inhalation + incidental oral) scenarios include adult residential handler, adult and toddler bystander exposure to the home and garden uses of malathion, and toddler bystander exposure to the wide area uses of malathion (BWEP, public health, and Medfly control). Since the estimated exposures resulting from the wide area use assessments incorporate potential exposure to malaoxon, they are more conservative than the estimated exposures resulting from the residential uses and, therefore, have been chosen for the aggregate assessment. Among the wide area uses of malathion, the Agency believes that aerial application of public health use of malathion represents the most likely, and

wide spread co-occurring exposure pathway for the general U.S. population. To be conservative, the Agency assessed this scenario at the 10% conversion rate of malathion to malaoxon.

Short-term bystander exposure from public health use considered incidental oral (hand to mouth), and dermal exposure to both malathion and malaoxon. MOEs for incidental oral exposure are 1,900, and for dermal are 9,100. Chronic aggregate dietary exposures for all infants (< 1 yr old), the most highly exposed population subgroup, is < 1% of the cPAD. The Agency combined these risks using the Aggregate Risk Index (ARI) method, since the target LOC for oral exposure (hand to mouth, and dietary) differs from that of dermal exposure. When using the ARI method, the Agency considers risks equal to or greater than 1 to be not of concern. As presented in Table 12, when chronic dietary (food + drinking water) is added to the oral and dermal exposure components, the total aggregate ARI is 6 and, therefore, below the Agency's LOC.

While the Agency believes that the public health use of malathion is the most appropriate scenario for short-term aggregate risk characterization, it is not the most conservative; rather toddler bystander exposure from the BWEP represents the most conservative residential exposure scenario. There are several reasons why EPA believes that the BWEP scenario is not the most appropriate co-exposure scenario for aggregation. First, the BWEP is a time limited program. The USDA Animal and Plant Health Inspection Service (APHIS) has projected that the eradication phase of the program will end by 2009. Thereafter, USDA/APHIS intends to control the boll weevil by applying malathion only where outbreaks occur, which will result in a significant reduction of malathion applied and, therefore, a significant reduction of potential exposure. The BWEP is also very targeted, being managed and administered in only those states and counties currently active in the eradication phase of the program. As of March 2006, USDA/APHIS reports that boll weevil has already been successfully eradicated in 10 states with active eradication efforts currently underway in 7 states and Mexico. In contrast, the public health use of malathion is national (on a yearly basis) and is broadcast over wider areas (including residential), not just to agricultural fields as malathion is used in the BWEP. Finally, the BWEP has a community outreach and notification component which helps reduce potential exposure from off target drift to bystanders. For these reasons, EPA believes that the BWEP is a less appropriate scenario for aggregation, than the public health use of malathion. Nonetheless, the Agency aggregated this use with the chronic dietary exposure as a worst-case scenario. When estimating risk from the BWEP, the Agency considered both the maximum application rate as well as the typical application rate. Based on information provided by USDA/APHIS which indicates that the predominantly used typical rate in the BWEP is 0.9 lb ai/A (greater than 99% of the acreage is treated at this rate or below), the Agency assessed the predominantly used typical rate (0.9 lb ai/A) for aggregate short-term risk as well as the maximum rate (1.2 lb ai/A). At the maximum application rate, and at the maximum 10% malaoxon conversion rate the estimated aggregate risk, combining the bystander BWEP scenario with chronic dietary (food + drinking water), results in an ARI of 0.8 and, therefore, above the Agency's level of concern. However, based on the predominantly used typical rate of 0.9 lb ai/A, and at the maximum 10% malaoxon conversion rate, the estimated ARI is 1 and, therefore, below the Agency's LOC.

Table 12 summarizes short-term aggregate risk to children 1-2 years of age for public health mosquitocide and BWEP.

Table 12. Short-term Aggregate Risk to Children 1 – 2 Years

Use Scenario	ARI Food + Water[1]	ARI Oral[1]	ARI Dermal[1]	Aggregate ARI[2]
Public Health Mosquito Control (10% malaoxon conversion)	160	19	9.1	6.0
BWEP at Max App. Rate (1.2 lb ai/A) (10% malaoxon conversion)	160	3.6	1.4	0.8
BWEP at Typ App Rate (0.9 lb ai/A) (10% malaoxon conversion)	160	3.6	1.6	1.0

[1] $ARI = [MOE_{CALCULATED} \div MOE_{ACCEPTABLE}]$ (Note: Target ARI = 1)

[2] Aggregate ARI $= \dfrac{1}{\frac{1}{ARI_{FOOD+WATER}} + \frac{1}{ARI_{ORAL}} + \frac{1}{ARI_{DERMAL}}}$

d. Malathion Pesticide and Pharmaceutical Use Co-Exposure Assessment

As indicated above, in determining the risk to human health, the Agency examines more than just dietary exposures. Section 408 of FFDCA requires EPA to consider potential sources of exposure to a pesticide and related substances in addition to the dietary sources expected to result from a pesticide use subject to the tolerance. In order to determine whether to maintain a pesticide tolerance, EPA must "determine that there is a reasonable certainty of no harm. . . ." Under FFDCA section 505, the Food and Drug Administration reviews human drugs for safety and effectiveness and may approve a drug notwithstanding the possibility that some patients may experience adverse side effects. EPA does not believe that, for purposes of the section 408 dietary risk assessment, it is compelled to treat a pharmaceutical patient the same as a non-patient, or to assume that combined exposures to pesticide and pharmaceutical residues that lead to a physiological effect in the patient constitutes "harm" under the meaning of section 408 of the FFDCA.

Rather, EPA believes the appropriate way to consider the pharmaceutical use of malathion in its risk assessment is to examine the impact that the additional non-occupational pesticide exposures would have to a pharmaceutical patient exposed to a related (or, in some cases, the same) compound. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical patient, EPA could make a reasonable certainty of no harm finding for the pesticide tolerances of that compound under section 408 of the FFDCA. If the potential impact on the pharmaceutical user as a result of co-exposure from pesticide use is more than minimal, then EPA would not be able to conclude that pesticide residues were safe and would need to discuss with FDA appropriate measures to reduce exposure from one or both sources. The Agency provided its preliminary findings with respect to malathion to FDA in a

letter dated August 10, 2005, which is available on the public docket (EPA-HQ-OPP-2004-0348).

The exposure estimates used in the determination of malathion pharmaceutical and pesticide co-exposure assessment, Attachments 1 and 2 to the July 25, 2005 letter, referenced above, reflects the external dermal dose of malathion a patient treated with a pharmaceutical malathion product would receive in a reasonable worst-case scenario. EPA's pesticide exposure assessment has taken into consideration the appropriate population, exposure route, and exposure duration for comparison with exposure to the pharmaceutical use of malathion. Using the malathion (Ovide® Lotion 0.05%) registered pharmaceutical label, EPA estimated exposure from a typical treatment of that product, and compared that to the potential exposure an individual would receive from the pesticide uses of malathion. Because the Ovide® Lotion is indicated for use over an 8 - 12 hour period, EPA considers the pharmaceutical use as a short-term exposure. To estimate combined pesticide exposure for a short-term scenario, EPA integrated average dietary exposure estimates (food + drinking water) with one of the non-occupational exposure scenarios (i.e. post-application to malathion residues from wide area public health applications). EPA chose the wide area public health exposure scenario because this application is a reasonable high-end scenario, and is likely to result in a large number of individuals potentially exposed to malathion pesticide residues.

In connection to its Revised Malathion Human Health Risk Assessment, issued September 2005, EPA worked with FDA to determine whether the additional malathion exposure from the pesticide uses would pose a safety concern to a patient using Ovide® Lotion. In a letter dated August 26, 2005, FDA stated that based on EPA calculations of potential high-end pesticide exposure (0.27 mg/kg/day), such exposure in patients receiving Ovide® Lotion treatment would fall within the expected upper range of exposure following Ovide® Lotion use alone, and would not present an increased safety risk.

As discussed above, comments were received in connection with the issuance of the Revised Malathion Human Health Risk Assessment that has resulted in a recalculation of the average dietary exposure and non-occupational exposure (wide area public health use) estimates. The recalculated combined pesticide exposure is within the dose range considered by FDA in its August 26, 2005 letter and below the high-end pesticide exposure estimate that FDA concluded would not increase risk beyond the range expected for the pharmaceutical use alone. Therefore, because the pesticide exposure has no more than a minimal impact on the pharmaceutical patient, the Agency believes that there is a reasonable certainty that the potential pesticide exposure will result in no harm to a patient also receiving Ovide® Lotion.

6. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying the pesticide, or re-entering a treated site. The Agency assessed risk to occupational handlers and workers in the same fashion as it used to assess risks to residential bystanders, i.e., by using the

Margin of Exposure (MOE) approach. The MOE reflects how close an occupational exposure comes to the No Observed Adverse Effect Level (NOAEL) or some other PoD, the dose considered to result in no adverse health effects. The Agency is not concerned if the estimated exposure is 100x less than the PoD (the difference equal to the UF which accounts for the intra-species and inter-species variation). Please see Table 2 for the summary of toxicological endpoints used in this assessment. Both short- and intermediate-term exposures are expected to occur to handlers from registered malathion use patterns. The risk assessment for short-term (1-30 days) and intermediate-term (1-6 months) occupational exposures are similar because the toxicity endpoints, the PODs and the target MOE, are the same for both durations. Chronic exposure (> 6 months) is not expected for handlers and, therefore, is not assessed. Even though the Agency selected separate endpoints for dermal exposure versus inhalation exposures (ChEI as the toxicity endpoint for dermal exposure and histopathologic lesions as the toxicity endpoint for inhalation exposure), the contribution of inhalation exposure to the ChE endpoint was also considered. Therefore, in calculating the short- and intermediate-term risks for ChEI, total MOEs were estimated for combined dermal and inhalation exposures, as well as MOEs for inhalation only to address risk from histopathological lesions.

For malathion, total MOEs that are greater than 100 generally do not exceed the Agency's LOC. However, when occupational MOEs are less than 100, EPA strives to reduce worker cancer risks through the use of personal protective equipment, engineering controls, or Restricted-Entry Intervals (REIs). MOEs for inhalation (histopathological lesions) greater than 1000 do not exceed the Agency's LOC.

a. Occupational Handler Exposure and Risk

Exposure to malathion by pesticide handlers (mixers, loaders, applicators and flaggers) is likely during the use of malathion based on the type of equipment and techniques that can potentially be used. Twenty-six occupational exposure scenarios were assessed based on registered labels, equipment, and techniques that could be used for malathion applicators. Due to the scope of the various malathion occupational uses (there are over 200 registered malathion products), it would be difficult to assess each individual exposure scenario. Therefore, the following selected scenarios are representative of the worse-case exposure scenarios to represent the major ways malathion can be handled in the occupational environment. The scenario numbers correspond to the non-cancer risk estimate tables presented in the *Malathion: Occupational Exposure and Risk Assessment for the Interim Reregistration Eligibility Decision (IRED) Document,* dated July 6, 2006.

The labeled use patterns indicate a number of exposure scenarios based on the types of equipment and activities used to make malathion applications. These scenarios include:

1) mixing/loading liquids for chemigation application;
2) mixing/loading liquids for groundboom application;
3) mixing/loading liquids for aerial application;

4) mixing/loading liquids for airblast sprayer;
5) mixing/loading liquids for dipping;
6) mixing/loading liquids for a fogger;
7) mixing/loading liquids for handgun sprayer;
8) mixing/loading liquids for truck mounted ULV sprays;
9) applying liquids via groundboom;
10) applying liquids via airblast;
11) applying liquids via aerial;
12) applying liquids via handgun sprayer;
13) applying liquids via truck mounted sprayer;
14) applying liquids via dip;
15) mixing/loading/applying liquids via handgun sprayer;
16) mixing/loading/applying liquids via low pressure handwand;
17) mixing/loading/applying liquids via backpack sprayer;
18) mixing loading/applying liquids via paint brush;
19) mixing/loading/applying liquids via dip;
20) flagging for aerial spray application;
21) mixing/loading wettable powders for aerial;
22) mixing/loading wettable powders for chemigation application;
23) mixing/loading wettable powders for groundboom application;
24) mixing/loading wettable powders for airblast application;
25) loading dusts for power duster; and
26) applying dusts with a power duster.

The level of personal protective equipment (PPE) varies on the numerous malathion labels. Some labels only require the minimum level of PPE, while others require additional PPE, such as chemical-resistant gloves, respirators, etc., depending on the labeled handler activity. Therefore, the Agency considered the following levels of PPE or engineering controls in the occupational exposure assessments:

- Baseline, or long-sleeved shirt, long pants, no gloves, and no respirator. (Baseline)
- Baseline plus chemical-resistant gloves, and no respirator. (PPE-G-NR)
- Coveralls worn over long-sleeved shirt and long pants, chemical-resistant gloves, and no respirator. (PPE-G-DL-NR)
- Baseline plus chemical-resistant gloves and an 80% PF (quarter-face dust/mist) respirator. (PPE-G-80%R)
- Coveralls worn over long-sleeved shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator. (PPE-G-DL-80%R)
- Engineering Controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit. (EC)

Except for malathion handlers and applicators using closed mixing/loading systems to support aerial application to cotton and dust application to dates, no chemical-specific handler

exposure data were submitted in support of the reregistration of malathion. Therefore, an exposure assessment for most scenarios was developed, where appropriate data are available, using the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED is a generic database containing measured exposure data for workers involved in the handling or the application of pesticides in the field (i.e., currently contains data for over 2,000 monitored exposure events).

For each of the 26 handler scenarios above, the Agency considered numerous crops or target use sites with various application rates and daily treated area to reflect the way in which malathion can be applied (approximately 555 various use patterns were assessed). Additionally, due to the broad spectrum use of malathion, the Agency believes that occupational exposure can occur over a single day or up to a week's time for many use-patterns, and intermittent exposure over several weeks are also anticipated. Therefore, the risk assessment considers both short- (1-30 days) and intermediate-term (1-6 months) exposure to malathion; combining dermal and inhalation exposures to assess risks from ChEI and evaluating inhalation exposures alone to assess histopathological lesions.

Handler Risks

The majority of the risk estimates were below the Agency's LOC, with MOEs ranging from 100 to 490,000 when baseline PPE and chemical-resistant gloves were applied and are, therefore, not tabulated in this document. However, 17 of the over 500 use patterns assessed either had no data available for conducting an assessment, or required additional PPE or engineering controls before the risk estimates were below the Agency's LOC, and are listed in Table 13. One scenario, however, mixing/loading/applying (M/L/A) liquid concentrates with a low pressure handwand to overhead/fruit trees, was assessed but no data were available to estimate MOEs with anything other than baseline clothing, which exceeded the LOC. This scenario is very similar to another low pressure handwand M/L/A scenario which has data available to calculate MOEs with baseline PPE and chemical-resistant gloves and which is not of concern with that level of protection. This scenario effectively serves as a surrogate for the overhead/tree fruit scenario with no data and is, therefore, not tabulated in Table 13 below.

Table 13. Summary of Malathion Occupational Handler Risk Estimates (MOEs) Requiring PPE greater than Baseline and Gloves

Exposure Scenario	Crop or Use	Application Rate	Max. Area Treated Daily	Base-line	PPE-G-NR	PPE-G-80%R	PPE-G-DL-80%R	EC
Mixer/Loader (M/L)								
M/L Liquids for ULV Aerial Application	Field & Row Crop (Rice, Barely , Oats, Rye, and Wild Rice)	0.61 lb ai/A	7500 A	1	67	ND	110	NA
	Field & Row Crops (Cotton)	1.22 lb ai/A	7500 A	0	34	ND	53	110
M/L Wettable Powders for Aerial Application	Blueberries (Low)	1.25 lb ai/A	350 A	5	53	96	120	NA
		0.76 lb ai/A	350 A	9	88	160	NA	NA

Exposure Scenario	Crop or Use	Application Rate	Max. Area Treated Daily	Base-line	PPE-G-NR	PPE-G-80%R	PPE-G-DL-80%R	EC
Mixer/Loader (M/L)								
	Blueberries (Vine/Trellis)	1.25 lb ai/A	350 A	5	53	96	120	NA
		0.76 lb ai/A	350 A	9	88	160	NA	NA
	Blackberry, Boysenberry, Dewberry, Loganberry, and Raspberry	2 lb ai/A	350 A	3	33	60	74	1,200
M/L Wettable Powder for Chemigation	Blueberries (Low)	1.25 lb ai/A	350 A	5	53	96	120	NA
		0.76 lb ai/A	350 A	9	88	160	NA	NA
	Blueberries (Vine/Trellis)	1.25 lb ai/A	350 A	5	53	96	120	NA
		0.76 lb ai/A	350 A	9	88	160	NA	NA
	Strawberries	2 lb ai/A	350 A	3	33	60	74	1,200
	Blackberry, Boysenberry, Dewberry, Loganberry, and Raspberry	2 lb ai/A	350 A	3	33	60	74	1,200
Application Only								
Liquids via Aerial Application	All 77 crop scenarios assessed	0.175 to 8 Lb ai/A	350 to 7500 A	ND	ND	ND	ND	180 to 27,000
Dust Via Mechanical Duster	Tree Fruit: Evergreens (Tropical)	4.25 lb ai/A	5 A	ND	ND	ND	ND	ND
		2.75 lb ai/A	5 A	ND	ND	ND	ND	ND
Mixing/Loading/Applying (M/L/A)								
Mixing/Loading/Applying Dip	Grape root	0.019 lb ai/gallon	100 gallons	ND	ND	ND	ND	NF
ND= No Data NF= Not Feasible NA=Not Assessed								

b. Occupational Post-Application Exposure and Risk

EPA uses the term "post-application" to describe exposure to an individual which occurs as a result of entering into an environment that has been previously treated with a pesticide (also referred to as reentry exposure). Many crops (or other pesticide treated environments) require distinct job functions which must occur in an environment, following the application of a pesticide product. The job requirements, the nature of the environment, or target that was treated, and how the chemical residues degrade in the environment can cause exposure levels to differ over time. Each factor has been considered in this assessment in determining the safety of persons who are subject to post-application pesticide exposure.

In estimating post-application exposure and risk, transfer coefficient data, which is a measure of the residue transferred from a treated surface to a person who is performing an activity in a treated area, are used in conjunction with dislodgeable foliar residue (DFR) data. DFR data is a unique measurement of the amount of pesticide residue on a treated surface which is available for transfer. DFR data is specific to a compound and describes (by algorithmic function) the dissipation of that chemical over time. EPA has six separate DFR studies on malathion. All agricultural occupational post-application scenarios for malathion were evaluated using one of these six DFR studies.

Occupational post-application exposure (for a given activity/crop combination) is calculated by multiplying the DFR data by the transfer coefficient(s) for that activity/crop combination. The calculation takes into account the application rate for each specific crop, and is normalized by body weight and adjusted for dermal absorption (if necessary). The frequency and duration of post-application occupational exposure is also considered in EPA's estimates of post-application exposure and risk. Short-term exposure durations (1-30 days) are typically considered, and intermediate-term exposure durations (1-6 months) are appropriate for exposures scenarios where the pesticide is reapplied several times over a growing season, or the pesticide residues persist for relatively long periods of time. For malathion, the exposure durations for noncancer post-application risk assessment were short-term and intermediate-term. The dermal toxicological endpoint of concern is the same for both exposure durations, i.e., ChEI. Since malathion has a very low vapor pressure, inhalation exposures are considered to be negligible in outdoor post-application scenarios. DFR data multiplied by the appropriate transfer coefficient yields an estimated dose. The estimated dose is then compared to the selected PoD endpoint (see Table 2), with a target MOE of 100.

EPA does not consider the use of personal protective equipment (PPE), or other types of equipment as a viable option to reduce occupational post-application exposures. However, the Restricted-Entry Interval (REI) is considered an acceptable risk mitigation approach for occupational post-application scenarios. The REI is the required time period, following a pesticide application, during which entry into the treated area is prohibited for workers performing conventional tasks. The Agency sets the REI equal to the time required for the estimated risk to be above the Agency's LOC (i.e., the REI is set equal to the time required for the MOE to be equal to or greater than 100). Currently, all malathion labels specify a 12-hour REI.

For this assessment, the Agency assessed not only the current maximum supported application rate, but also the proposed revised application rate. Based on a revised dermal toxicological endpoint of 127 mg/kg/day, and the proposed revised application rates, the vast majority of occupational post-application scenarios result in MOEs greater than 100 at 12 or 24 hours following application. In several cases a 2-day REI is required to reach the target MOE of 100, and for detasseling corn and tying grapes, a 4-day REI is required. Table 14 provides a summary of occupational post-application REIs for those use sites that require more than the

current 12 hour REI based on the maximum supported application rate and, where appropriate, the recalculated REI based on the proposed revised application rate.

Table 14. Summary of Use Sites that Require More than 12 Hour REI

Use Site	Application Rate (lb ai/A)	Application Rate Source	REI
Cotton	2.5	Current	2 days
	1.22	Current	24 hrs
Peanuts	2.5	Current	24 hrs
Peas	2.5	Current	2 days
	1.0	Amended	12 hrs
Corn (field, seed, sweet and pop)	1.0	Amended	4 days for detasseling and hand harvesting; 12 hrs for all other activities
	0.61	Current	3 days for detasseling and hand harvesting; 12 hrs for all other activities
Apricots	3.75	Current	12 hrs for med expos; 2 days for high expos
	1.5	Amended	12 hrs
Nectarine, peach	3.75	Current	2 days
	3.0	Amended	24 hrs
Figs	2.5	Current	24 hrs
	2.0	Amended	24 hrs
Cherries (sweet and tart)	3.75	Current	2 days
	1.75	Amended	12 hrs
Grapefruit, Lemon, lime, orange, tangelo, tangerine,	6.25	Current	3 days
	CA: 7.5	Amended	3 days
	Rest of US: 4.5	Amended	2 days
Avocado	4.70	Current	3 days
	4.7	Amended	2 days
Kumquat	6.25	Current	3 days
	4.5	Amended	2 days
Dates	4.25	Current	2 days
Pine seed orchards, Christmas tree plantations, slash pine plantations, forest trees	2.5	Current	24 hrs
Chestnuts	5	Current	2 days
	2.5	Amended	24 hrs
Pecans	2.5	Current	24 hrs
	8.0	Amended	3 days
Walnuts	2.5	Current	24 hrs
Forest trees	2.5	Current	24 hrs

Use Site	Application Rate (lb ai/A)	Application Rate Source	REI
Garden beets, carrot, horseradish, parsnip, radish, rutabaga, salsify, turnip	1.25	Current	24 hrs
Chayote root, yams	1.56	Current	24 hrs
Garlic, leeks, green onion, shallots	1.56	Current	24 hrs
Chayote fruit, cucumber	1.88	Current	24 hrs
Summer squash	1.88	Current	24 hrs
	1.75	Amended	24 hrs
Eggplant	3.43	Current	24 hrs
	1.56	Amended	12 hrs
Tomato (fresh and processed), tomatillo	3.43	Current	24 hrs
	1.56	Amended	12 hrs
Broccoli, broccoli raab, Brussels sprouts, cabbage, cauliflower, Chinese broccoli	1.25	Current	2 days
Celery, kohlrabi	1.25	Current	24 hrs
Collard, kale, mustard green, Chinese greens	1.25	Current	24 hrs
Dandelion	2	Current	2 days
	1.25	Amended	24 hrs
Parsley	2	Current	2 days
	1.5	Amended	24 hrs
Spinach	2	Current	2 days
Swiss chard	2	Current	2 days
Endive and escarole	1.88	Current	24 hrs
	1.24	Amended	12 hrs
Lettuce	1.88	Current	24 hrs
Chives	1.56	Current	24 hrs
Watercress	1.25	Current	24 hrs
Pineapples	5	Current	2 days
Grape (wine, table, raisin)	1.88	Current	3 days for girdling and cane turning; 12 hrs for all other activities

c. Incident Reports

The number of malathion exposures and poisonings has declined in recent years; however, most of this decline has occurred in the residential setting and there are no usage surveys to determine whether all or most of this decline is due to less use or safer handling.

Likely, some of the decline is due to less widespread use of malathion due to Medfly outbreaks and as a choice for use against carriers of West Nile Virus. Although agricultural use has declined slightly in California in recent years, it does not explain most of the decline in poisonings reported from that State.

Symptoms commonly reported for malathion exposure cover the spectrum normally associated with organophosphate exposure, and include headache, nausea, dizziness, muscle weakness, drowsiness, difficult breathing, diarrhea, excess secretions, agitation, confusion, blurred vision and, death from accidental or intentional ingestions (i.e., suicides). The most recent five years of data (1999-2003) from California show a marked decline of 59% (from 27.5 to 11.2) in total illnesses attributed to malathion from the 1982-1998 time span. There were 79 cases reported from 1999-2003 and, of these, malathion was determined to be the primary cause of illness in 55 cases. As before, cases were included if malathion was considered a possible, probable, or definite cause of the reported illness. Only 5 of the 55 cases were related to use in agriculture and 4 of the 5 were systemic poisonings. On average, there were 14,846 agriculturally-related applications of malathion from 1999 through 2003 in California. Thus, there were 0.27 systemic poisonings per 1,000 applications from 1999-2003, which compares favorably with much older data from 1982 through 1989, which found a median of 0.41 poisonings per 1,000 applications. However, the earlier data did not have a requirement that all agricultural applications be reported, just commercial and applications by a licensed pesticide applicator. Therefore, it is not clear whether the current rate of poisoning per thousand applications is due to a real decline or an artifact of use reporting. Still, the decline in systemic poisonings from 1990-96 (20.4 per year) to 1999-2003 (8.2 per year) demonstrates a 60% decline in all systemic poisonings, which appears to be not solely a result of the decline in malathion use.

The pattern of incidents was similar to previous years. There were three suicides (ingestions of concentrate: 6-8 ounces, over a cup, and an unknown quantity) and 3 attempted suicides (one case ingested about 8 ounces of 0.125% malathion). Also, a number of rescue personnel attending the suicide victims were also poisoned by the strong odor and from contact with contamination. There were four such individuals in one case, and nine persons sick from attending another suicide victim. Fourteen of the cases became sick from applications that occurred nearby (e.g., from drift). Some of these were due to highly concentrated applications that had not been diluted properly. Five cases involved the applicators themselves, and in six cases there was mention of a leaking or broken bottle.

Much of the information presented above has inherent limitations, including inadequate documentation of exposure and effects, reporting biases and absence of denominator information on the population at risk. However, certain consistent patterns of risk factors can be identified. The large majority of malathion incidents appear to involve minor symptoms, which in many cases may be a reaction to the odor rather than cholinergic poisoning. Nonetheless, symptoms brought on by odor effects are poisonings by definition. Broken bottles and other inadequate packaging accounted for over a quarter of the cases in California from 1982 through 1995. Drift and exposure to odors was another common cause of incidents in California. These latter

incidents typically resulted in mild and transient symptoms. In many cases it appears that symptoms are brought on by the offensive odor of the compound alone (i.e., ChE depression need not be present). More serious malathion cases typically involve application by hand or backpack sprayer and direct exposure to concentrate. Often, serious exposures result from equipment failure, such as hose breaks or failure to exercise minimal precautions during maintenance or clean-up. Though less hazardous than other OPs and carbamates on most measures, malathion has a higher incidence of life-threatening cases in Poison Control Center data. Extensive exposure to concentrates appears to be a likely risk factor in these cases.

B. Environmental Fate and Effects Assessment

A summary of the EPA's environmental fate and ecological effects of malathion is presented below. The full assessment, *Revised EFED RED Chapter for Malathion* (May, 2000) and response to public comments are available on the internet and in the public docket (EPA-HQ-OPP-2004-0348). Updates to the risk assessment include the following:

- incorporation of malaoxon fate data (hydrolysis and conversion data);
- refinement to surface water concentration estimates using typical application information, regional percent cropped area values, and crop specific application information;
- consideration of buffer zones to reduce off target drift from EC/WP formulation and ULV formulation applications;
- reassessment of off target drift resulting from the Boll Weevil Eradication Program; and
- revision to the public health use parameters based on the provision of the PR Notice 2005-1 for Public Health Use Pesticides.

1. Environmental Fate and Transport

The primary routes of dissipation of malathion in surface soils appear to be microbially mediated soil metabolism and hydrolysis. Malathion is generally nonpersistent; but open literature studies suggest that its persistence is longer on soil that is of dry, sandy, low nitrogen, low carbon, and acidic quality. Aerobic soil metabolism data indicate that half-life values for malathion range from several hours to nearly 11 days. The persistence of malathion is decreased with microbial activity, moisture, and high pH. While malathion exhibits short soil persistence, which reduces the likelihood it will leach to groundwater, its low Kd value, and data from various leaching studies, and groundwater detections in three states (CA, MS, and VA) indicate that malathion does have potential to leach to groundwater. Other important routes of dissipation from soil, suggested by the data, include leaching, plant uptake, and surface runoff.

In general, malathion and its degradates are soluble and do not adsorb strongly to soils, and, therefore, are likely to be mobile. Guideline studies and open literature show that malathion is unstable under alkaline conditions and increasingly stable under acidic conditions. While malathion is stable under sunlight, it photodegrades slowly in natural and distilled water (reported half lives ranging from 0.67 to 42 days). Open literature in conjunction with registrant

submitted studies suggest that malathion is unlikely to persist in anaerobic aquatic conditions. Aerobic aquatic metabolism data indicate that malathion's half-life can vary from 1 day to two weeks. Malathion has a relative low vapor pressure, indicating that gas phase reactions are only minor routes of degradation

EPA has limited data on malaoxon, the oxon analogue, and the other impurities/degradates of malathion. However, based upon the chemical similarity between malathion and malaoxon, it is expected that malaoxon will have similar fate properties as its parent. As discussed earlier in this document, malaoxon is shown to form under dry and microbially inactive environmental conditions, such as on dry soil, concrete, or roofing material, where oxidation can occur.

2. Ecological Exposure and Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic estimated environmental concentrations (EECs), based on environmental fate characteristics and pesticide use data, by ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs), and when the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern to that category. See Table 15 for the Agency's LOCs. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed. To the extent feasible, the Agency seeks to reduce environmental concentrations in an effort to reduce the potential for adverse effects to non-target organisms.

Table 15. EPA's Levels of Concern (LOCs) and Risk Presumptions

If a calculated RQ is greater than the LOC presented, then the Agency presumes that…	**LOC terrestrial animals**	**LOC aquatic animals**	**LOC Plants**
Acute Risk …there is potential for acute risk; regulatory action may be warranted	0.5	0.5	1.0
Acute Listed (Endangered and Threatened) Species …listed species may be adversely affected	0.1	0.05	1.0
Chronic Risk …there is potential for chronic risk	1	1	NA

In general, ecotoxicity data reveal that on an acute basis, malathion is moderately toxic to birds and only slightly toxic to mammals through dietary exposure. Malathion has shown to be more acutely toxic to aquatic species (including freshwater as well as estuarine marine species). On a chronic basis, malathion is moderately toxic to avian species and less toxic to mammals. Conversely, malathion is highly toxic to aquatic organisms.

Malathion's mode of action is through acetylcholinesterase (AChE) inhibition which disrupts nervous system function. Inhibiting this enzyme leads to accumulation of the neurotransmitter, thus causing signals in the nervous system to persist longer than normal. While these effects are intended for control of target insects, the toxicological effects of malathion also occur in other non-targeted organisms exposed to malathion.

The Agency does not believe that the conditions necessary for the formation of malaoxon exist such that residues of malaoxon will be found in or on the food sources for terrestrial wildlife. Malaoxon can enter surface water via urban runoff when malathion converts to malaoxon and is washed off by rainfall. However, the Agency does not expect malaoxon to be a significant component of the ecological hazard of malathion to non-target organisms. While other degradates and impurities of malathion exist, they too are not expected to be present in the environment at concentrations high enough to contribute to the toxicity of malathion to non-target organisms.

a. Terrestrial Organisms

Birds and Mammals

Residues of malathion from single and multiple application scenarios are expected to occur on avian and mammalian food items. Predicted maximum and mean concentrations of pesticide residues from single and multiple applications of malathion are based on the Kenaga nomogram as modified by Fletcher et al. (1994). Multiple applications of malathion lead to higher estimated environmental concentrations (EECs) and, therefore, these EECs were employed in the Agency's screening-level analyses. In cases where estimated RQs exceed the Agency's LOC, the Agency may refine its assessment by using mean foliar residue concentrations in estimating exposure. However, because the estimated RQs for terrestrial non-target organisms are relatively low, the Agency did not refine its assessment.

In estimating foliar residues from multiple applications, EPA employed first order dissipation calculations and based scenarios on maximum application rates, minimum application intervals, and maximum number of applications as reported in field trial data submitted by the technical registrant. The Agency estimated numerous EECs for various food sources, (grass, fruit and seed) associated with many of the registered malathion use sites.

Acute and chronic terrestrial organism toxicity studies are required to establish the hazard of malathion to non-target species. Malathion displays low to moderate acute and subacute oral toxicity to birds. To estimate acute avian risk, the Agency chose to use the toxicity endpoint from the subacute dietary study with the Ring-necked pheasant. To calculate chronic avian RQs, the Agency chose the reproduction study in Bobwhite quail as the toxicity reference value.

The Agency requires wild mammal acute toxicity testing on a case-by-case basis, depending upon the results of lower tier laboratory mammalian studies, intended use pattern, and

pertinent environmental fate characteristics. In the case of malathion, the Agency estimated acute mammalian risk, using a toxicity reference value (LD_{50}) from the acute toxicity study with rat. To calculate chronic mammalian RQs, the Agency selected the NOEL from the 2-year mouse feeding study as the toxicity reference value. Table 16 summarizes the terrestrial toxicity reference values for malathion.

A number of non-guideline laboratory and field studies, available through open literature, evaluated the effects of malathion to birds following commercial agricultural applications. Summaries of study findings are included in the *Revised EFED RED Chapter for Malathion* (2000). In addition, several non-guideline, and field monitoring studies with other non-target terrestrial organisms (mammals, reptiles, and insects) are also included in the *Revised EFED RED Chapter for Malathion* (2000).

Table 16. Terrestrial Toxicity Reference Values for Malathion

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value	Toxicity Category/Effect
Avian				
Acute	Ring-necked pheasant	8-day dietary	LC_{50} = 2369 ppm	Slightly toxic
Chronic	Bobwhite quail	21-week dietary	LOEL = 2400 ppm	Growth and viability
Mammalian				
Acute	Rat	32-day dietary	LD_{50} = 390 mg/kg	ChE reduction, reduced bodyweight, reduced pup survival
Chronic	Mice	2-year chronic growth study	500 ppm	

Based on estimated avian acute RQs, the LOC for non-endangered birds is only slightly exceeded. However, the acute endangered LOC for birds is exceeded. The chronic RQs for birds and mammals slightly exceed the LOC of 1.0, which applies to both endangered and non-endangered species. For mammals, both non-endangered and endangered, acute and chronic RQs only slightly exceed the LOC. RQs were estimated for many sites. The range of acute and chronic RQs are presented in Tables 17 and 18, respectively, below. The tables present both lower and upper bound for malathion use in a commercial agricultural setting using label recommended application parameters. The lower bound estimate represents the labeled application rate for a single ULV application to citrus, and the upper bound represents a multiple EC/WP application to chestnuts (for birds) and to citrus (for mammals).

Table 17. Terrestrial Organism Acute Risk Ranges

Species	Food Source	EEC (ppm)	Toxicity Reference Value	RQ
Avian	Short grass[1]	42 – 1987	LC_{50} = 2639 mg/kg	0.01 – 0.75
	Seed	1.2 - 119		0.0004 – 0.04

Species	Food Source	EEC (ppm)	Toxicity Reference Value	RQ
Mammal	Short grass	43 – 1500	LD_{50} = 390 mg/kg	0.07 – 3.65
	Fruit	2.7 - 44		0.005 – 0.16

[1]: estimated concentration of malathion residues on terrestrial short grass, following multiple applications is representative of foliar food items such as short grass, tall grass, and broadleaf plants.

Table 18. Terrestrial Organism Chronic Risk Ranges

Species	Food Source	EEC (ppm)	Toxicity Reference Value	RQ
Avian	Short grass[1]	42 – 1535	NOEC = 110 ppm	0.4 – 18.1
	Seed	1.2 – 46		0.01 – 1.1
Mammal	Short grass	43 – 1500	NOEL 500 ppm	0.09 – 3.0
	Fruit	2.7 - 44		0.005 – 0.13

[1]: estimated concentration of malathion residues on terrestrial short grass, following multiple applications is representative of foliar food items such as short grass, tall grass, and broadleaf plants.

Amphibians and Reptiles

Exposure to amphibians may occur either through surface water contamination from runoff or drift, or through dermal absorption that may occur from spray drift. EPA has limited amphibian aquatic toxicity data, and limited data on the possible effects to amphibians from dermal adsorption of malathion residues. Possible exposure may occur through ingestion or absorption of water contaminated with malathion. However, acute risk to reptiles is not expected as they, like mammals, are relatively efficient at detoxifying malathion.

Non-Target Plants and Non-Target Insects

Malathion has been shown to be systemically absorbed into plant tissues. However, the Agency does not expect malathion to pose a serious risk to terrestrial plants or aquatic algae, as its mode of action (effects on the nervous system) would not apply. Indeed the Agency has no reports of adverse reactions of crops or plants to malathion.

Malathion, however, has been shown to be lethal to many species of beneficial insects. Routes of exposure may either be through direct contact, contact through foliar residues, and contact with residue coated pollen transported back to nests or hives. A honeybee foliar residue contact toxicity study indicated that malathion is highly toxic to bees on an acute basis. In addition several toxicity studies with aquatic insect larvae were conducted by the USFWS which showed that malathion is highly to very highly toxic to non-target insects with aquatic early life stages.

b. Aquatic Organisms

Freshwater and Estuarine Fish and Invertebrates

As noted above, malathion is mobile, and can move from application sites into surface water and groundwater. Contamination of surface water from commercial agricultural uses results from both runoff and from off-target drift. Surface water contamination can also occur from urban runoff from residential uses and wide area applications, i.e., quarantine and public health mosquitocide uses.

The Agency used a tier two (PRZM-EXAMS model) assessment, on selected crops, to assess potential risks to aquatic organisms. The PRZM-EXAMS model is used for both ecological exposure and drinking water concentration exposure. Unlike the drinking water assessment described in the human health risk assessment section of this document, the exposure values used in the ecological risk assessment are neither based upon the Index Reservoir (IR), nor incorporate percent cropped area (PCA) factors, but rather are based upon the "standard pond" scenario. The "standard pond" scenario is intended to better represent the spatial and physical qualities of habitats relevant to risk assessment for aquatic non-target organisms such as ponds, or streams in, and adjacent to, treated agricultural fields. Therefore, the EEC values used to assess potential exposure and risk to aquatic animals are not the same as those used to assess exposure and risk to humans from pesticides in drinking water.

The tier two, PRZM-EXAMS water exposure assessment was conducted on four malathion crops and several non-agricultural use sites. The Pesticide Root Zone Model (PRZM) simulates the movement of a chemical in unsaturated soil just below the plant root zone. The Exposure Analysis Modeling System (EXAMS II) is a model that works with the PRZM model and predicts pesticide concentrations in a simulated pond. Because malathion is registered for use on over 100 different commercial agricultural crops, tier two EECs could not be generated on all registered use sites. In choosing crop surrogates for estimating surface water concentrations, the Agency considered crop location, application parameters, percent crop treated, and percent of total malathion use on that crop.

Application rates, number of applications and minimum retreatment intervals were based upon the maximum supported values identified by the technical registrant in residue field trials. Estimated water concentrations for selected crops are listed below in Table 19.

Table 19. Maximum and Typical EECs for Selected Crops

Site	Appl	Application Rate			Estimate Environmental Concentration (ppb)		
		lbs ai/A	no. of app	Retreatment Interval	21 day avg.	60 day avg.	Peak
Citrus	Max	6.25	3	30	23.2	10.7	156
	Typ	2.5	1	-	7.38	2.59	47.3

Site	Appl	Application Rate			Estimate Environmental Concentration (ppb)		
		lbs ai/A	no. of app	Retreatment Interval	21 day avg.	60 day avg.	Peak
Cotton[1]	Max	2.5	25	3	67.4	47.7	291
	Typ	0.3	4	3	1.48	0.5	7.9
Sorghum	Max	1.25	3	7	5.0	26.7	26.7
	Typ	0.8	1	-	0.5	0.18	2.94
Lettuce	Max	1.88	6	5	6.3	2.98	15.4
	Typ	2.0	1	-	1.58	0.56	5.63

[1]: application values for cotton modeled represent old maximum supported values; current maximum supported use rate for the Boll Weevil Eradication Program is 1.2 lb ai/A, and current typical application rate is 0.9 lb ai/A.

Numerous acute and chronic toxicity studies for freshwater and estuarine/marine fish have been reviewed by EPA. Depending upon species tested, malathion toxicity to freshwater fish is classified as very highly toxic. Acute and chronic toxicity data for freshwater and estuarine invertebrates were also required. Based upon these data, malathion is categorized as highly toxic to freshwater invertebrates. Table 20 summarizes the aquatic toxicity reference values for malathion.

Table 20. Aquatic Toxicity Reference Values for Malathion

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value	Toxicity Category/Effect
Freshwater Fish				
Acute	Bluegill sunfish	69 hr	LC_{50} = 30 ppb	Very highly toxic
Chronic	Rainbow trout	97 day	NOEC 21 ppb	LOEC = 44 ppb
Freshwater Invertebrates				
Acute	Water flea, *Daphnia magna*	48 hr	EC_{50} = 1.0 ppb	Highly toxic
Chronic	Water flea, *Daphnia magna*	21 day	NOEC = 0.06 ppb	LOEC = 0.01 ppb

Similar to RQs calculated for terrestrial organisms, aquatic acute and chronic RQs are derived by dividing the EEC by the LC_{50} or EC_{50} (for acute hazard) and the EEC by the NOEC (for chronic hazard). Based on actual monitored concentrations, predicted modeling results, and actual fish kill incidents, there is acute hazard from contamination of aquatic habitats adjacent to, or within target application areas. Tables 21 and 22 list acute and chronic RQs, respectively, for selected crops.

Many non-guideline laboratory and field studies on malathion's toxicity to aquatic non-target organisms have been conducted. These studies report behavioral and biologic effects which are not investigated or reflected in the guideline studies required by EPA. Summaries of these studies are included in the *Revised EFED RED Chapter for Malathion,* (2000).

Currently, the Agency does not have a model with which to predict concentrations of malathion in surface water, from home/garden applications, or urban uses. Runoff from these uses is expected to move over lawns, and impervious surfaces to storm sewers and then to surface water. Monitoring data from the USGS National Water Quality Assessment program (NAWQA) between 1992 and 2001 analyzed for malathion in 903 samples from urban streams, and found malathion at a maximum concentration of 0.648 ppb. Since the NAWQA data is not targeted, by location or time, it cannot be reliably considered representative of acute concentrations of malathion that may occur from urban uses. However, the magnitude of the concentrations sampled in NAWQA suggests that the acute concentrations from agricultural uses predicted by PRZM/EXAMS modeling is sufficiently conservative to be protective of potential concentrations from urban uses.

Table 21. Acute Risk Quotient Ranges for Aquatic Fish and Invertebrates

Site	Appl	EEC (ppb) (peak concentration)	Toxicity Reference Value		Risk Quotient	
			Fish	Invert	Fish	Invert
Cotton[1]	Max	291	Bluegill sunfish LC_{50} = 30 ppb	Daphnia magna EC_{50} = 1.0 ppb	9.7	291
	Typ	7.9			0.26	8
Sorghum	Max	26.7			0.9	27
	Typ	2.94			0.09	3
Citrus	Max	162			5.4	162
	Typ	47.3			1.57	47
Lettuce	Max	15.4			0.5	15
	Typ	5.63			0.18	6

[1]: RQs for cotton represent rates used in the BWEP. EEC of 291 is an overestimate as it is based on the old maximum application rate of 2.5 lb ai/A. Current maximum application rate for cotton (BWEP) is 1.2 lb ai/A, and typical rate is 0.9 lb ai/A.

Table 22. Chronic Risk Quotient Ranges for Aquatic Freshwater Fish and Invertebrates

Site	Appl	EEC (ppb)		Toxicity Reference Value		Risk Quotient	
		21 day (used with invert.)	60 day (used with fish)	Fish	Invert	Fish	Invert[2]
Cotton[1]	Max	67.4	47.7	Rainbow trout NOEC = 21 ppb	Daphnia magna NOEC = 0.06 ppb	2.3	1123
	Typ	1.48	0.5			0.02	25
Sorghum	Max	5.0	1.95			0.09	83
	Typ	0.5	0.18			0.01	8.3
Citrus	Max	25.2	11.1			0.5	416
	Typ	7.38	2.59			0.12	121
Lettuce	Max	6.26	2.98			0.14	104
	Typ	1.58	0.56			0.02	26

[1]: RQs for cotton represent rates used in the BWEP. EECs of 67.4, and 47.7 are overestimates as they are based on old maximum application rates of 2.5 lb ai/A. Current maximum application rate for cotton (BWEP) is 1.2 lb ai/A, and typical rate is 0.9 lb ai/A.
[2]: Chronic invertebrate RQs cited in the *Revised EFED RED Chapter for Malathion* (2000) were incorrectly calculated using the LOEC (0.1), instead of the NOEC value (0.06), which was used in this table.

RQs used to evaluate risk to all aquatic organisms were based on toxicity data for bluegill sunfish and *Daphnia magna*, which are both freshwater species. The risk assessment uses these organisms to represent both freshwater and estuarine/marine fish and invertebrates, because AChE inhibition is the same toxic mode of action for all of these taxa. Although there is a wide range of sensitivity to malathion exposure among aquatic organisms, the data do not indicate a difference attributable to the type of water body in which the animals live.

Were RQs to be calculated for estuarine/marine fish and invertebrates from estuarine/marine toxicity data, the finding of potential acute risk would be the same. The LC_{50} of 33 ppb for the most sensitive estuarine/marine fish tested, the sheepshead minnow, is essentially equivalent to the bluegill sunfish LC_{50} of 30 ppb used in the risk assessment to calculate acute RQs for all fish. The EC_{50} of 2.2 ppb for the estuarine/marine invertebrate *Mysidopsis bahia* is not as low as the *Daphnia magna* EC_{50} of 1.0 ppb used to calculate the acute RQs for all aquatic invertebrates. However, the peak EECs from PRZM/EXAMS scenarios representing crops most likely to be grown in estuarine watersheds (such as cotton, citrus and lettuce) would result in RQs that exceed the acute LOC for all four of these species, whether from a maximum or typical application rate.

A similar comparison of the chronic toxicity of malathion to freshwater and estuarine/marine animals is more difficult, due to a scarcity of laboratory toxicity data. There is only a single submitted chronic toxicity study for estuarine/marine fish, and no such data for estuarine/marine invertebrates. As with the assessment of acute risk, freshwater RQs are used to represent all aquatic organisms because of the equivalence of the mode of toxicity to freshwater and estuarine/marine fish and invertebrates.

c. Spray Drift

Monitoring results indicate that spray drift can be a significant source of aquatic contamination, and reducing off-target drift reduces aquatic EECs. Drifting malathion applications carried by air movement will reach unintended sites. Droplet size, wind speed, and release height tend to be the most important parameters in determining how much of a pesticide application will deposit off-target. Applications of nonvolatile oils, as in ULV formulations, do not evaporate rapidly and, therefore, settle more quickly than ULV formulations that may use water as a carrier. The AgDRIFT model used by the Agency to estimate buffer zones contains a sophisticated evaporation algorithm to account for evaporation during droplet's time in the air. The speed by which droplets fall is exponentially related to their size such that small droplets fall very slowly, resulting in more nontarget deposition. Application rate is also an important determinant for off-target spray drift exposure. The application rates EPA modeled were

representative of the range of rates supported by the technical registrant. Spray drift field studies show considerable variability in deposition under essentially the same conditions. Therefore, model estimates used for dissipation distances reflect mean values.

EPA modeled several combinations of wind speed, boom width, and formulation types to determine distances and related pesticide loading into a "standard pond" from aerial applications of malathion. The Agency estimated buffer zones that would result in concentrations less than 4 ug/L, the lowest LC_{50} value for fish, and in concentrations less than 20 ug/L, the lower 95th percentile LC_{50} for a freshwater species reported in EPA's *Revised EFED RED Chapter for Malathion* (2000). Model results showed that smaller buffer zones were required when wind speed is low, boom width is reduced, and non-ULV formulations are used. Model results also showed that buffer zones for ULV and non-ULV formulations were not necessary to prevent concentrations at or above 20 ug/L and, therefore, are not presented here. Results of model estimates of buffer zones, based on varying conditions and at the estimated concentration of 4 ug/L, are summarized below in Table 23.

Table 23. Dissipation Distances from Various Aerial Applications

Wind Speed (mph)	Boom Width (% of wing span)	ULV	Non-ULV Formulations (formulations using water carriers)
Most Sensitive Freshwater fish – Rainbow trout: LC_{50} = 4 ug/L			
10	60 ft	0	25 ft
	75 ft	0	100 ft
15	60 ft	0	50 ft
	75 ft	50 ft	150 ft

d. Wide Area Treatments with Malathion

Public Health Mosquito Treatment

EPA also conducted a screening-level ecological assessment of the public health use of malathion as a mosquito adulticide. The malathion mosquito abatement product is only formulated as an ULV product and is applied either aerially or by truck mounted sprayer. The Agency calculated aquatic EECs from off-target drift using the Agricultural Dispersal (AGDISP) model, which estimates the deposition of a compound into a "standard pond" (i.e., one hectare pond that is two meters deep next to a ten hectare plot).

Input parameters for the AGDISP model are chosen to reflect environmental conditions under which the mosquitocide product is applied (such as temperature and relative humidity), application practices (boom width, droplet size, and application rate), and physical characteristics of the compound (such as the evaporation rate or the volatilization fraction of the compound). Instead of using existing mosquitocide labels, which vary between manufacturers, the Agency relied upon labels recently submitted by the malathion technical registrant in connection with

Pesticide Registration (PR) Notice 2005-1. The PR Notice 2005-1 recommended specific label statements and organization principles intended to improve the lot of existing public health adult mosquitocide labels by clarifying language regarding environmental hazards posed by mosquitocide products, and by standardizing use direction and instructions for mosquitocide applicators.

Several variables drawn from the updated mosquitocide label (in compliance with PR 2005-1) include the proposed minimum release height of 100 feet. The updated labels, in line with the PR Notice also specify a droplet size of 60 ug. Finally, PR 2005-1 discusses that a buffer zone around aquatic habitat may not be warranted, noting that protecting human health from mosquito-borne diseases with pesticides often involves some degree of ecological risk, and that an aquatic buffer zone may require leaving potentially infested areas untreated. Therefore, in estimating ecological risk from the mosquitocide application scenario, the Agency assumed a zero foot buffer zone.

The Agency calculated a worst-case RQ for fish and invertebrates from the wide area public health use by assuming 100% of product (on a per area basis) drifts into a six foot deep pond. Estimated acute RQs for fish are 38 and 1.9 for freshwater invertebrates.

Fruit Fly (Quarantine) Treatment

Malathion is also used in liquid bait applications, such as for wide-area quarantine uses to control the Mediterranean and other fruit fly species. Non-target organisms may be exposed to the bait formulation of malathion as it is similar to granules foraged by wildlife. Based upon the current maximum Med-Fly application rate (0.18 lb ai/A), acute RQs are well below the LOC (< 0.00001) for both mammals and avian species. Chronic RQs were not calculated, since they too are likely to be below the Agency's LOC.

Other Non-Agricultural Uses

Other wide area, non-agricultural use sites include rangeland/pasture as well as commercial tree production. In these scenarios, EPA estimated acute RQs for freshwater fish to range from 36 to 190 for rangeland/pastures and commercial tree farms, respectively. Acute RQs for freshwater invertebrates ranged from 1.8 to 3.8. Similar to exposure estimates made in connection with the public health adulticide use, these RQs are considered very conservative as EPA estimated RQs assuming 100% of the applied product (on a per area basis) deposits into a subject water body. Wide area uses are intended to disperse and, therefore, 100% deposition is very unlikely to occur.

e. Down-the-Drain Assessment

The Agency also estimated potential exposure from malathion released into domestic wastewater which may eventually be introduced into Publicly Owned Treatment Works

(POTWs) from the pharmaceutical use of malathion. The Agency used the consumer product exposure model, Exposure and Fate Assessment Screening Tool (E-FAST) (Versar 1999) developed by OPPT.

The screening-level assessment assumes that in a given year the entire production volume of malathion pharmaceutical product is parceled out on a daily basis across the U.S. population, and is then converted to a mass release per capita. This mass is then diluted into the average daily volume of wastewater released per person per day to arrive at an estimated concentration of malathion in wastewater prior to entering a treatment facility. The concentration of malathion in untreated wastewater is then reduced by the fraction removed during the treatment process before it is released into a river or stream. The remaining pesticide is discharged into surface water where it is instantaneously diluted and no further removal is assumed.

Based on 2000-2001 production volume of Ovide®, EPA estimates the high-end acute surface water concentration to be 3.55×10^{-5} ppb, and chronic surface water concentration to be approximately 2.73×10^{-6}. Since Ovide® production has increased since 2000-2001 by approximately 3-fold, estimated environmental concentrations from down-the-drain sources are not expected to be greater than 1.0×10^{-4} ppb. Because E-FAST is a screening tool, and the estimated removal of malathion in wastewater of 3% may be an underestimate based on laboratory data, the estimated surface water concentrations from down-the-drain release of malathion from the pharmaceutical use remain very low and significantly less than predicted exposures from agricultural uses of malathion. Therefore, estimated RQs to non-target aquatic organisms from down-the-drain exposure to malathion is expected to be very low and not of concern to the Agency.

f. Endangered Species

Based upon the screening-level assessment conducted on malathion, the Agency has identified several exceedences of the acute and chronic endangered LOC in certain cases for birds, mammals, fish and invertebrates should exposures actually occur at modeled levels.

<u>Terrestrial Organisms</u>

- Mammals
  - Acute RQs for small mammals feeding on short grass exceeded the Agency's acute endangered LOC for sites with multiple applications at an application rate ≥ 0.175 lb ai/A.
  - Chronic RQs for small mammals exceeded the Agency's acute endangered LOC for sites with multiple applications at an application rate ≥ 0.61 lb ai/A.
- Birds
  - Acute endangered LOC is exceeded for grass-eating birds at use sites with single and multiple applications at an application rate ≥ 1.25 lb ai/A. The Agency's acute endangered LOC was not exceeded for seed-eating birds.

- Chronic RQs exceed the endangered LOC for grass-eating birds at use sites with single and multiple applications at an application rate ≥ 0.175 lb ai/A and for seed-eating birds with multiple applications at rates ≥ 0.61 lb ai/A or with single applications at rates ≥ 1.56 lb ai/A.

- Insects and Plants
  - Data indicate that malathion may be highly toxic to bees, and has been shown to be lethal to many species of beneficial insects when used near or over non-agricultural areas containing beneficial insect populations. However, the Agency does not yet have a method to estimate risk to bees and other non-target insect organisms. Therefore, the Agency cannot preclude possible adverse effects to beneficial and listed insect species. In addition, the Agency does have data with which to assess the malathion risk to non- target terrestrial plants or aquatic algae, and while the Agency has no data or reports of adverse reactions of crops or plants to malathion, it cannot preclude potential adverse effects to non-target terrestrial plant species.

Aquatic Organisms

- Fish and Invertebrates (fresh water and estuarine/marine)
  - The Agency's acute endangered LOC is exceeded for both fish and invertebrates in all sites modeled with PRZM-EXAMS. However, when typical use parameters were used to model these five sites, several RQs for fish fell below the Agency's acute endangered LOC.

The conclusions stated in this document are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of malathion can not be precluded based on the screening level ecological risk assessment.

3. Ecological Incidents

Wildlife incidents which involve aquatic organisms are reported to the Agency by local, state, other federal agencies, or at times, submitted under FIFRA sec. 6(a)(2). Eighteen of the twenty two ecological incidents reported to the Agency were related to fish kills, with most incidents having occurred since 1970 through the present. The highest rate of incidents is associated with the high volume and heavily monitored Boll Weevil Eradication Program (BWEP). Mosquito control and Mediterranean Fruit fly control are also associated with several incident reports. Incidents ranged in magnitude from just 2 fish to over 10,000 fish. The Agency expects the occurrence of aquatic incidents to decline over time, as the BWEP is a time limited program. The Agency has only two reported incidents involving terrestrial organisms. In one incident (1985), extensive mortality to honeybees was recorded and may have been associated with large area treatment of alfalfa. The second terrestrial incident involved waterfowl and was considered only to be possibly linked to a wide area (Medfly) treatment with malathion.

IV. Risk Management, Reregistration, and Tolerance Reassessment

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (technical or manufacturing-use grade) data required to support reregistration of products containing malathion as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the dietary, residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient malathion. Based on these data, the Agency has sufficient information on the human health and ecological effects of malathion to make its decisions as part of the tolerance reassessment process under FFDCA and the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing malathion will be eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted; and (ii) label amendments are made to reflect these measures. Needed label changes and language are listed in Section V. Appendix A is a detailed table listing all malathion uses that are eligible for reregistration, or uses which require tolerances or tolerance consideration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of malathion, and lists the submitted studies the Agency found acceptable. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data, or additional data necessary to confirm the decision presented here.

Based on its evaluation of malathion, the Agency has determined that malathion products, unless labeled and used as specified in Sections IV and V this document, would present risks inconsistent with FIFRA and FFDCA. 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 the use of malathion. If all changes outlined in this document are incorporated into the product labels, then all current risks for malathion will be adequately mitigated for the purposes of this determination under FIFRA. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary, as explained in Section IV.C.4. of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for malathion. EPA released its revised malathion risk assessments for public comment on September 23, 2005, for a 60-day public comment period (an

additional Phase 5 of the public participation process). During the public comment period on the risk assessments, which closed on November 22, 2005, the Agency received comments from the technical registrant, American Mushroom Institute, Natural Resources Defense Council, Armed Forces Pest Management Board, University of Hawaii, U.S. Department of Agriculture, various water quality associations and mosquito control districts, and others. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (EPA-HQ-OPP-2004-0348) and on the internet at http:www.regulations.gov.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide, as well as cumulative risks from total exposure to registered uses of OP pesticides. 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 OPs through a common biochemical interaction with the cholinesterase enzyme. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, aggregate human health risks as a result of exposures to malathion are within acceptable levels. In other words, EPA has concluded that the tolerances for malathion meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to malathion from all possible sources. In addition, the Agency has concluded that cumulative risks associated with OP pesticides, including malathion, are also below the Agency's level of concern.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for malathion, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of malathion. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of malathion. As discussed in this document, aggregate risks from malathion are below the Agency's level of concern. In addition, the Agency has concluded that cumulative risks associated with OP pesticides, including malathion, are also below the Agency's level of concern.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for malathion, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of malathion residues in this population subgroup. In addition, the Agency has concluded that cumulative risks associated with OP pesticides, including malathion, are also below the Agency's level of concern.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of malathion, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The Agency has determined that there is evidence that following acute or repeated dose exposures to malathion, young animals exhibit adverse effects more readily than adults. The Agency has oral data for this most sensitive subpopulation and is using it to determine the appropriate point of departure (PoD) for use in assessing risk for acute and chronic dietary and incidental oral scenarios. In those instances where the Agency is using a PoD derived on pup data, the FQPA SF is reduced to 1x. The Agency has decided to retain the FQPA SF (10x) for those scenarios where the PoD does not already reflect the most sensitive population (i.e., the PoD is derived from adult animal studies). Consequently, for dermal exposure scenarios, where the PoD is derived from adult animals and children are expected to be exposed, the FQPA SF of 10x has been retained. Similarly, for inhalation exposure scenarios where the endpoint selected is ChE inhibition (in order to aggregate non-occupational exposures) and the PoD is based on adult animals, the FQPA SF of 10x has also been retained. Finally, the Agency has retained the FQPA SF of 10x for the bystander inhalation scenario in order to account for the lack of a NOAEL, severity of effect, as well as any differential in susceptibility in the young.

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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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 for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on malathion, there was no estrogen or androgen mediated toxicity. However, thyroid effects were observed in the combined chronic/carcinogenicity study in rats, which included an increase in parathyroid hyperplasia in male and female rats, and a significant trend in thyroid follicular cell adenomas and/or carcinomas and thyroid c-cell carcinomas (all in males). However, the FIFRA SAP did not consider the thyroid effects of concern or necessarily related to malathion exposure (SAP, 2000).

3. Cumulative Risks

Section 408(b)(2)(D)(v) of FIFRA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Other substances are considered to account for the possibility that low-level exposures to multiple chemical substances that cause a common effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to each individual substance.

Malathion is a member of the OP class of pesticides, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate the risk from food, drinking water, residential, and other non-occupational exposures resulting from registered uses of OP pesticides, including malathion. EPA has concluded that the cumulative risks associated with OP pesticides are below the Agency's level of concern. For additional information, refer to the *OP Cumulative Assessment* (2006 Update), which is available in EPA docket EPA-HQ-OPP-2006-0618 and on EPA's website at http://www.epa.gov/pesticides/cumulative/.

4. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers 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. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time. A determination that there is a likelihood of potential

effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of malathion "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments for malathion result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program. Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will help to reduce the likelihood that endangered and threatened species may be exposed to malathion at levels of concern.

D. Tolerance Reassessment Summary

Tolerance Definition

Tolerances have been established for the residues of malathion *per se* in/on food/feed commodities, meat, milk poultry and eggs [40CFR§ 180.111]. Because animal metabolism data indicate that there is little likelihood of residue transfer to meat, milk, poultry and eggs, tolerances for malathion residues in these commodities may be revoked.

Tolerances for residues of malathion in/on plant and animal commodities, food commodities, and feed commodities are currently expressed in terms of malathion *per se*. Based on available plant metabolism data, the Agency has determined that the malathion residues of concern in plants consist of malathion and its metabolite, malaoxon. In vivo, malaoxon is the active ChE-inhibiting oxon metabolite of malathion, and under certain conditions, malaoxon can be formed as an environmental breakdown product of malathion. Monitoring data indicate malaoxon's presence in food. Therefore, tolerance expression should be revised to include malathion and malaoxon. The tolerance expression for plant commodities needs to be revised in order to reflect the Agency's determination that the residues of concern are malathion [*O,O*-dimethyl dithiophosphate of diethyl mercaptosuccinate] and its metabolite malaoxon [*O,O*-dimethyl thiophosphate of diethyl mercaptosuccinate]. Table 24 summarizes the metabolites and degradate included in the malathion risk assessment and tolerance expression.

Table 24. Metabolites and Degradates Included in the Risk Assessment and Tolerance Expression

Matrix		Residues Included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	Malathion and malaoxon	Malathion and malaoxon
	Rotational Crop	Malathion and malaoxon	Malathion and malaoxon
Livestock	Ruminant	180.6(a)(3)	180.6(a)(3)
	Poultry	180.6(a)(3)	180.6(a)(3)
Drinking Water		Malathion and malaoxon	Not applicable

The established tolerances for animal commodities should be revoked. The Agency published a Notice of Request for Deletion of Certain Uses and Directions for Use (FR vol. 56, No. 52, FRL-3874-4) in 1991 in which all direct application to livestock was requested for deletion from malathion labels. No comments have been received by the Agency in support of these uses, and this use has been removed from almost all labels. Remaining labels with direct animal treatment will be amended as part of the RED. Since neither malathion nor malaoxon were observed in eggs, milk, and animal tissues, there is no need for tolerances in these commodities based on dietary exposure to malathion.

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1, malathion tolerances for certain raw agricultural commodities (RACs) which have been removed from the livestock feeds table need to be revoked. Also, some commodity definitions must be corrected. A summary of malathion tolerance reassessments is presented in Table 25, below.

Tolerances Listed Under 40 CFR §180.111:

Sufficient data have been submitted (or were translated when appropriate) to reassess the established tolerances for the following commodities, pending label amendments for some crops: alfalfa; apricots; asparagus; avocados; barley, grain (postharvest); beans; beets (including tops); Birdsfoot trefoil, forage ; Birdsfoot trefoil, hay; blackberries; blueberries; boysenberries; carrots; chayote fruit; chayote roots; cherries; chestnuts; clover; corn, forage; corn, fresh (including sweet K + CWHR); corn, grain (postharvest); cottonseed; cucumbers; currants; dewberries; eggplants; figs; flax seed; garlic; grapefruit; gooseberries; grapes; grass; grass, hay; guavas; hops; horseradish; kumquats; leeks; lemons; lespedeza, hay; lespedeza, straw; limes; loganberries; lupine, seed; macadamia nuts; mangos; melons; mushrooms; nectarines; oats, grain (postharvest); okra; onions (including green onions); oranges; papayas; parsnips; passion fruit; peaches; pears; peas; pecans; peppermint; peppers; pineapples; potatoes; pumpkins; radishes; raspberries; rice, grain (postharvest); rice, wild; rutabagas; rye, grain (postharvest); salsify (including tops); shallots; sorghum, grain (postharvest); spearmint; squash, summer and winter; strawberries; sweet potatoes; tangerines; tomatoes; turnips (including tops); vegetables, leafy, *Brassica* (cole); vetch, hay; vetch, straw; walnuts and wheat, grain (postharvest).

Confirmatory data are required to support the reassessed following commodities: apples; dates; quinces; sorghum, forage; and vegetables, leafy (except *Brassica*).

No registrants have committed to support malathion uses on any greenhouse-grown crops. Therefore, the registered greenhouse uses of malathion on cucumber, endive, lettuce, radish, tomato, and watercress should be deleted from all malathion end-use product labels. The reassessment of tolerances has been conducted with the assumption that only field-grown cucumber, endive, lettuce, radish, tomato, and watercress are supported for reregistration.

Due to a lack of support for reregistration, the established tolerances for the following commodities should be revoked concomitant with the deletion of respective crops from all malathion product labels: almond hulls; almonds; almonds, shells; beets, sugar, roots; beets, sugar, tops; cowpea, forage; cowpea, hay; cranberries; filberts; lentils; peanut, forage; peanut, hay; peanuts; peavine, hay; peavines; plums; prunes; safflower, seed; soybeans (dry and succulent); soybean, forage; soybean, hay; sunflower seeds.

The tolerances for the following commodities should be revoked because they are no longer considered significant livestock feed items and have been deleted from Table 1 (OPPTS GLN 860.1000): flax straw; lespedeza, seed (PRE-H); and vetch, seed (PRE-H).

The tolerances for the following animal commodities should be revoked because the technical registrant(s) have voluntarily requested cancellation of direct animal treatment uses of malathion to poultry and other livestock including: cattle, fat (PRE-S); cattle, mbyp (PRE-S); cattle, meat (PRE-S); eggs (from application to poultry; goats, fat (PRE- S); goats mbyp (PRE-S); goats, meat (PRE-S); hogs, fat (PRE-S); hogs mbyp (PRE-S); hogs, meat (PRE-S); horses, fat (PRE-S); horses, mbyp (PRE-S); horses, meat (PRE-S); milk, fat (from application to dairy cows); poultry, fat (PRE-S); poultry, mbyp (PRE-S); poultry, meat (PRE-S); sheep, fat (PRE-S); sheep, mbyp (PRE-S); and sheep, meat (PRE-S).

Tolerances To Be Proposed Under 40 CFR §180.111:

Tolerances are required and must be proposed, based on available field trial data, for the following RACs: aspirated grain fractions; barley, straw; corn, field, stover; oats, forage; oats, straw; radish tops; rice, straw; rye, forage; rye, straw; watercress; wheat, forage; and wheat, straw. Tolerances are required and must be proposed for the following RACs after adequate data have been submitted and evaluated: barley, hay; stover; corn, sweet, stover; cotton, gin byproducts; oats, hay; sorghum, stover; and wheat, hay.

Tolerances need to be proposed on certain processed commodities which showed significant concentration of residues based on the results of acceptable processing studies. The results of processing studies which trigger the need for tolerances for the combined residues of malathion and malaoxon are briefly presented below.

The processing data for apple indicate that the combined residues of malathion and malaoxon concentrated 3.8x in wet pomace, but did not concentrate in apple juice processed from apples bearing detectable residues of malathion. A tolerance for apple wet pomace needs to be proposed once adequate field trial data are available for reassessment of the established tolerance on apples.

The processing data for preharvest-treated field corn grain indicate that the combined residues of malathion and malaoxon did not concentrate above the limit of detection (0.01 ppm) in starch, grits, meal, flour, dry- and wet-milled crude oil, dry- and wet-milled refined oil, and dry- and wet-milled bleached and deodorized oil processed from field corn grain bearing nondetectable residues of malathion and malaoxon (<0.01 ppm each) following three preharvest foliar treatments at 5x the maximum single application rate.

The processing data for postharvest-treated field corn grain indicate that the combined residues of malathion and malaoxon concentrated 1.8x in meal and 2.0x in flour processed from field corn grain bearing detectable combined residues of malathion and malaoxon following a series of postharvest treatments according to the use pattern the registrant wishes to support. The combined residues did not concentrate in grits, starch and dry- and wet-milled bleached and deodorized oil. The highest average field trial (HAFT) (combined residues) from trials reflecting postharvest treatment is 6.79 ppm. Based on this HAFT and the observed concentration factors, the maximum expected combined residues are 12.2 ppm for meal (6.79 x 1.8) and 13.6 ppm for flour (6.79 x 2.0). These maximum expected combined residues are higher than the reassessed tolerance of 8.0 ppm for field corn grain. Therefore, tolerances for the combined residues of malathion and malaoxon in corn meal and flour at 14.0 ppm must be proposed. Since residues did not concentrate in dry- and wet-milled bleached and deodorized oil, a tolerance for this commodity need not be proposed.

The available data for stored field corn processed commodities may be translated to stored sorghum processed commodities. A tolerance for the combined residues of malathion and malaoxon in/on sorghum flour need not be established at this time since sorghum flour is used exclusively in the United States as a component for drywall, and not as either a human food or a feedstuff.

The processing data for fig indicate that the combined residues of malathion and malaoxon concentrated 2.9x in dried fig processed from fresh fig bearing detectable residues and treated at 1x. A tolerance of 2 ppm should be appropriate for dried fig based on the concentration factor and the highest average field trial.

The mint processing data indicate that the combined residues of malathion and malaoxon concentrated up to 12.7x in mint oil processed from mint tops bearing detectable residues following applications at 5x. The HAFT (combined residues) from mint field trials reflecting the maximum proposed use pattern is 1.1 ppm. Based on this HAFT and the observed concentration factor, the maximum expected combined residues are 13.97 ppm for mint oil. These maximum

expected combined residues are higher that the reassessed tolerance of 2.0 ppm for peppermint and spearmint tops. Therefore, tolerances for the combined residues of malathion and malaoxon in peppermint and spearmint at 15.0 ppm must be proposed.

The processing data for preharvest-treated oranges indicate that the combined residues of malathion and malaoxon concentrated in oil (>208x) and dried pulp (9.5x) but reduced in juice (<0.1x) following processing of oranges bearing detectable residues. Based on the results of this study, and a HAFT of 1.9 ppm, a tolerance of 400 ppm must be proposed for citrus oil and a tolerance of 20 ppm must be proposed for citrus dried pulp.

The processing data submitted for cottonseed, potatoes, and tomatoes indicate that the combined residues of malathion and malaoxon did not concentrate in the respective processed commodities; therefore, tolerances are not required for the processed commodities of these crops. Additional processing studies remain outstanding for flax and postharvest-treated wheat.

Tolerances Listed Under 40 CFR §180.111(a)(2):

The established tolerance for raisins resulting from drying of grapes on treated trays should be revoked since adequate supporting data are not available and this use is not being supported for reregistration. An acceptable grape processing study reflecting preharvest treatment has been submitted and evaluated. The grape processing data indicate that the combined residues of malathion and malaoxon did not concentrate in raisin and juice processed from grapes bearing detectable residues following treatment with the 5 lb/gal EC formulation at 5x the maximum single application rate.

Tolerances Listed Under 40 CFR §180.111(a)(3):

The established tolerance for refined safflower oil should be revoked since no registrants have committed to support malathion use on safflower.

Tolerances Listed Under 40 CFR §180.111(a)(4):

The conditions listed in 40 CFR §180.111 (a)(4) allowing malathion use for the control of insects during the drying of grapes (raisins) should be deleted unless the registrant(s) submits supporting data.

Tolerances Listed Under 40 CFR §180(a)(5):

The tolerances for the following commodities should be revoked because the technical registrant(s) have voluntarily requested cancellation of animal feed uses: dehydrated citrus pulp (for cattle feed) and non-medicated cattle feed concentrate blocks.

A summary of malathion tolerance reassessment and recommended modifications in commodity definitions are presented in Table 25, below.

Table 25: Tolerance Summary for Malathion

Commodity	Tolerance Listed Under 40 CFR §180.111	Reassessed Tolerance[1]	Comment [*correct commodity definition*]
Tolerances Listed Under 40 CFR §180.111 (2)(1)			
Alfalfa	135	125	[*Alfalfa, forage*]
		185	[*Alfalfa, hay*]
Almond, hulls	50	Revoke	Not supported under reregistration
Almonds, postharvest	8	Revoke	Not supported under reregistration
Almonds, shells	50	Revoke	Not supported under reregistration
Apple	8	TBD [2]	Additional apple field trial data are required as confirmatory data
Apricot	8	1.0	
Asparagus	8	2.0	
Avocado	8	0.2	
Barley, grain, postharvest	8	8.0	[*Barley, grain (PRE- and POST-H)*] Translated from wheat data.
Beans	8	2.0	[*Bean, dry*]
		2.0	[*Bean, succulent*]
Beets (including tops)	8	4.0	[*Beet, garden, tops*] translated from turnip tops data.
		0.5	[*Beet, garden, roots*] Translated from turnip root data.
Beet, sugar, roots	1	Revoke	Not supported under reregistration
Beets sugar, tops	8	Revoke	Not supported under reregistration
Blackberry	8	6	
Blueberry	8	8	
Boysenberry	8	6.0	Translated from blackberry and raspberry data.
Carrots, roots	8	1	[*Carrot*]
Cattle, fat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Cattle, meat byproducts (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Cattle, meat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Chayote fruit	8	0.2	Translated cucumber data.
Chayote roots	8	0.1	Translated potato data.
Cherry	8	3.0	
Chestnut	1	1.0	
Clover	135	125	[*Clover, forage*]
		125	[*Clover, hay*]
Corn, forage	8	5.0	[*Corn, field, forage*]
		45.0	[*Corn, sweet, forage*]
Corn, fresh (including sweet,	2	0.1	[*Corn, sweet (K + CWHR)*]

Commodity	Tolerance Listed Under 40 CFR §180.111	Reassessed Tolerance[1]	Comment [*correct commodity definition*]
kernel plus cob with husks removed)			
Corn, grain, post harvest	8	8.0	[*Corn, field, grain (PRE- and POST- H)*]
Cotton, undelinted seed	2	20	
Cowpea, forage	135	Revoke	Not supported under reregistration
Cowpea, hay	135	Revoke	Not supported under reregistration
Cranberry	8	Revoke	Not supported under reregistration
Cucumber	8	0.2	
Currant	8	8.0	Translated from blueberry data.
Dates	8	TBD[2]	Further confirmatory data required (data under review)
Dewberry	8	6.0	Translated from blackberry data.
Eggplant	8	2.0	Translated from tomato data.
Eggs (from application to poultry)	0.1	Revoke	Contingent upon cancellation of direct animal treatment uses.
Fig	8	1.0	
Filbert	1	Revoke	Not supported under reregistration
Flax seed	0.1	0.10	[*Flax, seed*]
Flax straw	1	Revoke	Not a significant RAC of flax.
Garlic	8	1.0	Translated from onion bulb data.
Goat, fat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Goat, meat byproducts (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Goat, meat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Gooseberry	8	6.0	Translated from blackberry and raspberry data.
Grapefruit	8	4.0	Translated from orange data.
Grape	8	4.0	
Grass	135	200	[*Grass, forage*]
Grass, hay	135	270	
Guava	8	1.0	
Hog, fat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Hog, meat byproduct (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Hog, meat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Hop	1	1.0	[*Hops, dried*]
Horseradish	8	0.5	Translated from turnip root data.
Horse, fat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Horse, meat byproduct (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Horse, meat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.

Commodity	Tolerance Listed Under 40 CFR §180.111	Reassessed Tolerance[1]	Comment [*correct commodity definition*]
Kumquat	8	4.0	Translated from orange data.
Leek	8	6	Translated from green onion data.
Lemon	8	4.0	Translated from orange data.
Lentil, seed	8	Revoke	Not supported under reregistration
Lespedeza, hay	135	185	Translated from alfalfa hay data.
Lespedeza, seed	8	Revoke	Not a significant RAC of lespedeza
Lespedeza, straw	135	Revoke	Not a significant RAC of lespedeza
Lime	8	4.0	Translated from orange data.
Loganberry	8	6.0	Translated from blackberry and raspberry data.
Lupine, seed	8	2.0	Translated from dry beans data
Mango	8	0.2	
Melon	8	1.0	
Milk, fat (from application to dairy cows)	0.5	Revoke	Contingent upon cancellation of direct animal treatment uses.
Mushroom	8	0.2	
Nectarine	8	1.0	Translated from apricot data.
Nut, macadamia	1	0.2	
Oat, grain, postharvest	8	8.0	[*Oats, grain (PRE- and POST-H)*] Translated from wheat grain data.
Okra	8	3.0	
Onions (including green onion)	8	1.0	[*Onion, bulb*]
		6.0	[*Onion, green*]
Orange, sweet	8	4.0	[*Orange*]
Papaya	1	1	
Parsnip	8	0.5	Translated from turnip root data.
Passion fruit	8	0.2	[*Passion fruit*]
Peach	8	6.0	
Peanut, forage	135	Revoke	Not supported under reregistration
Peanut, hay	135	Revoke	Not supported under reregistration
Peanut, postharvest	8	Revoke	Not supported under reregistration
Pear	8	3.0	[Pear]
Pea	8	2.0	[*Pea, succulent*] Dry peas not being supported under reregistration.
Pea vine, hay	8	Revoke	Not supported under reregistration
Pea vines	8	Revoke	Not supported under reregistration
Pecans	8	0.20	[*Pecan*] Translated from walnut data.
Peppermint	8	2.0	[*Peppermint*]
Pepper	8	0.5	[*Pepper*]
Pineapple	8	0.2	[*Pineapple*]
Plum	8	Revoke	Not supported under reregistration
Potato	8	0.1	[*Potato*]
Poultry, fat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Poultry, meat byproduct (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Poultry, meat (PRE-S)	4	Revoke	Contingent upon cancellation of direct

Commodity	Tolerance Listed Under 40 CFR §180.111	Reassessed Tolerance[1]	Comment [*correct commodity definition*]
			animal treatment uses.
Plum, prune	8	Revoke	Not supported under reregistration.
Pumpkin	8	1.0	Translated from melon data.
Quince	8	TBD[2]	Translate from apple data. Further confirmatory data on apple required.
Radish	8	0.5	Translated from turnip root data.
Raspberry	8	6.0	
Rice, grain, postharvest	8	30	[*Rice, grain (PRE-H)*] Postharvest use on rice not supported under reregistration.
Rice, wild	8	30	[*Rice, wild*] Translated from rice grain data.
Rutabaga	8	0.5	[*Rutabaga*] Translated from turnip root data.
Rye, grain, postharvest	8	8.0	[*Rye, grain (PRE- and POST-H)*] Translated from wheat grain data.
Safflower, seed	0.2	Revoke	Not supported under reregistration
Salsify (including tops)	8	4.0	*[Salsify, tops (leaves)]* Translated from turnip tops data.
		0.5	*[Salsify, root]* Translated from turnip root data.
Shallots	8	6.0	[*Shallot*]Translated from green onion data.
Sheep, fat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Sheep, meat byproduct (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Sheep, meat (PRE-S)	4	Revoke	Contingent upon cancellation of direct animal treatment uses.
Sorghum, forage	8	TBD[2]	[*Sorghum, forage*] Additional data are required.
Sorghum, grain, postharvest	8	8.0	[*Sorghum, grain (PRE- and POST-H)*] Postharvest data translated from field corn grain data.
Soybean (dry and succulent)	8	Revoke	Not supported under reregistration
Soybean, forage	135	Revoke	Not supported under reregistration
Soybean, hay	135	Revoke	Not supported under reregistration
Spearmint, tops	8	2.0	[*Spearmint*]
Squash, summer and winter	8	0.2	[*Squash, summer*] Translated from cucumber data.
		1.0	[*Squash, winter*] Translated from winter squash data.
Strawberry	8	1	
Sunflower, seed (POST-H)	8	Revoke	Not supported under reregistration
Sweet potato, roots	1	0.1	[*Sweet potato*] Translated from potato data.
Tangerine	8	4.0	Translated from orange data.
Tomato	8	2.0	

Commodity	Tolerance Listed Under 40 CFR §180.111	Reassessed Tolerance[1]	Comment [*correct commodity definition*]
Trefoil, birdsfoot, forage	135	125	[trefoil, forage] Translate alfalfa and clover data
Trefoil, birdsfoot, hay	135	185	[trefoil, forage] Translate alfalfa and clover data
Turnip (including tops)	8	4.0	[*Turnip, tops*]
		0.5	[*Turnip, roots*]
Vegetables, Brassica, leafy, group 5	8	8.0	[*Brassica (cole) leafy vegetables group*]
Vegetables, leafy (except *Brassica*)	8	TBD[2]	[V*egetables, leafy, except Brassica group 4*] Further data required on representative commodity, celery.
Vetch, hay	135	185	Based on alfalfa data
Vetch, seed	8	Revoke	Not a RAC of vetch
Vetch, straw	135	Revoke	Not a RAC of vetch
Walnut	8	0.2	[*Walnut*]
Wheat, grain, postharvest	8	8	[*Wheat, grain (PRE- and POST-H)*]
Tolerance To Be Proposed Under 40 CFR §180.111 (a)(1)			
Apple, wet pomace	None	TBD[2]	Level will be determined when RAC tolerance reassessed. Further data are required on RAC.
Barley, hay	None	TBD[2]	Translate from wheat hay data when adequate data have been reviewed.
Barley, straw	None	50	Translated from wheat straw data.
Citrus, pulp, dried	None	20	
Citrus, oil	None	400	
Corn, field, stover	None	30.0	
Corn, sweet, stover	None	TBD[2]	Sweet corn stover data are required.
Corn, flour	None	14.0	
Corn, meal	None	14.0	
Cotton, gin byproducts	None	TBD[2]	Cotton gin byproducts data required.
Fig, dried	None	2.0	
Grain, aspirated, grain fractions	None	700	Based on postharvest treated corn grain; the highest value measured in aspirated grain fractions.
Lespedeza, forage	None	125	Translated from alfalfa and clover data.
Oats, forage	None	4.0	Translated from wheat forage data.
Oat, hay	None	TBD[2]	Translate from wheat hay data when adequate data reviewed.
Oat, straw	None	50	Translated from wheat straw data.
Pineapple, process residue	None	0.40	
Peppermint, oil	None	15.0	
Radish, tops	None	4.0	Translated from turnip tops data
Rice, hulls	None	150	
Rice, straw	None	60	
Rye, forage	None	4.0	Translated from wheat forage data.

Commodity	Tolerance Listed Under 40 CFR §180.111	Reassessed Tolerance[1]	Comment [*correct commodity definition*]
Rye, straw	None	50	Translated from wheat straw data.
Sorghum, grain, stover	None	TBD[2]	
Spearmint, oil	None	15.0	
Vetch, forage	None	125	Translated from alfalfa and clover data
Watercress	None	0.2	
Wheat, forage	None	4.0	
Wheat, hay	None	TBD[2]	Field trial data are required for wheat hay.
Wheat, straw	None	50	
Tolerances Listed Under 40 CFR §180.111 (a)(2)			
Raisins	12	Revoke	Not supported under reregistration
Tolerances Listed Under 40 CFR §180.111 (a)(3)			
Safflower, refined oil	0.6	Revoke	Not supported under reregistration
Tolerances Listed Under 40 CFR §180.111 (a)(4)			
Raisins	exempt	Revoke	Not supported under reregistration
Tolerances Listed Under 40 CFR §180. 111 (a)(5)			
Dehydrated citrus pulp [post-H]	50	Revoke	Not supported under reregistration
Non-medicated cattle feed concentrate blocks.	10	Revoke	Not supported under reregistration

[1]: The reassessed tolerance levels are contingent upon the recommended label revisions outlined in the *Residue Chemistry Chapter for the Malathion Reregistration Eligibility Decision (RED) Document*, (April 14, 1999)

[2]: TBD = To be determined

Codex Harmonization

The Codex Aliment Arius Commission has established several maximum residue limits (Marls) for residues of malathion in/on various raw agricultural and processed commodities. The Codex MRLs are expressed in terms of malathion *per se*. Reassessed U.S. tolerances include both residues of malathion and the metabolite malaoxon. A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 26.

Table 26: Codex MRLs and Applicable U.S. Tolerances for Malathion.

Codex			**Reassessed U.S. Tolerance, ppm**
Commodity, As Defined	**MRL (mg/kg)**	**Step**	
Apple	2.0	CXL	TBD[1]

Codex			Reassessed U.S. Tolerance, ppm
Commodity, As Defined	**MRL (mg/kg)**	**Step**	
Beans, (dry)	8.0 Po[2]	CXL	2.0
Blackberries	8.0	CXL	6.0
Blueberries	0.5	CXL	8.0
Broccoli	5.0	CXL	8.0
Cabbages, Head	8.0	CXL	8.0
Cauliflower	0.5	CXL	8.0
Celery	1.0	CXL	TBD
Cereal grains	8.0 Po [2]	CXL	Corn (field), sorghum, barley, oats, rye, and wheat grains = 8.0 (POST-H)
Chard	0.5	CXL	TBD
Cherries	6.0	CXL	3.0
Citrus fruits	4.0	CXL	4.0
Common bean (pods and/or immature seeds)	2.0	CXL	2.0
Dried fruits	8.0	CXL	--
Egg plant	0.5	CXL	2.0
Endive	8.0	CXL	TBD
Grapes	8.0	CXL	4.0
Kale	3.0	CXL	TBD
Kohlrabi	0.5	CXL	TBD
Lentil (dry)	8.0	CXL	Revoke
Lettuce, Head	8.0	CXL	TBD
Nuts (whole in shell)	8.0	CXL	--
Peach	6.0	CXL	6.0
Pear	0.5	CXL	3.0
Peas (pods and succulent=immature seeds)	0.5	CXL	2.0
Peppers	0.5	CXL	0.5
Plums (including prunes)	6.0	CXL	Revoke
Raspberries, Red, Black	8.0	CXL	6
Root and tuber vegetables	0.5 [3]	CXL	Potato, Sweet potato, beet, garden, roots; carrots; horseradish; parsnip; radish; rutabaga; and turnip = 0.1
Rye bran, Unprocessed	20.0 PoP [4]	CXL	--
Rye flour	2.0 PoP [4]	CXL	--
Rye wholemeal	2.0 PoP [4]	CXL	--
Spinach	8.0	CXL	TBD

Codex			Reassessed U.S. Tolerance, ppm
Commodity, As Defined	MRL (mg/kg)	Step	
Strawberry	1.0	CXL	1.0
Tomato	3.0	CXL	2.0
Turnip, Garden	3.0	CXL	4 tops 0.5 roots
Wheat bran, Unprocessed	20.0 PoP [4]	CXL	--
Wheat flour	2.0 PoP [4]	CXL	--
Wheat wholemeal	2.0 PoP [4]	CXL	--

[1] TBD = To be determined; residue data remain outstanding.
[2] Po = Postharvest treatment of the commodity.
[3] (Except Turnip, Garden)
[4] PoP = Postharvest treatment of the primary food crop.

E. Regulatory Rationale

The following is a summary of the rationale for mitigation measures necessary for managing risks associated with the use of malathion for malathion products to be eligible for reregistration. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V.

1. Human Health Risk Management

a. Acute and Chronic Dietary (Food Only) Mitigation

The estimated acute and chronic dietary risks from malathion, and malaoxon in food alone, are less than 100% of both the aPAD, and the cPAD and, therefore, are below the Agency's LOC. Acute dietary exposure to malathion and malaoxon in food at the 99.9th percentile is 5% of the aPAD for the general U.S. population, and 11% of the aPAD for all infants (<1 yr old), the most highly exposed population subgroup. The chronic dietary (food) exposure to malathion and malaoxon is less than 1% of the cPAD for all population subgroups. No mitigation is required to address either acute or chronic dietary risks from food alone.

b. Residential Risk Mitigation

<u>Residential Handlers and Post-Application</u>

Estimated dermal and inhalation risks for homeowners handling malathion products are below the Agency's LOC for all handling scenarios. The combined (dermal and inhalation) MOEs for all scenarios assessed are greater than 100 (ranging from 250 to 13000).

For all post-application scenarios, estimated dermal and inhalation MOEs for adults and toddlers are all greater than 100 (ranging from 270 to 7800) and, therefore, do not exceed the Agency's LOC.

The total combined MOEs for all assessed residential handler and post-application scenarios assumed to potentially occur the same day are all greater than 100 (ranging from 260 to 670) and, therefore, do not exceed the Agency's LOC. No mitigation is necessary to address residential handler or post-application risks.

Residential Bystander – Malathion Only

Public Health Mosquito Control. Combined inhalation and dermal short-term risk estimates for adults (MOEs ranging from 22,000 to 74,000), and combined dermal, inhalation and incidental oral risk estimates for toddlers (ARIs ranging from 9-20) from post-application exposure to malathion following public health mosquito treatment with malathion do not exceed the Agency's LOC. Therefore, no mitigation is necessary.

Boll Weevil Eradication Program. Combined risks from post-application dermal contact, inhalation and incidental ingestion of malathion residues in areas nearby fields being treated for boll weevil with the predominant application rate do not exceed the Agency's LOC for adults (MOE = 3000) or toddlers (ARI = 1.3); therefore, no mitigation is necessary.

Fruit Fly Eradication Treatment. Adult risk from combined dermal and inhalation exposure following aerial fruit fly treatment does not exceed the Agency's LOC (MOE = 5500). Likewise, combined exposure to toddlers from dermal, inhalation and incidental oral routes results in a risk that does not exceed the Agency's LOC (ARI =1.7); therefore, no mitigation is necessary.

Residential Bystander – Combined Residues of Malathion and Malaoxon

Post-application exposures of toddlers to combined residues of malathion and malaoxon on hard surfaces following public health mosquitocide, boll weevil eradication treatment, and fruit fly treatment have been estimated. Risks from individual routes of exposure (dermal and incidental oral) were combined using an aggregate risk index (ARI) and are not of concern to the Agency; therefore, no mitigation measures are necessary.

At the maximum 10% malaoxon conversion rate, the estimated ARI from the maximum use rate (1.2 lb ai/A) for malathion in the BWEP is above the LOC (ARI = 0.8); however, the estimated exposures at the predominantly used typical rate (0.9 lb ai/A) resulted in an ARI = 1, which is below the Agency's LOC. All other assessed malaoxon conversion scenarios at the maximum application rate resulted in ARIs that were also below the Agency's LOC. Information provided by the USDA/APHIS boll weevil eradication program managers indicate that the maximum use rate (1.2 lbs ai/A) is used on less than 1% of the acreage currently in the

active phase of the program. Recognizing that such a small percentage of acres may actually receive a malathion treatment at the maximum BWEP rate, the likelihood of playground equipment and/or decks being found within the estimated drift distance used in the assessment (75 feet) from a field edge is negligible. Furthermore, the BWEP is a time limited program and is expected to be largely completed by 2009, with each interim year seeing a substantial reduction in the overall number of cotton acres being treated with malathion.

c. Acute Aggregate Risk Mitigation

To estimate acute aggregate (food + drinking water) risk from malathion, EPA combined peak EDWCs, which included predicted concentrations of malaoxon, with food residues and consumption data, and compared this to the acute aPAD. The Agency assessed 16 separate screening-level model scenarios (PRZM-EXAMS) to evaluate acute aggregate risk for the 100+ agricultural use sites for which malathion is registered. When EPA estimated acute aggregate risks based on current maximum supported application values, many risks were above the Agency's LOC (see Table 10). However, when mitigated application values are used in conjunction with refinements to the drinking water model, the EDWCs are substantially reduced, and all acute aggregate risk estimates are below the Agency's LOC (<100% of the aPAD) for all population subgroups, including the highest exposed population subgroup, all infants.

The mitigated application values used to reduce peak EDWCs and, thus, acute aggregate risks below the Agency's LOC represent either a lower maximum application rate (lb ai/A), and/or a reduced number of applications per year. These values were developed in cooperation with users and growers, Regional Integrated Pest Management (IPM) Centers, USDA, and the technical registrant. Therefore, the Agency does not believe the mitigated application values, when implemented, will have an adverse impact on users. Tables 27 and 28 below summarize the mitigated application rates (lbs ai/A) and maximum number of applications per year for non-ULV and ULV applications, respectively, which will be required on all malathion product labels. Tables 27 and 28 lists only those sites where application values have changed from the currently supported maximum application values.

For several reasons the Agency believes that even the acute aggregate risk estimates, based on mitigated application values and refined inputs, do not underestimate risk, since several assumptions associated with the EDWC may overestimate potential residues in drinking water. First, the Agency has assumed that 100% of the predicted concentration value at the "edge of the field" reaches the POTW. However, monitoring data indicates that concentrations of malathion are likely to decrease as distance from the application site increases. Second, based on laboratory data and monitoring data, the Agency assumed 100% conversion of malathion to malaoxon during the water treatment process. However, the Agency lacks data on the conversion of malathion to malaoxon under varying treatment processes, or under different water qualities and, therefore, while the assumption of 100% conversion to malaoxon clearly is a reasonable upper bound estimate, the Agency lacks the data with which to establish a lower bound rate of conversion. Third, the Agency's drinking water model is designed to predict

surface water runoff as if a large portion of an entire watershed is treated with a compound at the same time, and in temporal proximity to a major rainfall event. However, multiple-year data indicates that malathion is used on a relatively small percent of almost all crops (< 5%), thereby reducing the probability of large "spikes" of malathion residues in drinking water. Finally, because acute comparative ChEI data remains outstanding, some uncertainty regarding the malaoxon TAF (61x) also remains. Upon receipt of the required comparative ChEI data, the Agency will review the malaoxon TAF, and the associated dietary (food + drinking water) risks if necessary.

Table 27: Current and Amended Agricultural Use Patterns for Non-ULV Applications

Crop	Application Values: Max. Appl. Rate (lb ai/A) x Max. No. of Appls. Per Year x Retreatment Interval (Days)	
	Current Maximum Supported Application Values	**Mitigated Application Values**
Apricots	3.75 x 4 x 7	1.5 x 2 x 7
Asparagus	1.25 x 9 x 7	1.25 x 2 x 7
Barley	1.25 x 3 x 7	1.25 x 2 x 7
Beets, garden	1.25 x 5 x 7	1.25 x 3 x 7
Blackberry	2.0 x 4 x 7	2.0 x 3 x 7
Blueberry	1.25 x 4 x 4	1.25 x 3 x 4
Broccoli	1.25 x 5 x 7	1.25 x 1 x 7
Broccoli Chinese	1.25 x 5 x 7	1.25 x 1 x 7
Broccoli raab	1.25 x 5 x 7	1.25 x 1 x 7
Brussels sprouts	1.25 x 4 x 7	1.25 x 1 x 7
Cabbage	1.25 x 10 x 7	1.25 x 6 x 7
Cantaloupe	1.0 x 6 x 7	1.0 x 2 x 7
Carrots	1.25 x 7 x 7	1.25 x 2 x 7
Cauliflower	1.25 x 5 x 7	1.25 x 1 x 7
Chayote fruit	1.88 x 3 x 7	1.75 x 2 x 7
Cherries (sweet)	3.75 x 6 x 7	1.75 x 4 x 3^2
Cherries (tart)	3.75 x 6 x 7	1.75 x 4 x 3^2
Chestnut	5.0 x 4 x 7	2.5 x 3 x 7
Chinese greens (Chinese cabbage)	1.25 x 10 x 7	1.25 x 2 x 7
Collards	1.25 x 10 x 7	1.25 x 3 x 7
Corn, field	1.25 x 3 x 7	1.0 x 2 x 7

Crop	Application Values: Max. Appl. Rate (lb ai/A) x Max. No. of Appls. Per Year x Retreatment Interval (Days)	
	Current Maximum Supported Application Values	**Mitigated Application Values**
Corn, sweet	1.25 x 5 x 5	1.0 x 2 x 5
Cucumber	1.88 x 3 x 7	1.75 x 2 x 7
Dandelion	2 x NS	1.25 x 2 x 7
Dates	4.25 x 6 x 7	4.25 x 5 x 7
Eggplant	3.43 x 5 x 5 1.56 x 5 x 5	1.56 x 4 x 5
Eggplant, oriental	3.43 x 5 x 5 1.56 x 5 x 5	1.56 x 5 x 5
Endive	1.88 x NS x NS	1.25 x 2 x 7
Flax	0.5 x 1	0.5 x 3 x 7[2]
Figs	2.5 x 3 x 5	2.0 x 2 x 5
Garlic	1.56 x 5 x 7	1.56 x 3 x 7
Grapefruit	6.25 x 3 x 30	Rest of US: 4.5 x 1 CA: 7.5 x 1[1]
Horseradish	1.25 x 5 x 7	1.25 x 3 x 7
Kale	1.25 x 10 x 7	1.25 x 3 x 5[2]
Kohlrabi	1.25 x 10 x 7	1.25 x 2 x 7
Kumquats	6.25 x 3 x 30	4.5 x 1 x 30
Leeks	1.56 x 5 x 7	1.56 x 2 x 7
Lemons	6.25 x 3 x 30	FL: 4.5 x 1 CA: 7.5 x 1[1]
Lettuce, head	1.88 x 6 x 6	1.88 x 2 x 6
Lettuce, leaf	1.88 x 6 x 5	1.88 x 2 x 5
Limes	6.25 x 3 x 30	Rest of US: 4.5 x 2 x 30 CA: 7.5 x 1[1]
Loganberry	2.0 x 4 x 7	2.0 x 2 x 7
Macadamia Nut	0.94 x 7 x 7	0.94 x 2 x 7
Melons	1.0 x 6 x 7	1.0 x 2 x 7
Nectarines	3.75 x 4 x 7	3 x 3 x 7
Mustard greens	1.25 x 6 x 7	1.25 x 3 x 5[2]
Oats	1.25 x 3 x 7	1 x 2 x 7
Okra	1.5 x 6 x 7	1.2 x 5 x 7
Onions, bulb	1.56 x 6 x 7	1.56 x 2 x 7

Crop	Application Values: Max. Appl. Rate (lb ai/A) x Max. No. of Appls. Per Year x Retreatment Interval (Days)	
	Current Maximum Supported Application Values	**Mitigated Application Values**
Onion green	1.56 x 6 x 7	1.56 x 2 x 7
Oranges	6.25 x 3 x 30	Rest of US: 4.5 x 1 CA: 7.5 x 1[1]
Papaya	1.25 x 13 x 3	1.25 x 4 x 3
Parsnip	1.25 x 5 x 7	1.25 x 3 x 7
Passion Fruit	1.25 x 8 x 7	1 x 8 x 7
Peaches	3.75 x 5 x 11	3.0 x 3 x 11
Pears	1.25 x 5 x 7	1.25 x 2 x 7
Peas, succulent	2.5 x 5 x 7	1.0 x 2 x 7
Pecans	2.5 x 3 x 7	2.5 x 2 x 7
Peppers	1.56 x 5 x 5	1.56 x 2 x 5
Pineapple	5.0 x 3 x 7	2.0 x 3 x 7
Pumpkin	1.0 x 6 x 7	1.0 x 2 x 7
Radishes	1.25 x 5 x 7	1.25 x 3 x 7
Raspberry	2.0 x 4 x 7	2.0 x 2 x 7
Rice	1.25 x 3 x 7	1.25 x 2 x 7
Rutabagas	1.25 x 5 x 7	1.25 x 3 x 7
Rye	1.25 x 3 x 7	1.0 x 2 x 7
Salsify	1.25 x 5 x 7	1.25 x 3 x 7
Shallots	1.56 x 5 x 7	1.56 x 2 x 7
Spinach	2.0 x 3 x 7	2.0 x 2 x 7
Squash, summer	1.88 x 3 x 7	1.75 x 3 x 7
Squash, winter	1.0 x 6 x 7	1.0 x 3 x 7
Strawberry	2.0 x 6 x 7	2.0 x 4 x 7
Tangelos	6.25 x 3 x 30	Rest of US: 4.5 x 1 CA: 7.5 x 1[1]
Tangerines	6.25 x 3 x 30	Rest of US: 4.5 x 1 CA: 7.5 x 1[1]
Tomatoes	3.43 x 5 x 5 1.56 x 5 x 5	1.56 x 4 x 5
Tomatillo	3.43 x 5 x 5 1.56 x 5 x 5	1.56 x 4 x 5
Turnip, greens, roots	1.25 x 5 x 7	greens: 1.25 x 3 x 5[2] roots: 1.25 x 3 x 7

Crop	Application Values: Max. Appl. Rate (lb ai/A) x Max. No. of Appls. Per Year x Retreatment Interval (Days)	
	Current Maximum Supported Application Values	Mitigated Application Values
Watermelons	1.0 x 6 x 7	1.5 x 4 x 7
Wheat, spring	1.25 x 3 x 7	1.0 x 2 x 7
Wheat, winter	1.25 x 3 x 7	1.0 x 2 x 7
Wild rice	1.25 x 3 x 7	1.25 x 2 x 7

NS: Not specified

[1]: Although the single maximum application rate is increased, the number of applications permitted per year decreased; thus, the overall potential exposure from this use is lower.

[2]: Retreatment intervals were shortened or additional applications are allowed for these uses based on grower comments and are supported by existing field trial data.

Table 28: Current and Amended Agricultural Use Patterns for ULV Applications

Crop	Application Values: Max. Appl. Rate (lb ai/A) x Max. No. of Appls. Per Year x Retreatment Interval (Days)	
	Current Maximum Supported Application Values	Amended Application Values
Barley	0.61 x 3 x 7	0.61 x 2 x 7
Beans, dry, lima	0.61 x 3 x 7	0.61 x 2 x 7
Beans, snap	0.61 x 3 x 7	0.61 x 2 x 7
Blueberry	0.77 x 5 x 10	0.77 x 3 x 10
Cherries, sweet	1.22 x 6 x 7	1.22 x 4 x 7
Corn, field	0.61 x 3 x 7	0.61 x 2 x 7
Corn, sweet	0.61 x 5 x 5	0.61 x 2 x 5
Grapefruit	0.175 x 10 x 7	0.175 x 3 x 7
Kumquats	0.175 x 10 x 7	0.175 x 2 x 7
Lemons	0.175 x 10 x 7	0.175 x 2 x 7
Limes	0.175 x 10 x 7	0.175 x 1 x 7
Lupine	0.61 x 3 x 7	0.61 x 1 x 7
Oats	0.61 x 3 x 7	0.61 x 2 x 7
Oranges	0.175 x 10 x 7	0.175 x 2 x 7
Rice	0.61 x 3 x 7	0.61 x 2 x 7
Rye	0.61 x 3 x 7	0.61 x 1 x 7
Sorghum	0.61 x 3 x 7	0.61 x 2 x 7
Tangelos	0.175 x 10 x 7	0.175 x 2 x 7

Crop	Application Values: Max. Appl. Rate (lb ai/A) x Max. No. of Appls. Per Year x Retreatment Interval (Days)	
	Current Maximum Supported Application Values	Amended Application Values
Tangerines	0.175 x 10 x 7	0.175 x 2 x 7
Wheat, spring	0.61 x 3 x 7	0.61 x 2 x 7
Wheat, winter	0.61 x 3 x 7	0.61 x 2 x 7
Wild rice	0.61 x 3 x 7	0.61 x 2 x 7

d. Chronic Aggregate Risk Mitigation

Chronic aggregate risk for malathion and malaoxon from food and drinking water is below the Agency's LOC for the U.S. general population and all population subgroups. For all drinking water scenarios assessed, including the worst-case aerial CA lettuce scenario with maximum application rates, all chronic aggregate dietary exposure from food and drinking water for the U.S. population and all infants <1 yr, the most highly exposed population subgroup, was <1% of the cPAD. No mitigation is required for chronic aggregate exposures to malathion.

e. Short-Term Aggregate Risk Mitigation

Short-term aggregate risk combines chronic dietary (food + drinking water) exposure with short-term residential exposure. Several malathion uses, such as home fogger, or the wide area treatments, result in short-term residential exposure which could be aggregated with the chronic dietary to estimate short-term aggregate risk. Among the malathion residential exposure scenarios, the Agency believes that aerial application of public health use of malathion represents the most likely and wide spread co-occurring exposure pathway for the general U.S. population. To be conservative, the Agency assessed this scenario at the 10% conversion rate of malathion to malaoxon. For more information regarding the transformation of malathion to malaoxon in the residential exposure and risk analysis, refer to *Malathion: Residential Exposure and Risk Assessment for the Interim Reregistration Eligibility Decision (RED) Document*, dated July 6, 2006.

The Agency aggregated the estimated risks from acute aggregate dietary with the estimated risks from the wide area public health uses of malathion using the Aggregate Risk Index (ARI) method, since the target MOE for oral exposure (hand to mouth, and dietary) differs from that of dermal exposure. When using the ARI method, the Agency considers risks equal to or above 1 to be not of concern. When chronic dietary (food + drinking water) exposure is added to the residential bystander oral and dermal exposure components from the public health use of malathion, the total aggregate ARI is 6. The estimated ARI of 6 is below the Agency's LOC and, therefore, no mitigation is necessary.

While the Agency believes the wide area use of malathion as a public health pesticide is the most reasonable scenario to aggregate for short-term aggregate risk, it is not the most

conservative. Rather, the highest estimated risk to a residential bystander from the Boll Weevil Eradication Program (BWEP). For the BWEP bystander scenario, the Agency estimated risks using the maximum supported application rate of 1.2 lb ai/A, and the typical rate of 0.9 lb ai/A. When the Agency combined chronic aggregate dietary (food + drinking water) with the BWEP bystander scenario, using the maximum supported application rate of 1.2 lb ai/A, the ARI is 0.8 which indicates exposure slightly above the Agency's LOC. However, when the Agency estimated short-term aggregate risk from the BWEP at the typical rate of 0.9 lb ai/A, the ARI is 1, which indicates exposure below the Agency's LOC.

The Agency estimated aggregate short-term risks from the BWEP using the 1.2 lb ai/A, because it is Agency policy to characterize risk using the maximum supported rate. However, based on communications with USDA/APHIS, which sponsors the BWEP, the Agency believes that the typical application rate of 0.9 lb ai/A is predominantly used and, therefore, the appropriate rate at which to asses potential residential risk from the BWEP. USDA/APHIS provided information which characterized the 0.9 lb ai/A rate (or lower) as the predominant rate used in the BWEP, as it provides the optimum combination of efficacy, and cost effectiveness. The 1.2 lb ai/A rate was mainly used prior to 1997, and is currently maintained by the BWEP for select situations, such as finishing up the active phase of the program in a certain area with the objective of preventing boll weevil survival into another season. On an annual basis, the 1.2 lb ai/A rate is used on less than 1% of the active program acreage. Therefore, the Agency has a high degree of confidence that short-term aggregate exposures, using the wide area BWEP exposure scenario, are below the Agency's LOC, and no mitigation is necessary.

While the short-term aggregate risk incorporating the BWEP is below the Agency's LOC, the Agency has taken steps to strengthen malathion product labeling for the BWEP. The Agency has worked with the technical registrant and USDA to develop spray drift label language for the BWEP. The additional label language will assist program operators to convey more information on application requirements and potentially reduce spray drift (see Table 30 in Section V).

f. Occupational Risk Mitigation

A wide range of factors is considered in making risk management decisions for worker risks. These factors include, in addition to the estimated MOEs, incident data, the nature and severity of adverse effects observed in the animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other factors. Mitigation measures may include reducing application rates, adding personal protective equipment (PPE) to end-product labels, requiring the use of engineering controls, extending the post-application re-entry period, and other measures.

<u>Handler Risk Mitigation</u>

Occupational handler (mixers, loaders and applicators) exposure assessments are completed by the Agency considering the use of baseline PPE and, if warranted, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The combined dermal and inhalation target MOE for malathion is 100. When estimated MOEs for handler risk are less than 100, EPA strives to reduce worker risks through the use of PPE and engineering controls or other mitigation measures. In some cases, the Agency may accept MOEs less than 100 when all mitigation measures that are feasible and practical have been applied, particularly when there are critical pest management needs associated with the use of the pesticide.

To address handler risks of concern, the Agency is requiring the following PPE and/or engineering controls be specified on product labels for formulations and use patterns of malathion, in addition to the use pattern changes identified in Tables 27 and 28, to be eligible for reregistration. Following the implementation of these formulation specific and activity specific risk mitigation measures, handler risks for malathion will no longer be of concern to the Agency.

- For all malathion formulations and use patterns, flaggers and applicators using motorized ground equipment are required to wear baseline PPE (long-sleeved shirt, long pants, and shoes);
- For all malathion formulations and use patterns—except those identified below—baseline PPE plus chemical-resistant gloves are required for mixers and loaders;
- Closed mixing/loading systems are required for all ULV applications and mixers and loaders are required to wear baseline PPE, chemical-resistant gloves, and chemical-resistant apron;
- All wettable powder (WP) formulations must be packaged in water soluble packaging;
- Mixers, loaders and applicators of dust (D) formulations are required to wear coveralls over long-sleeve shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator;
- For all dip applications, mixers, loaders and applicators are required to wear baseline PPE plus chemical-resistant gloves, and chemical-resistant apron;
- For all airblast applications applicators are required to wear baseline PPE, chemical-resistant gloves, and chemical-resistant hat; and
- Enclosed cockpits are required for all aerial applications.

Two formulation specific scenarios assessed lacked data in PHED for evaluation: loading/applying dusts with a power duster to treat dates and stored grain, and mixing/loading and applying dips.

Loading and Applying Dusts

The Agency used surrogate data for WP formulations for handlers loading dust formulations in mechanical dusters for use on stored grain and dates, but has no data available for assessing individuals who apply or load/apply dusts. A published study, "Malathion

Deposition, Metabolite Clearance, and Cholinesterase Status of Date Dusters and Harvesters in California," (2000) authored by Krieger and Dinoff. *Arch. Environ. Contam. Toxicol*. Volume 38, Pages 546-553, was submitted by the USDA for consideration in this malathion assessment. The study reports estimated daily exposure doses of from 0.4 - 1.0 mg malathion/kg/day (i.e., MOEs ranged from 130 to 3200, if the total dose is attributed to dermal exposure) for handlers who load/operate power dusters to treat dates with malathion 5% dust. Workers in this study were already wearing coveralls over baseline attire, gloves and dust/mist respirators. It is not expected that engineering controls would be feasible to the operator of the power-duster. Thus, dust formulations are eligible for reregistration provided handlers wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator. No additional data will be required by the Agency for this scenario.

Mixing/Loading and Applying Dips

Exposure data is not available to assess potential occupational risks associated with mixing, loading and applying dip applications. Currently the dip application method is only registered for use on grape roots. The Agency believes the same individual typically mixes, loads and applies the dip to the grape roots rather than multiple workers being involved in the operation. The Agency believes that based on the risk estimates for occupational handlers using the liquid formulation of malathion for agricultural crop uses, which involve much higher volume of product, baseline PPE and chemical-resistant gloves will be adequately protective for all dip applications as well. However, to reduce additional exposure that may result from potential splashing of product onto the individual during the dip application, the Agency is also requiring chemical-resistant aprons to be worn. Therefore, for dip applications to be eligible for reregistration, handlers must wear baseline PPE, chemical-resistant gloves and chemical-resistant aprons. No additional data will be required by the Agency for this scenario.

Post-Application Risk Mitigation

Based on the post-application scenarios assessed, the number of days estimated to reach the target MOE following applications of malathion exceed the current label REI of 12 hours established under the Worker Protection Standard for some uses. Considering refinements to the risk assessment, including the use pattern changes identified in Tables 27 and 28**,** the Agency has determined that extension of some REIs is needed in order to mitigate risks to workers entering previously treated areas to conduct various activities.

Generally, occupational post-application risks to workers were not a concern (MOEs >100) by 24 hours after treatment for the vast majority of malathion use sites, based on the mitigated use rates and other refinements to the assessment. In general, when application rates were 4.5 lb ai/A and higher, the REI needed to achieve risks that are not a concern increased to two or three days (24 to 72 hours after treatment), depending on the application rate associated with the crop and the transfer coefficient associated with the post-application activity. For two tasks with very high transfer coefficients (detasseling/hand harvesting corn with a TC of 17,000

cm^2/hr and girdling/cane turning grapes with a TC of 10,000 cm^2/hr), the REI needed to achieve risks that are not of concern is three days even though the application rates are 2.0 lb ai/acre or less.

The Agency, through its regulatory partner, USDA, Office of Pest Management Policy, contacted land grant universities, regional IPM centers, and grower groups to obtain additional information about malathion use patterns and post-application worker activities and maximum feasible REIs. The goal of this exercise was to determine when high contact, high exposure, and high risk activities were performed relative to malathion application and to collect other information about malathion use that might factor into the regulatory decision on REIs for this RED. Based on information provided through this effort, the Agency is confident the extended REIs necessary to avoid risks of concern will not adversely impact malathion users. Table 29 lists those crops and specific activities (where appropriate) which require REIs of 24 hours or greater. All other use sites eligible for reregistration not listed in these tables are required to have a 12 hour REI. Following the implementation of these REIs, post-application risks for malathion will no longer be of concern to the Agency

Table 29. Use Sites Which Require REIs Longer than 12 Hours

Use Sites that Require a 24 Hour REI		
Carrot	Horseradish	Pineapple
Celery	Kale	Radish
Chayote (root, fruit)	Kohlrabi	Rutabaga
Chestnut	Leeks	Salsify
Chinese greens	Lettuce (head, leaf)	Shallots
Collards	Mustard greens	Spinach
Cucumber	Nectarines	Summer squash
Dandelion	Parsley	Swiss chard
Endive	Parsnip	Turnips
Figs	Peach	Walnuts
Garlic	Pecan	Yams
Use Sites that Require a Two Day (48 hour) REI		
Avocado	Cabbage	Dates
Broccoli	Cauliflower	Kumquats (if not w/ citrus)
Broccoli raab	Chinese broccoli	
Brussels sprouts	Citrus crops @ 4.5 lb ai/A	
Use Sites that Require a Three Day (72 hour) REI		
Citrus crops @ 7.5 lb ai/A	Corn (field, seed, sweet, and pop) detasseling and hand harvesting only[1]	Grapes (table, wine, raisin) girdling and cane turning only[1]

[1] All other reentry activities for corn and grapes require a 12 hour REI

2. Non-Target Organism (Ecological) Risk Management

a. Terrestrial Organisms

Birds and Mammals

EPA's screening-level ecological assessment resulted in estimated acute risks to birds and mammals which only slightly exceeded the Agency's LOC. The highest acute and chronic RQ for avain species was associated with malathion use on chestnut (0.75 and 18, respectively), and the highest acute and chronic RQs for mammals was associated with malathion use on citrus (3.6 and 3, respectively). RQ estimates were based on maximum concentrations of pesticide residues on animal feed items from multiple applications, and reflect maximum number of applications and maximum labeled use rates for malathion.

However, through comments and feedback from the user community, and communication with USDA and the technical registrant, EPA has received agreement to reduce the maximum application use and number of applications for numerous agricultural uses (see Tables 27 and 28 for summary of amended use rates). Reductions to the use patterns (lbs ai/A and the maximum number of applications) will significantly reduce potential malathion residues on food and feed items through which non-target terrestrial organisms are exposed to malathion. The Agency expects that while the acute and chronic RQs to both avian and mammalian species will be greatly reduced when reduced application rates are used, the estimated RQs may not fall entirely below the Agency's LOC.

In addition, instructions are to be added to the malathion product labels to reduce the potential for off target spray drift; thus reducing the potential exposure to non-target terrestrial organisms. Specific label language aimed at reducing off target drift is contained in Table 30.

Non-Target Plants and Non-Target Insects

As stated above, since the mode of action for malathion is well defined (effects nervous system), and the Agency has no reports of adverse effects to plants, the Agency has no risk concerns and is not proposing any mitigation measures for exposure to non-target plants.

The Agency has classified malathion as highly toxic to bees; therefore, a precautionary statement is required on malathion product labels to limit the exposure to honeybees and other beneficial insects during applications of malathion (see Table 30).

b. Aquatic Organisms

Agricultural Uses

As stated above, numerous reductions to application rates are to be implemented for malathion; however, the majority of changes to be made to malathion labels are for reducing the maximum number of applications per year. Revised exposure assessments indicate that reducing the number of applications may have a greater impact on reducing potential exposure to non-target aquatic organisms than a reduction in the application rate. Moreover, a reduction in the number of applications not only reduces potential accumulation of malathion that may be transported in surface run-off, but also reduces occurrences of off-target drift.

To further reduce potential exposure to both non-target fish and aquatic invertebrates, the technical registrant has agreed to add instructions to product labels to reduce potential off-target drift to aquatic areas, including requirements for a 25 foot buffer zone along aquatic areas for all non-ULV aerial applications, and a 50 foot buffer zone along aquatic areas for all ULV aerial agricultural applications. These buffer zones were determined by considering typical application speed, boom width, and a representative application rate (see Table 23) and are considered to be protective of the most sensitive freshwater fish species (bluegill sunfish). By imposing language on product labels to reduce off-target drift and the use of buffer zones, potential exposure to non-target invertebrates is further reduced.

In addition, since the toxicological response between freshwater fish and estuarine fish is similar, the Agency expects that the risk reduction being realized for non-target freshwater organisms will also be seen for non-target estuarine organisms.

Aquatic Risks

Aquatic toxicity data indicates that on an acute basis malathion is classified as highly toxic to non-target aquatic invertebrates, and very highly toxic to non-target fish. EPA conducted a Tier II risk assessment using PRZM-EXAMS modeling on several crops to represent the 100+ agricultural crops for which malathion is registered. For the several agricultural crop scenarios modeled, the Agency estimated RQs based on both maximum application values (lbs ai/A, and maximum number of applications) as well as typical application values, which better reflect actual field application practices and will be required on product labels (see Tables 27 and 28). When assessed with maximum application values, most scenarios resulted in RQs above the Agency's LOC. However, the Agency expects that acute and chronic RQs to aquatic organisms will be greatly reduced, with RQs for some scenarios being below the Agency's LOC, when reduced application rates are assessed.

Estimated acute RQs for non-target fish, using maximum application values for commercial agricultural sites ranged from 0.5 - 5.4, with the highest RQ based on applications to citrus. When typical application values were used, the range of estimated acute RQs for non-target fish was from 0.09 - 1.57. Acute RQs for invertebrates were also estimated using both maximum and typical application values. Estimated acute RQs for invertebrates, based on maximum application values ranged from 15 - 162, and when typical application values were used, RQs ranged from 3 - 47, again with the highest RQ based on application to citrus.

Based on maximum application rates, estimated chronic RQs for non-target fish ranged from 0.09 - 0.5; however, when typical application values were used, chronic RQs ranged from 0.01 - 0.12. Estimated chronic RQs for invertebrates ranged from 83 - 416 when maximum application values were used, and ranged from 8.3 - 121 when typical application values were used.

Public Health Uses

The Agency conducted a screening-level ecological assessment for the wide area uses of malathion including public health, fruit fly, and BWEP uses. For public health uses, the Agency estimated that the acute RQ for freshwater fish is 38, and the acute RQ for invertebrates is 1.9. However, when the Agency estimated these RQs, it assumed 100% deposition into a six foot deep pond, which may overestimate potential exposure since modeling information indicates that some applied material remains aloft and disperses to such a degree, it does not reach the target site. In addition, the current maximum application rate for public health adulticide is 0.23 lb ai/A, which is approximately three times less than the rate assessed in EPA's screening-level assessment of 2000. Further, comments received during the Phase 5 public comment period indicate that mosquito control officials typically use rates lower than the current maximum of 0.23 lb ai/A. Therefore, while the Agency did not revise non-target RQs to reflect more appropriate application rates, the Agency believes that risks to non-target aquatic organisms from adult adulticide applications will be lower than those reflected above. However, while the estimated RQs associated with the public health use of malathion are be lower than 38 and 1.9, respectively, for fish and invertebrates, some level of risk to non-target aquatic organisms from this use likely remain.

Malathion, like other adult mosquitocide products, was the subject of PR Notice 2005-1 which aimed to improve current adult mosquitocide labeling to reduce ecological risks and improve the handling and use of these products. In addition, the Agency has required additional measures be added to labels for public health mosquito abatement to further reduce potential bystander and ecological exposure. These measures, listed below, are being required of other public health mosquito abatement products as well.

- Specify droplet size for aerial and ground applications (see Table 30 for details);
- Specify minimum release height of 100 ft for planes, and 75 feet for helicopter;
- Specify wind speed for applications; and
- Specify use pattern by setting a single maximum application, and yearly maximum application rate. (However, public health labels also permit more frequent applications to be made to prevent or control a threat to public and/or animal health under certain conditions.)

Wide Area Fruit Fly Treatment

Based on a screening-level analysis of the fruit fly treatment use, estimated acute RQs were very low (< 0.00001) and, therefore, below the Agency's LOC. While chronic RQs were not calculated, the Agency believes them to be similarly low and below the Agency's LOC. Therefore no mitigation action is required for this use.

Boll Weevil Eradication Program

Based on maximum application rates, the estimated acute RQs for the BWEP were 9.7 for non-target fish and 291 for non-target invertebrates. Estimated chronic RQs ranged from 2.3 for fish to 1123 for invertebrates. For several reasons, the Agency believes that these estimates are overestimated. First, estimated RQs were based on maximum application values (2.5 lb ai/A applied 25 times per year). Currently, the maximum application rate is 1.2 lb ai/A, and the predominantly used typical rate is 0.9 lb ai/A (>99% of treated acreage). Also, based on communications with USDA/APHIS far fewer applications are typically made in a year. Secondly, while the BWEP is an eradication program and, therefore, cannot support buffer zones, it does however require operators to identify natural water bodies as "sensitive areas," and make efforts to protect sensitive areas from off-target drift. For example, operators are advised to use ground applications to treat the edge of a field when sensitive areas are adjacent to application sites.

In addition, the Agency also recognizes that the BWEP is a time limited program, with a goal of completing the eradication phase by 2009. After such time, the use of malation through BWEP will be greatly reduced, and so to will potential exposure to non-target organisms. Reduction to potential exposure is also realized through the BWEP as the National Cotton Council estimates that areas where the boll weevil has been eradicated via the BWEP have realized a 40% – 90% reduction in insecticide use on cotton, which is in part because of the reduction in the use of malathion. For additional information on the direct and indirect benefits of the BWEP, see section section IV.E.3, Benefits of Malathion to Users.

Urban Uses

One of the risk assessment goals of the Agency is to estimate pesticide exposure through all significant routes of exposure from both agricultural and non-crop uses. However, the ecological risk assessment for malathion pesticides focuses primarily on the agricultural and wide area uses, because pesticide transport models are available to estimate potential aquatic exposure from these uses. Based on laboratory toxicity tests with aquatic animals, aquatic exposure could cause adverse effects in the environment.

Malathion is used for a number of non-crop pesticidal uses, including use as a garden insecticide and as a building perimeter treatment. As described earlier, malathion is used as a wide-area spray as a mosquito adulticide and by prescription for head-lice control.

The ecological risk assessment evaluates the head-lice control use with the "down-the-drain" model E-FAST 2.0. In these simulations, wastewater containing malathion flows from buildings in which it is used and passes through sanitary sewers and publicly owned treatment works (POTW) before being discharged to surface water. The E-FAST model uses the total national production of a pesticide and distributes it among all households in the nation. The amount of malathion produced for this use was estimated at 100 kg. The assessment uses a malathion removal efficiency at the POTW of 3%, which was estimated using the model EPISuite.

Predicted concentrations from E-FAST indicate that the head-lice control use should not pose a risk to fish and invertebrates. An acute EEC of 3.55×10^{-5} ppb was estimated based on a high-end stream dilution factor (i.e., upper 10^{th} percentile), and a chronic EEC of 2.73×10^{-6} ppb was estimated based on a median stream dilution factor (i.e., 50^{th} percentile). These EECs result in acute and chronic RQs several orders-of-magnitude below the acute, chronic and endangered species LOCs.

For outdoor urban uses, the Agency assumes that runoff water from rain and/or lawn and garden watering may transport pesticides to storm sewers and then directly to surface water. Although malathion use on lawns is not supported, it can be used on ornamentals plants, including fruit trees, and gardens. Malathion transported by runoff or erosion in an urban setting would take a path not only over lawns, but also impervious surfaces such as walkways, driveways and streets. The Agency is unaware of any model which can simulate the different application methods for urban use and the physical representation of the urban landscape, storm sewer and receiving water configuration.

There are models available which can be calibrated to simulate sites and pesticides for which extensive flow and pollutant data have been collected in advance. The HSPF/NPSM model, for instance, which is included in the EPA's BASINS shell, has been used to calibrate stream flow and malathion pesticide use data to simulate loading of these pesticides consistent with concentrations measured in surface water monitoring. Risk assessors with the California Department of Environmental Protection confirmed in conversations with the Agency that they also have used watershed models to calibrate previously collected flow and pesticide monitoring data, but that they did not know of any models capable of predicting concentrations of pesticides that might occur because of outdoor urban uses.

Development of a screening model which could simulate the fate and transport of pesticides applied in an urban setting would require a large body of data which is currently unavailable. For instance, an urban landscape cannot be simulated as easily as an agricultural field. The PRZM model simulates runoff from an agricultural field using readily available data describing surface soil characteristics and laboratory data detailing the persistence and mobility of pesticides in these soils. The agricultural field simulated is homogenously planted to a single crop, and soil and water are transported from the field to a receiving water body with dimensions consistent with USDA farm-pond construction guidelines.

By contrast, an urban landscape or suburban housing development consists of impervious surfaces such as streets and sidewalks, and pervious surfaces such as lawns and parkland. One could expect much greater mobility for pesticides applied to impervious surfaces, but laboratory soil metabolism studies may not provide an accurate measure of the persistence of pesticides on these surfaces. The path runoff water and eroded sediment might take is less obvious for an urban setting than an agricultural field. First, an urban landscape cannot be considered homogeneous, as the proportion of impervious and pervious surfaces varies for different locations. In addition, the flow path of runoff water and sediment is not necessarily a direct path over land, but can pass below ground through storm sewer networks, be directed, or slowed by pumping stations or temporary holding ponds. Finally, the timing and magnitude of urban uses is less well defined for urban uses than agricultural uses. While agricultural uses would occur within a predictable window during the growing season, urban uses of malathion, either from home owner or from different wide area uses may the occur at different times each year, and might occur at different times within the same watershed.

The apparent difficulties in accurately characterizing surface water contamination via urban pesticide use also make it difficult to develop an urban pesticide transport model as well as identify meaningful mitigation at this time. The next opportunity to assess malathion will be through the new Registration Review program, which is expected to begin in 2007. The purpose of Registration Review is to ensure the periodic review of all pesticides to make sure they continue to meet current scientific and regulatory requirements, with the goal of reviewing each pesticide every fifteen years. The Agency expects to begin malathion within the first several years of the Registration Review. During the interim, several actions are planned which should improve the Agency's ability to assess the level of aquatic exposure to pesticides from urban use. First, research is currently underway which is aimed at defining the conditions of urban pesticide use that may lead to greater transport. While this research is being conducted on pyrethroids, it may be applicable to malathion as well. In addition, further investigation into the dominant urban uses and application practices of malathion, as well as other pesticides, may help contribute to understanding the contribution malathion may have as a contaminant in urban runoff. Finally, the Agency will also continue in its efforts to develop a screening-level model for urban pesticide uses. Advances in the resolution of GIS databases may allow better representation of the impervious and pervious portions of a typical urban landscape. As information regarding urban pesticide use and transport becomes clearer, the conceptual model of how urban transport should be simulated will also become clearer.

Runoff from urban uses of malathion are likely to occur from either outdoor residential uses (home garden, or home perimeter), or from wide area treatments such as the public health use, or fruit fly (quarantine) uses. While it is possible that the residential use of malathion contributes to urban runoff, wide area applications are likely to result in greater deposition on impervious surfaces, such as roof tops, roads, and driveways and, therefore, lead to larger concentrations of malathion in urban runoff. While the wide area uses of malathion may be a larger contributor to

urban runoff compared to the home garden uses, the benefits of the wide area uses are significant.

3. Benefits of Malathion to Users

FIFRA provides for the Agency to consider the economic, societal, and environmental costs and benefits of pesticidal use when weighing the risks associated with occupational (handler and post-application) and ecological exposures. The mitigation measures required for malathion are based on EPA's review of comments received; direct consultation with other federal departments, knowledgeable experts, and growers; close evaluation of malathion's use patterns and user pest management needs; refinements to the risk assessments where appropriate; and other information available to the Agency.

Based on Agency data, approximately 15 million pounds of malathion active ingredient are used annually in the US. A large percent of that use, almost 70%, is used on cotton as part of the USDA Boll Weevil Eradication Program. The program, which began in the late 1970s, has been the largest consumer of malathion for the past decade or so. In 2006, less than 3,000,000 acres (or approx. 20% of the US cotton acreage) remain in the active eradication phase, with 12,000,000 acres now considered weevil-free and in the post-eradication phase. The program is expected to be largely complete by 2009 with essentially 100% of US cotton acreage to be weevil-free and in the post-eradication phase. Malathion use will decline dramatically as the remaining acres in the active eradication phase of the program are declared weevil-free.

According to the National Cotton Council, in the Southeast, where the weevil has been eradicated, the combined annual direct economic benefits from increased yields, reduced insect damage and lower insect control costs are more than $80 million. Additionally, the Council estimates that by eradicating the boll weevil from the remaining infested areas, cotton growers in those states will see annual insect control costs reduced by $30 per acre and yield increases of more than 10%. Eradicated areas have realized a 40% to 90% reduction in insecticide use on cotton, which in large part is because of the reduction in the use of malathion (http://www.cotton.org/tech/pest/bollweevil/index.cfm).

For the remainder of malathion uses, two of the most frequently identified reasons it is used is its low cost when compared to alternatives and the broad spectrum of pests controlled. Further, for some use sites, malathion is perhaps the only insecticide registered, or one of only a few. According to comments received from various stakeholders, the broad spectrum of pests that malathion targets makes its use highly beneficial since the agricultural industry has been losing a number of insecticides, and the newer insecticides replacing them have chemistries that target specific insects and are narrow in their spectrum. Additionally, malathion is registered for use on over 100 crops, most of which are classified as minor crops (grown on <300,000 acres), while many of the alternative pest control options are registered on fewer crops.

Risks were identified for malathion which exceeded the Agency's LOC for certain terrestrial and aquatic organisms. With the reductions in malathion use rates and number of

applications allowed per year to such a large percentage of the crop uses, combined with spray drift buffers, the Agency believes, on balance, that the benefits of malathion outweigh remaining terrestrial and aquatic organism risks. Therefore, malathion-containing products are eligible for reregistration, provided the risk mitigation measures are adopted and labels are amended accordingly.

4. Isomalathion

Isomalathion is a known impurity present as a component of malathion during the manufacturing process. The current upper certified limit of isomalathion in the technical product is 0.2% by weight. Data submitted by the technical registrant indicate that the presence of isomalathion, as a percent of the product, increases when malathion is stored under high temperatures, for long periods of time, or a combination of these two variables. Current guideline data indicate that malathion is stable for one year, at 25^0C (77^0 F) and under these conditions, the percent of isomalathion remains below the certified limit. The current storage statement recommends against product storage in temperatures above 25^0C (77^0 F). In 2004, the EPA's Office of Enforcement and Compliance Monitoring collected and analyzed product samples collected from two primary Cheminova distribution centers and found that all samples were within certified limits. However, since malathion is used in numerous markets on a national basis, storage conditions are likely to vary greatly once products leave the distribution center, and depend upon the type of product, and state or region where the product is ultimately used.

The Agency has limited toxicity data on either isomalthion alone or products containing elevated levels of isomalathion. The limited data suggests that isomalathion increases the toxicity of malathion. It is assumed, however, that the current toxicological data base on malathion reflects the presence of isomalathion up to the certified limit.

To better understand the presence and effect of isomalathion in malathion products, the Agency is requiring data and/or information to characterize the storage conditions and general life cycle of malathion products. In addition, the technical registrant has agreed to submit to the Agency existing data on the formation of isomalathion as well as a 2-year storage stability study, currently being conducted by the technical registrant to fulfill a FAO/WHO requirement. The Agency is currently reviewing a battery of acute toxicity data submitted by the technical registrant on malathion spiked with 0.4% isomalathion. Pending its review of the acute toxicity data, the Agency may require additional toxicity data on isomalathion, if necessary.

The technical registrant has also agreed to add to malathion product labels an amended storage stability statement. The amended storage statement differs from the current statement by advising against storing malathion products for long periods of time and in conditions where the temperatures are in excess of 25^0C (77^0 F).

5. Summary of Mitigation Measures

The following mitigation measures are necessary for malathion products to be eligible for reregistration:

- Reduce maximum use patterns for a large number of agricultural crops (see Tables 27 and 28):
    - 4 crop uses require reduced maximum application rates only,
    - 69 crop uses require reduced maximum allowed number of applications per year only, and
    - 29 crop uses require both reduced maximum application rates and maximum number of applications allowed per year;
- For all malathion formulations and use patterns, flaggers and applicators using motorized ground equipment are required to wear baseline PPE (long-sleeved shirt, long pants, and shoes);
- For all malathion formulations and use patterns—except those identified below—baseline PPE plus chemical-resistant gloves are required for mixers and loaders;
- Closed mixing/loading systems are required for all ULV applications and mixers and loaders are required to wear baseline PPE, chemical-resistant gloves, and chemical-resistant apron;
- All wettable powder (WP) formulations must be packaged in water soluble packaging;
- Mixers, loaders and applicators of dust (D) formulations are required to wear coveralls over long-sleeve shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator;
- For all dip applications, mixers, loaders and applicators are required to wear baseline PPE plus chemical-resistant gloves, and chemical-resistant apron;
- For all airblast applications applicators are required to wear baseline PPE, chemical-resistant gloves, and chemical-resistant hat;
- Enclosed cockpits are required for all aerial applications;
- REIs are extended for 46 agricultural crops (although most are 12-24 hours) (see Table 29);
- Buffer zones of 25 feet for all non-ULV applications and 50 feet for all ULV agricultural applications are required for aerial applications along all water bodies;
- Spray drift management language specific to BWEP and non-BWEP product labels are to be added; and
- An amended storage stability statement is to be added to product labels advising against storing malathion products for long periods of time and in conditions where the temperatures are in excess of 25^0C (77^0 F).

Unsupported Use Sites

The following use sites have not been included in the revised risk assessments. The Agency received and published a request from the technical registrants to delete the following uses from malathion product labels (FRL-3874-4, p. 11420). Following the publication announcing the request for use deletion, the Agency subsequently received comments indicating that the uses listed below would not be supported by any interested party. Therefore, the following uses must be removed from all end-use product labels.

- stored commodity treatment for almonds
- field or garden seeds
- feed rooms
- manure piles
- rabbits on wire
- human clothing (woolens and other fabrics)
- mattresses
- commercial and industrial uses for bagged flour
- cereal processing plants
- edible and inedible commercial establishments
- edible and inedible eating establishments
- edible and inedible food processing plants
- packaged cereals
- pet foods and feed stuff
- dairies/cheese processing plant equipment (food contact)
- forest trees (including Douglas fir, eastern pine, hemlock, larch, pines, red pine, spruce, and true fir)
- cattle feed concentrate blocks (non-medicated)
- cats
- dogs
- all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating)
- animal premise and barns used for dairy and livestock
- tobacco
- stables and pens
- poultry houses
- animal kennels/sleeping quarters (commercial)
- cattle feedlots and holding pens

In addition, the following use sites/formulations have been requested for deletion by the technical registrant in a letter to the Agency dated July 25, 2006. The Agency intends to announce this request in the Federal Register in the near future.

- apples
- commercial shipping containers –feed/food- empty
- commercial storages/ warehouses premises
- commercial transportation facilities –feed/food –empty
- commercial transportation facilities –nonfeed/nonfood
- commercial/institutional/industrial premises/equipment (outdoor)
- commercial/institutional/industrial premises/equipment (indoor)
- golf course turf
- greenhouse –empty
- greenhouse –in use
- lentils
- quince
- residential lawns (broadcast)
- sewage systems
- residential pressurized can formulations
- residential dust formulations

F. Other Labeling Requirements

To be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing malathion. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

1. Endangered Species Considerations

At this time, the Agency is not requiring label changes specific to the protection of listed species for malathion. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program. While RQs exceeded the Agency's endangered species LOC for several taxa (see Section III), these results were based on a screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act.

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 (ESA) 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 that may affect any particular species, EPA uses basic toxicity and exposure data developed for

the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of malathion; other measures to mitigate any potential impact; or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines that use of malathion "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to malathion at levels of concern. EPA is not requiring specific malathion label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, EPA will continue to work with all interested parties on this important issue.

From its assessment of malathion, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for malathion, including requirements for medium to coarse droplet size, not applying when wind velocity exceeds 15 mph or into areas of temperature inversions, and other measures. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 30) in Section V of this RED document. In the future, malathion product labels may need to be revised to include additional or different drift label statements.

In addition to generic spray drift management language to the malathion label, the Agency has required, and the technical registrant has agreed to include on non-BWEP malathion product labels the requirement of buffer zones along all water bodies of 25 feet for all non-ULV applications and a 50 feet for all ULV agricultural applications.

Finally, the Agency has worked with UDSA/APHIS to develop spray drift management language specific to the BWEP, including specifications on droplet size, wind velocity, boom length, and other measures, for inclusion on the malathion label. The full list of spray drift measures for the BWEP are listed in Table 30.

V. What Registrants Need to Do

The Agency has determined that malathion is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section C below. In the near future, the Agency intends to issue Data Call-In (DCI) Notices requiring label amendments, product-specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for malathion to be eligible for reregistration.

A. Manufacturing-Use Products

1. Generic Data Requirements

The generic data base supporting the reregistration of malathion has been reviewed and determined to be substantially complete. However, the Agency has identified data necessary to confirm the reregistration eligibility decision for malathion. These studies are listed below and will be included in the generic DCI for this RED, which the Agency intends to issue at a future date.

Guideline No.	Study Title
870.7800	Immunotoxicity study with malathion
835.4300	Aerobic aquatic metabolism with malathion
835.4300	Aerobic aquatic metabolism with malaoxon
Special study:	Conversion of malathion to malaoxon on hard dry surfaces
81-8-SS	Comparative ChE study with malathion and malaoxon (previously required 10/2004)
860.1500	Field crop trials (various crops where data are necessary to support the established tolerance)

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MP labeling should bear the labeling contained in Table 30.

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. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific product-specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 30. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific 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.

C. Labeling Changes Summary Table

For malathion to be eligible for reregistration, all malathion labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 30 describes specific label amendments.

Table 30 Labeling Changes Summary

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 30: Summary of Labeling Changes for Malathion		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an insecticide **or *miticide*** for the following use(s): [fill blank only with those uses that are being supported by MP registrants]." "This product can not be formulated into end-use products formulated as a dust with directions for use in residential settings." "This product can not be formulated into end-use products that are formulated as a pressurized (i.e., aerosol) can." This product can **NOT** be formulated into end-use products that contain directions for use on: • all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating) • animal kennels/sleeping quarters (commercial) • animal premise and barns used for dairy and livestock • stables and pens • poultry houses • animal kennels/sleeping quarters • cattle feedlots and holding pens • feed rooms • cattle feed concentrate blocks (non-medicated) • dogs and cats • pet food and pet stuffs • cereal processing plants • packaged cereals • commercial and industrial uses for bagged flour • commercial shipping containers –feed/food- empty • commercial storages/ warehouses premises	Directions for Use

	• commercial transportation facilities –feed/food –empty • commercial transportation facilities –nonfeed/nonfood • commercial/institutional/industrial premises/equipment (indoor) • commercial/institutional/industrial premises/equipment (outdoor) • dairies/cheese processing plant equipment (food contact) • edible and inedible commercial establishments • edible and inedible eating establishments • edible and inedible food processing plants • field or garden seeds • forest trees • rabbits on wire • golf course turf • greenhouse – empty, or in-use • human clothing (woolens and other fabrics) • manure piles • mattresses • quince • residential lawns (broadcast) • sewage systems • lentils • tobacco	
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 MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards	"This pesticide is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."	Precautionary Statements immediately following the User Safety Recommendations
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
Personal Protective Equipment		

PPE Requirements Established by the RED[1] for **liquid concentrate and wettable powder end-use products** *Note: all wettable powder products must be in water soluble packets to be eligible for reregistration.* Note: if the end-use product does not contain directions for use as a dip, the statement referring to dip applications may be eliminated. Note: if the end-use product does not contain directions for use permitting application with aerial or motorized ground equipment, the exception to the glove statement may be removed.	"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." "For all formulations and all use patterns – mixers, and loaders, applicators, flaggers, and other handlers must wear: • Long sleeved shirt and long pants, shoes plus socks, (referred to as "*baseline PPE"*) For all formulations and all use patterns – mixers and loaders must wear: • Baseline PPE and, • Chemical resistant gloves. For all formulations being applied using either aerial or motorized ground equipment – flaggers and applicators must wear: • Baseline PPE; and, • Chemical resistant gloves such as *(registrant insert correct chemical-resistant materials).* For all ULV formulations, applications must be Closed Systems – mixers and loaders must wear: • Baseline PPE, and, • Chemical resistant gloves; and, • Chemical resistant apron For all dip applications – mixers, loaders, and applicators must wear: • Baseline PPE; and, • Chemical resistant gloves; and, • Chemical resistant apron. For all airblast applications – applicators must wear: • Baseline PPE; and, • Chemical resistant gloves; and, • Chemical resistant headgear." "All ULV formulations must be packaged in closed mixing and loading systems." "All wettable powders (WP) formulations must be packaged in water soluble packaging." "See engineering controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

PPE Requirements Established by the RED[1] for **dust end-use products.** Note: if the end-use product does not have directions permitting use in power duster equipment, the statements related to persons participating in power duster applications may be removed.	"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." "For all dust formulations – mixers, loaders, and applicators must wear: • Coveralls over baseline PPE; and, • Chemical resistant gloves such as (*registrant insert correct chemical-resistant materials)*; and, • A NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter" and, • Chemical-resistant headgear (if overheat exposure is expected)" "All other loaders, applicators, and other handlers must wear: • Baseline PPE; and, • Chemical resistant gloves, such as (*registrant insert correct chemical-resistant materials)* when loading."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for **ready-to-use liquid products**	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H]* on an EPA chemical-resistance category selection chart." For all ready-to-use liquid products; applicators, and other handlers must wear: • Baseline PPE	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
Engineering Controls		
Engineering Controls for **liquid concentrate end-use products** which may	"Engineering Controls" "Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural	Precautionary Statements: Hazards to Humans and Domestic Animals

be aerially applied.	Pesticides [40 CFR170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators."	(Immediately following PPE and User Safety Requirements.)
Engineering Controls for **wettable powders packaged in water-soluble packets.** *All wettable powders must be in water soluble packets to be eligible for reregistration.*	"Engineering Controls" "Water soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4). Mixers and loaders using water soluble packets must: ➢ wear the personal protective equipment required on this labeling for mixers and loaders, and ➢ be provided, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: ➢ chemical resistant footwear and ➢ NIOSH-approved respirator equipped with -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter." "Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazard Statement	"This pesticide is toxic to aquatic organisms, including fish and invertebrates." "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate." "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff after application. Use care when applying in or to an area which is adjacent to any body of water, and do not apply when weather conditions favor drift from target area. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. "	Environmental Hazards

	"A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours." *Environmental Hazards for Wide Area Mosquito Adulticide Applications* "When applying as a wide area mosquito adulticide, before making the first application in a season, it is advisable to consult with the state or tribal agency charged with primary responsibility for pesticide regulation to determine if other regulatory requirements exist." "This product is toxic to bees. Do not apply this product while bees are actively visiting a treatment area." "When applying as a wide area mosquito adulticide, do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body."	
Restricted-Entry Interval (for labels with WPS uses)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). " "Required REIs are listed with each crop."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the RED (for labels with WPS uses)	"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, ➢ shoes plus socks, and ➢ chemical-resistant gloves made of any waterproof material."	Place in the Directions for Use In Agricultural Use Requirements box, immediately following the REI
Entry Restriction for Non-WPS uses	***Entry Restriction for non-WPS uses applied as a spray:*** "Do not enter or allow others to enter until sprays have dried." ***Entry Restriction for non-WPS uses applied dry:***	If no WPS uses on the label, place the statements in the Directions for Use Under General Precautions and Restrictions.

	"Do not enter or allow others to enter until dusts have settled."	If WPS uses are also on the labeling, place these statements in a NonAgricultural Use Requirements box as specified in PR Notice 93-7 and 93-11.
General Application Restrictions (for labels with WPS uses)	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	**All Products/Formulations Containing Malathion** Delete all directions for use for the following use-patterns: • all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating) • animal kennels/sleeping quarters (commercial) • animal premise and barns used for dairy and livestock • stables and pens • poultry houses • animal kennels/sleeping quarters • cattle feedlots and holding pens • feed rooms • cattle feed concentrate blocks (non-medicated) • dogs and cats • pet food and pet stuffs • cereal processing plants • packaged cereals • commercial and industrial uses for bagged flour • commercial shipping containers –feed/food- empty • commercial storages/ warehouses premises • commercial transportation facilities –feed/food –empty • commercial transportation facilities –nonfeed/nonfood • commercial/institutional/industrial premises/equipment (indoor) • commercial/institutional/industrial premises/equipment (outdoor) • dairies/cheese processing plant equipment (food contact) • edible and inedible commercial establishments • edible and inedible eating establishments • edible and inedible food processing plants	Directions for Use

	• field or garden seeds • forest trees • rabbits on wire • golf course turf • greenhouse – empty, or in-use • human clothing (woolens and other fabrics) • manure piles • mattresses • quince • residential lawns (broadcast) • sewage systems • lentils • tobacco • All uses at residential sites – for dust formulations only	
Buffer Zones	**"Buffer Zones for Aerial Application** When making a Non-ULV application with aerial application equipment, a minimum buffer zone of 25 feet must be maintained along any water body. When making a ULV application with aerial application equipment, a minimum buffer zone of 50 feet must be maintained along any water body."	In the Directions for Use section in a section titles: "Buffer Zones for Aerial Application"
Storage and Disposal	"*Product Name Here* should be stored in the original unopened container in a secure, dry place." "Do not contaminate with other pesticides or fertilizers. The product should never be heated above 55^0 C (131^0 F), and should not be stored for long periods of time at a temperature in excess of 25^0 C (77^0 F)."	In the Storage and Disposal section of the labeling
Products with use instruction for use as a Wide Area Mosquito Adulticide	Note: All product labels must be amended to reflect requirements and recommendations specified in Pesticide Registration Notice 2005-1. The following statements must also be added. "Do not apply more than 0.23 lb ai/A/day. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne diseases in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort."	Directions for Use under General Precautions and Restrictions

	"Apply when wind speed is greater than or equal to 1 mph." "Do not apply by fixed wing aircraft at height less than 100 feet, or by helicopter at a height less than 75 feet unless specifically approved by the state or tribe based on public health needs." "Aerial Application: Spray equipment must be adjusted so that the median diameter product is less than 60 microns (Dv 0.5 < 60 um) and that 90% of the spray is contained in droplets smaller than 80 (Dv 0.9< 80 um). The effect of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated." "Ground-based application: Spray equipment must be adjusted so that the volume median diameter is less than 30 microns (Dv 0.5 < 30 um), and that 90% of the spray is contained in droplets smaller than 50 microns (Dv 0.9 < 50 um). Directions from the equipment manufacturer or vendor, pesticide registrant or test facility using a laser-based measurement instrument must be used to adjust equipment to product acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated."	
Spray Drift	Observe the following requirements when spraying in the vicinity of aquatic areas such as lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries and commercial fish ponds. "Use the largest droplet size consistent with acceptable efficacy. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure." "For groundboom and aerial applications, use only medium or coarser spray nozzles according to ASAE (S572) definition for standard nozzles, or a volume mean diameter (VMD) of 300 microns or greater for spinning atomizer nozzles. Aerial applicators must consider flight speed and nozzle orientation in determining droplet size." "Make aerial or ground applications when the wind velocity favors on target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 15 mph. Avoid applications when wind gusts approach 15 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application." "Do not make aerial or ground applications into areas of temperature inversions. Inversions are	

	characterized by stable air and increasing temperatures with increasing distance above the ground. Mist or fog may indicate the presence of an inversion in humid areas. Where permissible by local regulations, the applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface." "Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of increased spray drift to aquatic areas. Avoid spraying during conditions of low humidity and/or high temperatures." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind." "For aerial applications, the spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used and must not exceed 75% of wing span or 90% rotor diameter." "Spray should be released at the lowest height consistent with pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided. For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy."	
Specific Application Restrictions for Use on Cotton to Control Boll Weevil	**ULV Malathion Label Regarding Applications Made for Boll Weevil Eradication** "Treatment supervisors and applicators must be aware of all sensitive areas near cotton fields, including: schools, hospitals, nursing homes, churches, occupied dwellings, parks, recreation areas, bodies of water, and potential habitat for threatened and endangered species." "For aerial applications, spray equipment must be adjusted so that the volume median diameter is 100 microns (Dv 0.5 = 100um) or greater. The effects of flight speed, nozzle angle and type, and pump pressure on the droplet size spectrum must be considered." "For aerial applications, the spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used and outermost nozzles must not be placed beyond 75% of the wingspan or rotor diameter." "Spray should be released at the lowest height consistent with pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided."	Directions for Use associated with the specific crop or use-site.

	"Global positioning systems (GPS) should be used to guide pilots and to monitor each application." "Ground equipment should utilize a controlled air flow to facilitate particle size and spray deposition, and should be used at a vehicle speed of 4 to 10 mph. Spray equipment must be adjusted so that the volume median diameter is 100 microns (Dv 0.5 = 100um) or greater." "Ground equipment should be used to treat field edges when possible, covering areas that can not be treated effectively with aircraft because of obstructions which may affect applicator safety, or where there is boll weevil over-wintering habitat adjacent to the treatment area, or if there are adjacent sensitive areas." "Do not apply when wind velocity exceeds 10 mph. Treatments should be applied when winds are calm, or moving away from adjacent sensitive areas." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind." "Do not make aerial or ground applications into temperature inversions. Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface." "Applications will not be made when people are in or near infested cotton fields or, to the degree possible, when people are present in or near adjacent sensitive areas." "Application will not be made when rainfall is imminent. "Before beginning treatment, program personnel shall notify all registered apiarists in or near the treatment area of the date and approximate time of treatment."	

Specific Application Restrictions (Note: The maximum allowable rate per crop per application or per year must be listed as pounds or gallons of formulated product per acre, not solely as pounds active ingredient per acre.)	Alfalfa: the Restricted-Entry Interval (REI) is 12 hours. Apricot: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Asparagus: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Avocado: The Restricted-Entry Interval (REI) is 48 hours. The maximum application rate is 4.7 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 30 days. Barley: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Beans (dry, lima, and snap): The Restricted-Entry Interval (REI) is 12 hours. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Beets (including tops): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Blackberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Blueberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.77 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 10 days. Boysenberry: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 2.0	Directions for Use associated with the specific crop or use-site

	pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7days. Broccoli: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Broccoli raab: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Brussels sprouts: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Cabbage: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Cabbage, Chinese: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Cantaloupe: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Carrots, roots: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Cauliflower: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 1; and the minimum retreatment interval is 7 days. Celery: The Restricted-Entry Interval (REI) is 24 hours. The maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7days. Chayote fruit and roots: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the	

	maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Cherry (sweet): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.75 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 3 days. For ULV applications: the maximum application rate is 1.22 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Cherry (tart): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.75 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 3 days. For ULV applications: the maximum application rate is 1.22 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Chestnut: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.5 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Chinese Broccoli: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 1; and the minimum retreatment interval is 7 days. Chinese Greens (Chinese Cabbage): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Citrus (grapefruit, lemon, lime, orange, tangerine, and tangelo): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is in California, EITHER 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1; OR 1.5 pounds active ingredient per acre; and the maximum number of applications per year is 3, and the minimum retreatment interval is 30 days. In all other states, EITHER 4.5 pounds active ingredient per acre; with a maximum number of applications per year is 1; OR 1.5 pounds active ingredient per acre; and the maximum number of applications per year is 3, and the minimum retreatment interval is 30 days. Collards: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days.	

	Corn (field): The Restricted-Entry Interval (REI) is 72 hours for detasseling, and 12 hours for all other activities. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Corn (sweet, pop): The Restricted-Entry Interval (REI) is 72 hours for detasseling, and 12 hours for all other activities. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 5 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 5 days. Cucumber: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.75 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Currant: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 1 pounds active ingredient per acre; the maximum number of applications per year is 1. Dandelion: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Dates: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.25 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 7 days. Dewberry: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7 days. Eggplant: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 5 days. Eggplant (Oriental): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 5 days.	

	Endive: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Fig: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 5 days. Flax: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 0.5 pounds active ingredient per acre; the maximum number of applications per year is 32; and the minimum retreatment interval is 7 days. Garlic: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Gooseberry: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7days. Grapefruit (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Grapefruit (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Grapes: The Restricted-Entry Interval (REI) is 72 hours for girdling and tying, and 24 hours for all other activities. The maximum application rate is 1.88 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 14 days. Horseradish: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days.	

	Kale: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 5 days. Kohlrabi: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Kumquat: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Leeks: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Lemon (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Lemons (Florida only): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Lespedeza: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Lettuce, head: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.88 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 6 days. Lettuce, leaf: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.88 pounds active ingredient per acre; the maximum number of applications per year	

	is 2; and the minimum retreatment interval is 5 days. Limes (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Limes (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 30 days. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Loganberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Lupine, seed: The Restricted-Entry Interval (REI) is 12 hours. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 1. Macadamia Nut: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 0.94 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Mushrooms: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 1.7 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 3 days. Mustard greens: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 5 days. Nectarines: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 3.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Oats: For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For	

	ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Okra: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.2 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 7 days. Onions (bulb and green): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Oranges (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Oranges (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Papaya: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 3 days. Parsley: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Parsnip: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Passion fruit: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 8; and the minimum retreatment interval is 7 days. Peach: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum	

	application rate is 3.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 11 days. Pears: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Peas (succulent): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Pecans: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Peppers: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 5 days. Pineapple: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Pumpkin: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Radish: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Raspberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Rice: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days.	

	Rutabagas: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Rye: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.00 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 1 Salsify (including tops): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Shallots: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Sorghum: The Restricted-Entry Interval (REI) is 12 hours. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Spinach: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Squash, summer: The Restricted-Entry Interval (REI) is 24 hours. . For Non-ULV applications: the maximum application rate is 1.750 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Squash, winter: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Strawberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7 days. Swiss Chard: The Restricted-Entry Interval (REI) is 24 hours. The maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum	

	retreatment interval is 7 days. Tangerine (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tangerine (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tangelos (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tangelos (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tomatoes: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 5 days. Tomatilloes: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 5 days. Trefoil, birdsfoot: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 14 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 14 days.	

	Turnip (greens): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 5 days. Turnip (roots): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Vegetables, leafy, Brassica (Cole) are listed above, and include: broccoli, Chinese broccoli, broccoli raab; Brussels sprouts; cabbage; Chinese cabbage; cauliflower; collards; kale; and mustard greens. Vegetables, leafy (except Brassica) are listed above and include: celery; dandelion; endive; lettuce (head, and leaf). Parsley: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Spinach: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Swiss chard: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Walnut: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.5 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Watermelon: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7 days. Wheat (spring and summer): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days.	

	Wild Rice: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Yams: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days.	
End Use Products Intended Primarily for Use by Homeowners		
Environmental Hazards	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate." "Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to organisms in neighboring areas."	Precautionary Statements
Application Restrictions	**All products:** "Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions Statements must be in the color red and in all caps.
Entry Restrictions	**Products Applied as a Liquid:** "Do not allow people or pets to enter the treated area until sprays have dried." When applied as a fogger, do not enter treated area until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated	Directions for Use under General Precautions and Restrictions
Other Application Restrictions (Risk Mitigation)	**All Products/Formulations Containing Malathion** Delete all directions for use for the following use-patterns: • all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating)	Directions for Use

	• animal kennels/sleeping quarters (commercial) • animal premise and barns used for dairy and livestock • stables and pens • poultry houses • animal kennels/sleeping quarters • cattle feedlots and holding pens • feed rooms • cattle feed concentrate blocks (non-medicated) • dogs and cats • pet food and pest stuffs • cereal processing plants • packaged cereals • commercial and industrial uses for bagged flour • commercial shipping containers –feed/food- empty • commercial storages/ warehouses premises • commercial transportation facilities –feed/food –empty • commercial transportation facilities –nonfeed/nonfood • commercial/institutional/industrial premises/equipment (indoor) • commercial/institutional/industrial premises/equipment (outdoor) • dairies/cheese processing plant equipment (food contact) • edible and inedible commercial establishments • edible and inedible eating establishments • edible and inedible food processing plants • field or garden seeds • forest trees • rabbits on wire • golf course turf • greenhouse – empty, or in-use • human clothing (woolens and other fabrics) • manure piles • mattresses • quince • residential lawns (broadcast) • sewage systems • lentils • tobacco	

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

[2] The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil.

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.

Appendix A
List of Malathion Use Sites and Application Rates

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
Alfalfa	Foliar Ground/aerial		1.25	2 per cutting	14	0	12 hr
Apricot	Foliar Ground		1.5	2	7	6	12 hrs
Asparagus	Foliar Ground/aerial		1.25	2	7	1	12 hrs
Avocado	Foliar ground		4.7	2	30	7	2 days
Barley	Foliar Ground/aerial	Non-ULV	1.25	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	7	
Beans, dry, snap, Lima	Foliar Aerial	ULV only	0.61	2	7	1	12 hrs
Beets, garden	Foliar Ground		1.25	3	7	7	12 hrs
Blueberry (high bush and low bush)	Foliar Ground	Non ULV	1.25	3	7	1	12 hrs
		ULV/RTU	0.77	3	10	1	12 hrs
Broccoli, Chinese Broccoli, Broccoli rabb	Foliar Ground/aerial		1.25	1	7	2	2 days
Brussels sprouts	Foliar Ground/aerial		1.25	1	7	2	2 days
Cabbage	Foliar		1.25	6	7	7	2 days

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Cantaloupe	Foliar Ground/aerial		1.0	2	7	1	12 hrs
Caneberries (blackberry, boysenberry, dewberry, loganberry, raspberry)	Foliar ground		2.0	3	7	1	12 hrs
Carrots	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Cucumber	Foliar Ground/aerial		1.75	2	7	1	24 hrs
Cauliflower	Foliar Ground/aerial		1.25	1	7	2	2 days
Celery	Foliar Ground/aerial		1.5	2	7	7	24 hrs
Cherries, sweet	Foliar Ground/ Aerial	Non-ULV	1.75	4	3	3	12 hrs
		ULV/RTU	1.22	4	7	1	
Cherries, tart	Foliar Ground/ Aerial	Non-ULV	1.75	4	3		12 hrs
		ULV/RTU	1.22	6	7	1	
Citrus Fruits (grapefruit, lemon, lime, organge, tangerine, tangelo)	Foliar Ground/ aerial	Non-ULV	**All states other than CA:** 4.5 or 1.5	1 3	NA 30	7	3 days
			~~CA only:~~				

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
			7.5 or 1.5	1 3	NA 30		
		ULV/ RTU	0.175	3	7	7	12 hrs
Clover	Foliar Ground/ aerial	Non-ULV	1.25	2 per cutting	14	0	12 hrs
		ULV/RTU	0.61	2 per cutting	14	0	
Collards	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Corn, field	Foliar Ground/ aerial	Non-ULV	1.0	2	7	7	3 days for detasseling 12 hrs for all other activites
		ULV/RTU	0.61	2	7	7	
Corn, sweet, and pop	Foliar Ground/ aerial	Non-ULV	1.0	2	5	5	3 days for detasseling 12 hrs for all other activities
		ULV/RTU	0.61	2	5	5	
Chayote fruit	Foliar Ground/aerial		1.75	2	7	1	24 hrs
Chayote root	Foliar Ground		1.56	2	7	0	24 hrs
Chestnut	Foliar Ground		2.5	3	7	2	24 hrs
Chinese greens (Chinese cabbage)	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Clover	Foliar		1.25	2 per cutting	14	0	12 hrs

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Cotton (non boll weevil treatment use)	Foliar Ground/aerial	Non-ULV	2.5	3	7	7	2 days
		ULV/RTU	1.22	3	7	7	
Currant	Foliar Ground/aerial		1.25	3	7	1	12 hrs
Dandelion	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Dates	Dust		4.25	5	7	21	2 days
Eggplant	Foliar Ground/aerial		1.56	4	5	3	12 hrs
Eggplant, oriental	Foliar Ground/aerial		1.56	5	5	3	12 hrs
Endive (escarole)	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Fig	Foliar Ground		2.0	2	5	5	24 hrs
Flax	Foliar Ground		0.5	3	7	52	12 hrs
Garlic	Foliar Ground/aerial		1.56	3	7	3	24 hrs
Grains, stored (barley, corn, oats, rye, wheat)	Surface treatment		Loading: 0.624 lb ai/1000 bushels Storage: 0.312 lb ai/100 bushels	3 per storage period	60	NA	12 hrs
Grapes, raisin, table, wine	Foliar Ground Root dip		1.88	2	14	3	3 days for girdling and tying; 24 hrs for all other

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
							activities
Grass, forage, hay	Foliar Ground/aerial		1.25	1	NA	0	12 hrs
Grasses, Bermuda,	Foliar Ground/ aerial	Non-ULV	1.25	1 per cutting	NA	0	12 hrs
		ULV/RTU	0.92				
Guava	Foliar Ground		1.25	13	3	2	12 hrs
Hops	Foliar Ground/aerial		0.63	3	7	10	12 hrs
Horseradish	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Kale	Foliar Ground/aerial		1.25	3	5	7	24 hrs
Kohlrabi	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Kumquats	Foliar Ground	Non-ULV	4.5	1	30	7	2 days
		ULV/RTU	0.175	2	7	1	12 hrs
Leeks	Foliar Ground/aerial		1.56	2	7	3	24 hrs
Lespedeza	Foliar Ground/ aerial	Non-ULV	1.25	2 per cutting	14	0	12 hrs
		ULV/RTU	0.61				
Lettuce, head	Foliar Ground/aerial		1.88	2	6	14	24 hrs
Lettuce, leaf	Foliar Ground/aerial		1.88	2	5	14	24 hrs
Lupine	Foliar Ground/	ULV only	0.61	1	NA	1	12 hrs

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Aerial						
Turnips	Foliar Ground/aerial		1.25	3	5 day for turnip greens 7 day for turnip root	7	24 hrs
Macadamia nut	Foliar Ground		0.94	2	7	1	12 hrs
Mango	Foliar Ground		1.25	8	7	1	12 hrs
Melons (other than watermelon)	Foliar Ground/aerial		1.0	2	7	1	12 hrs
Mint	Foliar Ground/aerial		0.94	3	7	7	12 hrs
Mushrooms	Foliar		1.7	4	3	1	12 hrs
Mustard greens	Foliar Ground/aerial		1.25	3	5	7	24 hrs
Nectarines	Foliar Ground		3.0	3	7	7	24 hrs
Oats	Foliar Ground/ aerial	Non-ULV	1.0	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	7	12 hrs
Okra	Foliar Ground/aerial		1.2	5	7	1	12 hrs
Onions, bulb, and green	Foliar Ground/aerial		1.56	2	7	3	12 hrs
Papaya	Foliar Ground		1.25	4	3	1	12 hrs
Parsley	Foliar		1.5	2	7	2	24 hrs

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Parsnip	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Passion fruit	Foliar Ground		1.0	8	7	3	12 hrs
Pasture and rangeland	Foliar Ground/ aerial	ULV only	0.9375	2	7	1	12
Peaches	Foliar Ground		3.0	3	11	7	24 hrs
Pears	Foliar Ground		1.25	2	7	1	12 hrs
Peas, dried	Foliar Ground		1.0	2	7	3	12 hrs
Peas, green	Foliar Ground/aerial		1.0	2	7	3	12 hrs
Pecans	Foliar Ground		2.5	2	7	7	24 hrs
Peppers	Foliar Ground/aerial		1.56	2	5	3	12 hrs
Pineapple	Foliar Ground		2.0	3	7	7	24 hrs
Potatoes	Foliar Ground/aerial		1.56	2	7	0	12 hrs
Pumpkins	Foliar Ground/aerial		1.0	2	7	1	12 hrs
Radish	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Rutabagas	Foliar		1.25	3	7	7	24 hrs

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Rice	Foliar Ground/ aerial	Non-ULV	1.25	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	14	
Rye	Foliar Ground/ Aerial	Non-ULV	1.0	3	7	7	12 hrs
		ULV/RTU	0.61	1	NA	7	
Salsify	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Shallot	Foliar Ground/aerial		1.56	2	7	3	24 hrs
Sorghum	Foliar Ground/ aerial	ULV only	0.61	2	7	7	12 hrs
Spinach	Foliar Ground/aerial		2.0	2	7	7	24 hrs
Squash, summer	Foliar Ground/aerial		1.75	3	7	1	24 hrs
Squash, winter	Foliar Ground/aerial		1.0	3	7	1	12 hrs
Strawberry	Foliar Ground/aerial		2.0	4	7	3	12 hrs
Sweet potatoes	Foliar Ground/aerial		1.56	2	7	0	12 hrs
Swiss chard	Foliar Ground/aerial		1.5	2	7	14	24 hrs
Tomatoes, Tomatilloes	Foliar Ground/aerial		1.56	4	5	1	12 hrs
Vetch	Foliar Ground/ aerial	Non-ULV	1.56	5	14	3	12 hrs
		ULV/RTU	0.61	2 per cutting	14	0	

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
Walnuts	Foliar Ground		2.5	3	7	7	24 hrs
Watercress	Foliar Ground/aerial		1.25	5	3	3	24 hrs
Watermelons	Foliar Ground		1.5	4	7	1	12 hrs
Wheat, spring and winter	Foliar Ground/ aerial	Non-ULV	1.0	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	7	12 hrs
Wild Rice	Foliar Ground/ aerial	Non-ULV	1.25	2	7	7	24 hrs
		ULV/RTU	0.61	2	7	14	12 hrs
Yams	Foliar Ground/aerial		1.56	2	7	0	24 hrs

Non-Agricultural Use Sites				
Site	Form	Maximum Single Application Rate	Unit	Use Pattern Limitations
Agricultural, uncultivated areas	Non-ULV	1.0	Lb ai/A	
	ULV	0.1875		
Christmas tree plantations	Non-ULV	3.2	Lb ai/A	Maximum of 2 applications per year. 12 hr restricted reentry interval
	ULV	0.9375		
Cull piles	Non-ULV	6.857	Lb/1000 ft^2	Drench
Drainage systems	Non-ULV	0.625	Lb/2.5 gal	
Fence rows/hedge rows	Non-ULV	0.2439	Lb/1000 ft^2	
Grain/cereal/flour bins (empty)	Non-ULV	0.4762	Lb/1000 ft^2	Contact or surface treatment
	Non-ULV	5	Lb/25 gal	
Grain/cereal/flour elevators (empty)	Non-ULV	0.4762	Lb/1000 ft^2	Contact or surface treatment
	Non-ULV	5	Lb/25 gal	
Greenhouse (empty)	Non-ULV	0.0434	Lb/1000 ft^2	Apply as needed, 7 day minimum retreatment interval Soil treatment by sprayer
Household/domestic dwellings (perimeter outdoor only)	Non-ULV	0.2439	Lb/1000 ft^2	Application is limited to the structure base and a 2 ft wide swath from the structure base.
Intermittently flooded areas	Non-ULV	0.5078	Lb ai/A	
	ULV	0.232	Lb ai/A	
Non-agricultural outdoor building structures	Non-ULV	0.2057	Lb/1000 ft^2	
Non-agricultural rights-of-way/fencerows	ULV	0.9281	Lb ai/A	
Non-agricultural uncultivated areas/soil	Non-ULV	0.6	Lb ai/A	
	ULV	0.9281		
Ornamental and/or shade trees	Non-ULV	2.5	Lb/100 gal	Maximum of 2 applications per year. 10 day minimum retreatment interval. 12 hr restricted reentry interval
Ornamental herbaceous plants	Non-ULV	2.5	Lb/100 gal	12 hr restricted reentry interval
Ornamental non-flowering plants	Non-ULV	2.5	Lb/100 gal	
Ornamental woody shrubs and vines	Non-ULV	2.5	Lb/100 gal	Maximum of 2 applications per year/growing cycle. 10 day minimum re-treatment interval. 12 hr restricted reentry interval.
Pine seed orchards	Non-ULV	0.9375	Lb ai/A	Maximum of 2 applications per

Non-Agricultural Use Sites				
Site	Form	Maximum Single Application Rate	Unit	Use Pattern Limitations
	ULV	0.9375		year/growing season. 7 day minimum re-treatment interval. 12 hr restricted reentry interval
Refuse/solid waste containers (outdoors)	Non-ULV	0.2439	Lb/1000 ft^2	
Refuse/solid waste sites (outdoors)	Non-ULV	0.2439	Lb/1000 ft^2	
Swamps/marshes/stagnant water	Non-ULV	0.5075	Lb ai/A	
Wide Area – Public Health Use	ULV	0.23	Lb ai/A	Label must comply with PR-Notice 2005-1, and additional requirements outlined in the Label Table.

1: Not all formulations are supported by data, only those formulations supported by data will elegible for reregistration.

Appendix B
Data Supporting Guideline Requirements for the Reregistration of Malathion

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

The data table is organized in the following formats:

1. Data Requirement. The data requirements are listed by Guideline Number. The Guideline Numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

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

A. Terrestrial Food
B. Terrestrial Feed
C. Terrestrial Non-Food
D. Aquatic Food
E. Aquatic Non-Food Outdoor
F. Aquatic Non-Food Industrial
G. Aquatic Non-Food Residential
H. Greenhouse Food
I. Greenhouse Non-Food
J. Forestry
K. Residential
L. Indoor Food
M. Indoor Non-Food
N. Indoor Medical
O. Indoor Residential

3. Bibliographic Citation. If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
860.1200		Directions for Use	Data Required[1]
830.7000	63-12	pH	40944103
830.7300	63-10	Dissociation constant in water	40966603
830.7550	63-11	Octanol/water partition coefficient	40944103
830.7840	63-8	Water solubility	40944106, 40966603, 41126201
830.7860	63-8	Solvent solubility	40944106, 40966603, 41126201
830.7200	63-5	Melting point/melting range	40966603
830.7300	63-7	Density	40944104
830.7950	63-9	Vapor pressure	40944103, 40966603
835.2120	161-1	Hydrolysis	40941201, 43166301
835.2240	161-2	Direct Aqueous Photolysis	41673001, 43166301
835.2410	161-3	Soil Photolysis	40658009, 41695501, 43166301
835.	161-4	Air Photolysis	40969301, 43166301
835.4100	162-1	Aerobic Soil Metabolism	41721701, 43166301
835.4400	162-3	Anaerobic Aquatic Metabolism	42216301, 43163301
835.	162-4	Aerobic Aquatic	42271601, 43163301
835.1240	163-1	Leaching/Adsorption/Desorption	41345201, 43163301, 43868601
835.1410	163-2	Volatility-lab	42015201
835.1100	164-1	Soil Dissipation	41748901, 41727701, 43042401, 43042402, 43166301
835.1200	164-2	Aquatic Dissipation	42058401, 42058402, 43166301
		Irrigated Crop	42058401, 42058402, 43166301
	165-4	Fish Accumulation	43106401, 43106402, 43340301
850.2100	71-1(a)	Acute Avian Oral, LD50 – Quail/Duck	00160000
850.2100	71-1 (b)	Avian Acute Oral - Quail (TGAI)	00022923
850.2100	71-1 (b)	Avian Acute Oral - Mallard Duck (TEP)	00022923

165-3

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
850.2300	71-4(a)	Avian Chronic Reproduction - Quail (TGAI)	43501501
850.2300	71-4(b)	Avian Chronic Reproduction - Bobwhite quail (TGAI)	42782101
850.1075	72-1 (a)	Freshwater Fish – Bluegill (TGAI)	40098001
850.1075	72-1 (b)	Freshwater Fish LC50's – Bluegill (TEP)	Required
850.1075	72-1-(c)	Freshwater Fish LC50's - Rainbow Trout (TGAI)	40098001
850.1075	72-1-(d)	Freshwater Fish LC50's - Rainbow Trout(TEP)	Required
850.1010	72-2(a)	Freshwater Invertebrate - Daphnia magna (TGAI)	40098001
850.1010	72-2(b)	Freshwater Invertebrate - Daphnia magna (TGAI) and (TEP)	41029701
850.1045	72-3(a)	Estuarine/Marine Fish - Sheepshead Minnow	41174301
850.1045	72-3(b)	Estuarine/ Marine Mollusk - Mollusk (TGAI)	40098001
850.1045	72-3(c)	Estuarine/ Marine Shrimp -Mysid shrimp (TGAI)	41474501
850.1045	72-3(d)	Estuarine/Marine - Fish (TEP)	41252101
850.1045	72-3(e)	Estuarine/Marine - Mollusk (TEP)	42249901
850.1045	72-3(f)	Estuarine/Marine – Shrimp (TEP)	Required
850.1400	72-4	Freshwater Fish Early Life Stage Toxicity(TGAI)	Required
850.1400	72-4(a)	Estuarine/marine fish early-life stage (TGAI)	41422401
850.1300	72-4(b)	Estuarine/marine aquatic invertebrate life-cycle test	41718401
1850.3020	141-1	Acute Contact LD50 - Honeybee	05001991, 001999, 05004151, 05004003
1850.3020	141-2	Honey Bee Residue on Foliage	41208001, 41284701
860.1200	171-3	Directions for Use	Required[1]
860.1300	171-4a	Nature of Residue – Plants (Plant Metabolism)	00153985, 40397102, 40397103, 42317401, 42482601, 42538901, 42583401
860.1300	171-4a	Nature of Residue – Animal (Animal Metabolism)	00108942, 00120105, 40415701, 42581401, 42715401, 42744401

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
860.1340	171-4c	Residue Analytical Method - Plant Commodities	00033810, 00034342, 00035014, 00035318, 00035330, 00035870, 00058823, 00080769, 00089237, 00089521, 00096676, 00102376, 00104631, 00108941, 00113099, 00113100, 00113135, 00113137, 00113141, 00113142, 00113143, 00113147, 00113149, 00113150, 00113171, 00113173, 00113186, 00113188, 00113203, 00113205, 00113212, 00113223, 00113229, 00113230, 00122714, 40397104, 42894601, 43630301
860.1340	171-4c	Residue Analytical Method - Animal Commodities	00058823, 00089256, 00098775, 00108941, 00113116, 00120105, 40397101, 40397105
860.1380		Storage Stability Data- Plant Commodities	00048370, 00089256, 00089521, 00089808, 00113137, 00113206, 43549001, 43684801, 43910901
860.1400	171-4f	Water, Fish, and Irrigated Crops	Required[2]
Magnitude of the Residue			
860.1500	153-3	Magnitude of the Residue	Required[3]
860.1500	153-3	**Root and Tuber Vegetables Group**	
		Beet, garden, roots	00113116
		Carrot	00100020, 00159270, 44441601
		Parsnip	00100020
		Potato	00089248, 43360401
		Radish, roots	00100020
		Turnip, roots	44266401
		Leaves of Root and Tuber Vegetables Group	
		Beet, garden, tops	00113116, 00113212

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
		Beet, sugar, tops	00113188
		Turnip, tops	00089260, 44266401
		Onion, bulb and green	00089248, 43350401, 43383301
		Leafy Vegetables (Except *Brassica* Vegetables) Group	
		Celery	Data Required 00089247, 00113212
		Endive	00100020
		Lettuce	00057674, 00089260, 00100020, 00113143, 00113171, 00120105, 43362501, 43367201
		Parsley	00100020, 00159270
		Spinach	00057674, 00089260, 00113143, 44272401
		Swiss chard	00100020, 00159270
		Brassica (Cole) Leafy Vegetables Group	
		Broccoli	00089259, 00089260, 44203901
		Cabbage	00089260, 00113143, 44232601
		Cauliflower	0089260
		Collards	00100020
		Kale	00089260
		Kohlrabi	00057674, 00100020
		Mustard greens	00089260, 44271101
		Legume Vegetables (Succulent or Dried) Group	
		Bean (succulent and dry)	00089245, 00100020, 00113143, 00113166, 43372701, 43376801, 43417601
		Pea (succulent)	00113099, 00113120, 44205901
		Soybean seed and aspirated grain fraction	00145201
		Foliage of Legume Vegetables Group	
		Pea (field) vines and hay	00113099, 00113120

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
		Soybean forage and hay	00108941
		Eggplant	00089250, 00113212
		Pepper	00089250, 00113212, 43175501
		Tomato	00089250, 00100020, 00113143, 00113182, 00113212, 00113214, 00120105, 43372901
		Cucurbit Vegetables Group	
		Cucumber	00089249, 00100020, 43370601
		Melon	00089249, 43107602, 44098401
		Squash	00100020
		Citrus Fruits (*Citrus spp. And Fortunella spp.*) Group	
		Grapefruit	00089052
		Lemon	00113203
		Tangerine	00113182
		Pome Fruit Group	
		Apple	Additional Data Required 00057674, 00089258, 43107601, 43107603, 44009601
		Pear	00089258, 44013701
		Quince	Data Required
		Stone Fruits Group	
		Apricot	00089239, 44120001
		Cherry	00035314, 00035870, 00057674, 00089239, 00113143, 43108201, 43078702
		Peach	00057674, 00113182, 44016001
		Berries Group	
		Blackberry	00100020, 00159270, 44282201
		Blueberry	00035015, 00089242, 00113165, 00113170,

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
			00113176, 00113193, 00113229, 43372601
		Raspberry	44282101
		Tree Nut Group	
		Almond, nutmeat and hulls	00108941
		Chestnut	00116023, 44478401
		Macadamia Nut	00108941, 44076801
		Walnut	00104631, 00120105, 44383301
		Cereal Grains Group	
		Barley grain	00089253
		Corn (field) grain and aspirated grain fractions	00138431, 43468201, 43577401
		Corn (sweet) K+CWHR	00057674, 00138431, 43361101
		Oat grain	00120105, 00153987
		Rice grain	43468101
		Sorghum grain and aspirated grain fractions	00035013, 00105387, 43360001
		Wheat grain and aspirated grain fractions	43414901, 43350402
		Wild rice grain	00113143
		Forage, Fodder, and Straw of Cereal Grains Group	
		Barley hay and straw	Data Required
		Corn (field) forage and stover	43468201
		Corn (sweet) forage and stover	43361101
		Oat forage, hay, and straw	Data Required
		Rice straw	43468101
		Sorghum forage and stover	00035013, 00153987
		Wheat forage, hay, and straw	43414901, 43350402
		Grass Forage, Fodder, and Hay Group	
		Grass (pasture and rangeland)forage and hay	00089251, 00108941, 43362601
		Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group	

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
		Alfalfa forage and hay	00035330, 00035886, 00035890, 00089252, 00089521, 43546101
		Clover forage and hay	00089521, 43545201
		Vetch forage and hay	00034458
		Miscellaneous Commodities	
		Asparagus	00034344, 00120105, 44436101
		Avocado	00113116, 43383501
		Cotton, seed and gin by products	00035318, 00102291, 00102376, 00103342, 00103343, 00108949, 00113097, 00113147, 00113186, 43596601
		Cranberry	00089242
		Date	0089242
		Fig	00089593, 00120105, 44061201
		Flax	00113137, 43991401
		Grape	00048370, 00089242, 00101150, 00113095, 00113205, 00113206, 43383401
		Guava	00120105, 44391501
		Hops, dried	00113118
		Mango	00089254, 00113182, 44480301
		Mint (peppermint and spearmint)	00120105, 44124801
		Mushroom	00030482, 00120105, 44001101
		Okra	00100020, 00108941, 44232701
		Papaya	00108941, 44331001
		Passion fruit	00113182, 44472801
		Pineapple	00113116, 44613801
		Safflower	00113230
		Strawberry	00085524, 00089242, 00115967, 43368301,

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
			44094401
		Watercress	00120105, 44094801
		Stored Raw Agricultural and Processed Commodities	
		Almond and nutmeat and hulls	00104631, 00113121, 00113134
		Citrus pulp	00113203
		Corn grain and aspirated grain fractions	00058827, 00058828, 43666801
		Oats, grain	Data Required
		Peanut nutmeat	00035130, 00080769, 00089808
		Rice grain	00058824
		Sorghum grain and aspirated grain fractions	00058828
		Sunflower seeds	00096676
		Wheat grain and aspirated grain fractions	00034951, 00058826, 00058828, 00089808, 43661401
860.1520	153-3	Processed Food/Feed	
		Apple	44009601
		Barley	Data Required
		Citrus	00113203, 43451701
		Corn, field	00058827, 00058828, 43577401, 43666801
		Cottonseed	43585301
		Cottonseed, processed commodities (meal, hulls, and refined oil)	Required[4]
		Fig	44061201
		Flax	43991401
		Grape	43548401
		Mint	44124801
		Oats	Data Required
		Peanut	00035130, 00080769, 00089808

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
		Pineapple	44613801
		Potato	43524101
		Rice	00058824, 43562301
		Rye	Data Required
		Sorghum	00058828
		Sunflower	00096676
		Tomato	43499901
		Wheat	00034951, 00058826, 00058828, 00089808, 43510501, 43661401
860.1480	153-3	**Meat, Milk, Poultry, Eggs**	
		Fat, Meat, and Meat Byproducts of cattle, goats, hogs, horses, and sheep	00082336, 00113120, 00113191, 00120105
		Milk	0005309, 00034457, 00034461, 00088051, 00089255, 00089562, 00113101, 00113175, 00120105, 05006630
		Eggs and the Fat, Meat, and Meat Byproducts of Poultry	00108941, 00113234, 00113236
		Water, Fish and Irrigated Crops	Data Required 00163283
860.1460	171-4i	Food Handling	00058825
860.1850	153-3	Confined Rotational Crops	To be determined
860.1900	153-3	Field Rotational Crops	Required[5]
870.1000	81-1	Oral - Rat	00159876
870.1100	81-2	Acute Dermal -Rabbit	00159877
870.1200	81-3	Acute Inhalation Toxicity	00159878
870.2400	81-4	Primary Eye Irritation - Rabbit	00159880
870.2500	81-5	Primary Dermal Irritation	00159879

New Guideline Number	Old Guideline Number	Study Description	Citation/ Data Required
870.2600	81.6	Dermal Sensitization	00159881
870.3200	82-2	21-Day Dermal - Rabbit	41054201, 46790501
870.3465	82-4	90-Day Inhalation – Rat (range finding study)	43266601 (44554301)
870.3700a	83-3a	Developmental Toxicity - Rat	41160901
870.3700b	83-3b	Developmental Toxicity - Rabbit	00152569
870.4100b	83-1b	Chronic Toxicity (nonrodent)	40188501
870.4200a	83-2a	Oncogenicity (rat)	43942901, 43975201
870.3800	83-4	2 - generation Reproduction, Rat	41583401
870.4300	83-5	Chronic/Oncogenicity (rat)	43407201
870.5100	84-2a	Mutagenicity—Gene Mutation - bacterial	40939302
870.5300	84-2	Mutagenicity – Lymphoma Forward Gene Mutation Assay	45554501
870.5385	84-2	Mutagenicity – Bone Marrow Chromosome Aberration Test	41451201
870.5550	84-2	DNA Synthesis	41389301
870.6100		Acute Oral Delayed Neurotoxicity	40939301
870.6200(a)		Acute Neurotoxicity - Rat	43146701
870.6200(b)		Subchronic Neurotoxicity - Rat	43269501
870.6300		Developmental Neurotoxicity - Rat	45646401
870.6300(x)		Comparative ChE Study - Rat	45566201
870.7485		Metabolism - Rat	41367701
870.7800		Immunotoxicity	Required

1: Required regarding use of ground or aerial equipment, unless adequate field trial data reflecting aerial application of malathion in <2 gallons of water per acre (<19 gallons of water per acre for tree or orchard crops) are available, malathion product labels must specify that aerial application ar to be made in a minimum of 2 gallons of water per acre (10 gallons per acre in the case of tree or orchard crops).
2: This data requirement(s) imposed in the Malathion Reregistration Standard remain outstanding. In lieu of the required residue data, the registrant(s) may modify malathion use to allow broadcast use only over intermittently flooded areas, and that applications may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially.
3: Residue in/on the following RAC's following preharvest uses have not been fulfilled: barley hay; celery; corn (sweet) stover; cottonseed; cotton gin byproducts; date (currently under review); oat hay; quince; sorghum forage and stover; and, wheat hay.
4: The reregistration data requirements for magnitude of the residue in the processed commodities of the following crops are required: flax; and wheat (reflecting postharvest treatment). Additionally, processing data for peanut, plum, rice (reflecting postharves treatment) safflower; sugarbeet; soybean; and, sunflower are required should any registrant elect to support uses of malathion on these crops.
5: Rotational crop restrictions are needed on malathion end-use product labels. The appropriate PBIs will be determined pending submission of the required field rotational crop studies.

Appendix C
Technical Support Documents for the Malathion RED

Health Effect Documents

Malathion: Revised Acute, Probabilistic and Chronic Dietary (Food + Drinking Water) Exposure and Risk Assessments for the Malathion Reregistration Eligibility Decision. PC Code: 057701. DP Barcode: D330636. Sheila Piper, July 13, 2006.

Malathion: Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document. (DP Barcode: D330678; Chemical Number: 057701; EPA MRID No.: 43945001). Jack Arthur, July 6, 2006.

Malathion: Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 057701. DP Barcode: D321547. Jack Arthur. September 12, 2005.

Malathion: Occupational Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document. (DP Barcode: D330675; Chemical Number: 057701; EPA MRID Nos.: 45005910, 45491901, 45138202, 45491902, 45138201 and 45469501). Jack Arthur, July 6, 2006.

Malathion: Occupational Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 057701. DP Barcode: D315898. Jach Arthur. June 2, 2005.

Second Update Review of Malathion Incident Reports. PC Code: 057701. DP Barcode D315907. Jerome Blondell. May, 2005.

Product Chemistry Chapter for the Malathion Reregistration Eligibility Decision (RED) Document. William O. Smith. DP Barcode D256522. June 2, 1999.

Residue Chemistry Chapter for the Malathion Reregistration Eligibility Decision (RED) Document. PC Code: 057701. DP Barcode: D239453. William O. Smith. April 14, 1999.

Benchmark Dose Analysis of Brain and Rbc Data from the Malathion Comparative Cholinesterase Study in Juvenile and Adult Rats. PC Code: 057701. DP Barcode: D315405. Anna Lowit. April 11, 2005.

Malathion and Malaoxon: Comparative Toxicity and Estimation of Toxicity Adjustment Factor. PC Codes: 057701, 657701. DP Barcodes: D293912, D295144, D310501, D310800. Anna Lowit. April 11, 2005.

Environmental Fate and Ecological Effects Documents

Revised EFED RED Chapter for Malthion. PC Code: 057701. DP Barcodes: D238903, and D238906. Brian Montague, Norman Birchfield, Richard Mahler. October 18, 2000.

Estimates of Malathion Concentrations in Drinking Water as a Result of Terrestrial Uses and Rice Use. PC Code: 057701. DP Barcode: D285199. Norman Birchfield. September 16, 2002.

Transmittal of Estimated Daily Drinking Water Concentrations of Malaoxon Resulting from Malathion use on Multiple Crops at Typical and Maximum Intensity. PC Code: 057701. DP Barcode: D292663. Norman Birchfield. June 30, 2004.

Estimated Chronic Drinking Water Exposure Values for Malaoxon. PC Code: 057701. DP Barcode: D315267. Norman Birchfield. March 24, 2005.

Drinking Water Exposure Modeling Evaluating the Effect of Varying Crop Scenarios, Application Rate, Application Interval, Spray Drift Levels, Soil Half Life. PC Code: 057701; DP Barcode: D327331. Norman Birchfield, June 15, 2006.

Spray Drift Deposition and Dissipation Distances from Aerial Application opf Aqueous and Oil Malathion Formulations. PC Code: 057701. DP Barcode: D328380. Norman Birchfield. June 15, 2006.

Biological and Economical Analysis Documents

Summary Tables of Malathion Grower Impact on Selected Crops. Donald Atwood. Jan 18, 2006.

Registered Crops with Little to No Use of Malathion. Donald Atwood, Jin Kim, Tim Kiely. Dec. 23, 2005.

Appendix D

MRID	Citation Reference
1999	Atkins, L., Jr.; Anderson, L.D. (1967) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. (Unpublished study received Jan 30, 1969 under 9G0802; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Hercules, Inc., Agricultural Chemicals, Wilmington, Del.; CDL:093111-D) Author: Atkins, L., Jr. Anderson, L.D.
5309	Eschle, J.L.; Miller, J.A. (1967) Ultra-Low-Volume Application of Insecticides to Cattle for Control of the Horn Fly: Report No. 20820. (Unpublished study received Feb 6, 1969 under 11556- 16; prepared by U.S. Agricultural Research Service, Entomology Research Div., Livestock Insects Investigations for Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL: 007194-G)
22923	Hill,E.F., R.G. Heath, J.W. Spann and J.D. Williams. 1975. Lethal dietary toxicities of environmental pollutants to birds. USDI, Fish and Wildlife Service, Patuxent Wildlife Research Center. USFWS Special Scientific Report - Wildlife, No. 191. (unpublished report).
30482	Snetsinger, R.; Chung, S.L.; Kielbasa, R.; et al. (1979) Ethoprop: Sciarid Fly Control in Mushrooms. (Unpublished study including PR No. 908 and published data, received Mar 27, 1980 under 0E2341; prepared in cooperation with Pennsylvania State Univ., Dept. of Entomology, submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:099351-C)
33810	American Cyanamid Company (1965) Malathion Residues on Tomatoes. (Unpublished study received Aug 26, 1968 under 241-47; CDL: 001672-B)
34342	McGregor, H.E. (1972) Progress Report: Malathion for Insect Control in Flour Mills. Includes undated method entitled: Determination of Malathion in various mill streams of wheat. (Unpublished study received Feb 15, 1973 under 241-47; prepared by U.S. Agri- cultural Research Service, Mid-West Grain Insects Investiga- tions, Grain Marketing Research Center in cooperation with Gen- eral Mills, submitted by American Cyanamid Co., Princeton, N.J.; CDL:001678-A)
34344	Amen, C.R.; Telford, H.S.; Legault, R.R.; et al. (1959) Monthly Re-port: Malathion-- Residues in Asparagus. (Unpublished study re- ceived Nov 3, 1959 under 241-30; prepared in cooperation with State College of Washington, Depts. of Entomology and Agricul- tural Chemistry, submitted by American Cyanamid Co., Princeton, N.J.; CDL:001635-A)
34457	Turner, C. (1959) Horn Fly Tests. (Unpublished study received Mar 10, 1959 under 241-33; prepared by Virginia Polytechnic Insti- tute, submitted by American Cyanamid Co., Princeton, N.J.; CDL: 001653-A)
34458	Dickason, E.A.; Amen, C.R.; Tuft, T.O. (1960) ?Control of Insects on Vetch|. (Unpublished study received Oct 10, 1960 under 241- 33; prepared in cooperation with Oregon State College and Hazle- ton Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:001654-A)

34461 Wells, A.L.; Stelmach, Z.; Guyer, G.E.; et al. (19??) A Study of Malathion for Controlling Flies in Dairy Barns and on Dairy Cat- tle. Michigan Quarterly Bulletin 40(4):786-795. (Also~In~un- published submission received Apr 2, 1962 under 241-33; submit- ted by American Cyanamid Co., Princeton, N.J.; CDL:001656-B)

34951 Phillips, G.L.; Moore, S., III (1970) ?Efficacy Data for Malathion on Wheat|. (Unpublished study including letter dated Sep 30, 1970 from J.R. Dogger to E. Brad Fagon, received Feb 10, 1971 under 241-47; prepared by U.S. Agricultural Marketing Service, Marketing Research Div., Stored-Grain Insects Laboratory in co- operation with Univ. of Illinois, Cooperative Extension Service, Illinois Natural History Survey, submitted by American Cyanamid Co., Princeton, N.J.; CDL:001674-A)

35013 Orloski, E.J.; Whalen, R.T.; Owens, W.L., Jr. (1968) Malathion Res- idues in Grain Sorghum: Report No. C-162. (Unpublished study received Aug 16, 1968 under 241-110; submitted by American Cyanamid Co., Princeton, N.J.; CDL:001998-A)

35014 American Cyanamid Company (19??) ?Extraction of Malathion from Grain Sorghum; Determination of Malathion in Carbon tetrachlo- ride Extracts|. (Unpublished study received Aug 16, 1968 under 241-110; CDL:001998-B)

35015 Orloski, E.J.; Snyder, E.H.; Roberts, W.W. (1964) Malathion Resi- dues in Blueberries: Report No. C-66. (Unpublished study re- ceived Apr 26,1965 under 241-110; submitted by American Cyana- mid Co., Princeton, N.J.; CDL:001994-A)

35130 American Cyanamid Company (1960) Malathion Recovery Studies on Pea-nut Products: Project BS 1-32. (Unpublished study received Aug 30, 1960 under241-47; prepared in cooperation with U.S. Dept. of Agriculture, Stored Product Insects Branch, Savannah Station; CDL:001668-B)

35314 Kiigemagi, U.; Terriere, L.C. (1968) Malathion Residues on Cherries Treated with an Ultra Low Volume Formulation. (Unpublished study including letter dated Dec 1, 1969 from U. Kiigemagi to C. R. Amen, received Feb 6, 1970 under 241-108; prepared by Oregon State Univ., Dept. of Agricultural Chemistry,submitted by American Cyanamid Co., Princeton, N.J.; CDL:002001-B)

35318 Orloski, E.J.; Whalen, R.T.; Cowan, C.B.; et al. (1966) Malathion Residues in Cottonseed: Report No. C-103. Includes method dated Jan 18, 1966. (Unpublished study including report no. C-104, received Jan 26, 1966 under 241-110; submitted by American Cyan- amid Co., Princeton, N.J.; CDL:001995-B)

35330 Orloski, E.J.; Devine, J.M.; Pass, B.C.; et al. (1969) Malathion and Methyl parathion Residues in Alfalfa: Report No. C-217. Includes undated method entitled: Gas chromatographic deter- mination of Malathion and Methyl parathion residues in alfalfa (green foliage and dry hay). (Unpublished study received Feb 19, 1970 under 241-219; prepared in cooperation with Syracuse Univ. Research Corp., submitted by American Cyanamid Co., Princeton, N.J.; CDL:002059-C)

35870 Zabik, M. (1970) ULV Malathion Residues on Cherries: Sample Analyt- ical Procedure. Undated method. (Unpublished study received Feb 18, 1971 under 241-224; prepared by Michigan State Univ., Pesticide Analytical Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL:002062-C)

35886 Orloski, E.J.; Bohn, W.R.; Whalen, R.T.; et al. (1967) Malathion Residues in Green Alfalfa: Report No. C-139. Includes method entitled: Determination of Malathion in Benzene extracts. (Un- published study received Apr 8, 1968 under 241-110; submitted by American Cyanamid Co., Princeton, N.J.;CDL:001996-B)

35890 Dorough, H.W.; Randolph, N.M. (1967) Comparative Residual Nature of certain Insecticides Applied as Low Volume Concentrate and Water Emulsion Sprays. Bulletin of Environmental Contaimination & Toxicology 2(6):340-342.(Also~In~unpublished submission re- ceived Apr 1, 1969 under 241-219; submitted by American Cyanamid Co., Princeton, N.J.; CDL:002059-F)

35890 Dorough, H.W.; Randolph, N.M. (1967) Comparative Residual Nature of certain Insecticides Applied as Low Volume Concentrate and Water Emulsion Sprays. Bulletin of Environmental Contaimination & Toxicology 2(6):340-342. (Also~In~unpublished submission re- ceived Apr 1, 1969 under 241-219; submitted by American Cyanamid Co., Princeton, N.J.; CDL:002059-F)

48370 U.S. Department of Agriculture (1973) ?Efficacy Studies--Raisins|. (Compilation; unpublished study; CDL:221775-H)

57674 American Cyanamid Company (1952) Malathon. N.P. (Technical bulletin no. 2; also~In~unpublished submission received Mar 15, 1952 under unknown admin. no.; CDL:001580-A)

58823 Manuel, A.J. (1976) Malathion: Determination of Residues of Mala- thion, (CL 6,601), S-?1,2-Bis(ethoxycarbonyl)ethyl|-O,O-dimeth- yldithiophosphate, and Malaoxon (CL 23,269) in Beef and Pork Muscle, Bread, Cake, Corn Flakes, Milk, Coca-Cola, and Cranberry Sauce by Gas-Liquid Chromatography: Report No. C-919. Includes method M-647 dated Mar 12, 1976. (Unpublished study received Aug 16, 1976 under 241-EX-83; submitted by American Cyanamid Co., Princeton, N.J.; CDL:230458-D)

58824 Alvarez, C.G.; McGaughey, W.H. (1975) Malathion on Milling Frac- tions of Three Varieties of Rough Rice: Duration of Protection and Residue Degradation, USDA, ARS, Market Quality Research Division, Beaumont, Texas--1969:Report No. 75-123. (Unpub- lished study including published data, received Aug 16, 1976 under 241-EX-83; prepared in cooperation with U.S. Agricultural Research Service, Market Quality Research Div., Stored-Product Insects Research Branch, submitted by American Cyanamid Co., Princeton, N.J.; CDL:230458-E)

58825 Alvarez, C.G.; Bliznick, A.; McGregor, H.; et al. (1975) Malathion in Flour Mills, USDA, ARS, Mid-west Grain Insects Investiga- tions, Manhattan, Kansas--1971: Report No. 75-124. Includes un- dated method entitled: Determination of Malathion in various mill streams of wheat. (Unpublished study received Aug 16, 1976 under 241-EX-83; prepared in cooperation with U.S.Agricultural Research Service, Market Quality Research Div., Stored-Product Insects Research Branch, Mid-West Grain Insects Investigations Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL:230458-F)

58825 Alvarez, C.G.; Bliznick, A.; McGregor, H.; et al. (1975) Malathion in Flour Mills, USDA, ARS, Mid-west Grain Insects Investiga- tions, Manhattan,Kansas--1971: Report No. 75-124. Includes un- dated method entitled: Determination of Malathion in various mill streams of wheat. (Unpublished study received Aug 16, 1976 under 241-EX-83; prepared in cooperation with U.S. Agricultural Research Service, Market Quality Research Div., Stored-Product Insects Research Branch, Mid-West Grain Insects Investigations Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL:230458-F)

58826 Alvarez, C.G.; Edmonds, W.O. (1975) Malathion Residues on Milled Fractions of Malathion Treated Wheat, Minneapolis, Minnesota-- 1958-59: Report No. 75-40. Includes method M 18 dated Feb 1955. (Unpublished study received Aug 16, 1976 under 241-EX-83; pre- pared in cooperation with U.S. Dept. of Agriculture, Stored Products Insects Section and Pillsbury Mills, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:230458-G)

58827 Alvarez, C.G.; McGregor, H.E.; Henderson, L.S.; et al. (1975) Resi- due Studies on Corn and Milled Corn Fractions, USDA, ARS, Mid- west Grain Insects Investigations, Manhattan, Kansas--1972: Report No. 75-125. (Unpublished study received Aug 16, 1976 under 241-EX-83; prepared in cooperation with U.S. Agricultural Research Service, Mid-west Grain Insects Investigations Laboratory and Stored Products Laboratory, submitted by American Cy- anamid Co., Princeton, N.J.; CDL:230458-H)

58828 Alvarez, C.G.; Schesser, J.H.; Wilson, J.L.; et al. (1975) Persistence of Cythion^(R)I Residues on Stored Grains: Corn, Wheat and Grain Sorghum: Report No. 75-122. (Compilation by submit- ter; unpublished study including published data, received Aug 16, 1975 under 241-EX-83; submitted by American Cyanamid Co., Princeton, N.J.; CDL:230458-I)

80769 ICI Americas, Incorporated (1977) ?Efficacy of Pirimiphos-methyl on Peanuts|. (Compilation; unpublished study, including published data, received Dec 1, 1978 under 10182-EX-15; CDL: 097674-H)

82336 Claborn, H.V. (1956) Insecticide Residues in Meat and Milk: ARS- 33-25. (U.S. Agricultural Research Service, Entomology Research Branch; unpublished study; CDL:097556-J)Author: Claborn, H.V.

85524 California Spray-Chemical Company (1955) Spray Residue Remaining from the Use of Captan as an Agricultural Fungicide. (Compilation; unpublished study received May 1, 1955 under PP0015; CDL: 090983-N)

88051 Claborn, H.V. (1955) Insecticide Residues in Meat and Milk. (U.S. Agricultural Research Service, Entomology Research Branch; un-published study; CDL:090081-X)Author: Claborn, H.V.

89052 American Cyanamid Company (1956) Method of Residue Analysis. (Un- published study received on unknown date under PP0064; CDL: 090062-A)

89237 Norris, M.V.; Vail, W.A.; Averell, A.R. (1954) Colorimetric Method for the Determination of Malathion Residues on Fruits, Vegetables, etc. Method dated Jan 1954, including method dated Aug 1954 entitled: Freeze-drying of milk. (Unpublished study received Jun 1, 1955 under PP0019; CDL:090018-AM)

89239 American Cyanamid Company (1954) ?Residue Study of Malathion on Various Fruits|. (Compilation; unpublished study received on unknown date under PP0019; CDL:090018-AO)

89242 American Cyanamid Company (1954) ?Residue Study of Malathion on Blueberries and Various Other Berries|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-AR)

89245 American Cyanamid Company (1954) ?Residue Study of Malathion on Beans|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-AV)Citation: American Cyanamid Company (1952) Malathion Residues: Beets. (Un-published study received Jun 1, 1955 under PP0019; CDL: 090018-AW)

89247 American Cyanamid Company (1954) Malathion Residues: Celery. (Un- published study received Jun 1, 1955 under PP0019; CDL: 090018-AX)

89248 American Cyanamid Company (1954) ?Residue Study of Malathion on Rutabagas, Onions and Potatoes|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-AY)

89249 American Cyanamid Company (1955) ?Residue Study of Malathion on Cantaloupes, Cucumbers and Squash|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-AZ)

89250 American Cyanamid Company (1954) ?Residue Study of Malathion on Eggplants, Peppers and Tomatoes|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BA)

89251 American Cyanamid Company (1952) Malathion Residues: Peas. (Unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BB)

89252 American Cyanamid Company (1955) ?Residue Study of Malathion on Alfalfa and Red Clover|. (Compilation; unpublished study re- ceived Jun 1, 1955 under PP0019; CDL:090018-BC)

89253 American Cyanamid Company (1955) ?Residue Study of Malathion on Pasture Grass, Barley, Oats and Wheat|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BD)

89254 American Cyanamid Company (1955) ?Residue Study of Malathion on Pineapples and Various Other Fruits|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BF)

89255 American Cyanamid Company (1955) Malathion Residues: Milk. (Unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BG)

89256 Gjullin; C.M.; Scudder, H.I.; Erwin, W.R. (1955) Determination of Malathion and Its Influence on Flavor of Milk from Cows Fed Malathion-sprayed Alfalfa. (Unpublished study received Jun 1, 1955 under PP0019; prepared by U.S. Dept. of Agriculture, Entomology Research Branch and others, submitted by American Cyanamid Co., New York, N.Y.; CDL:090018-BH)

89258 American Cyanamid Company (1954) ?Residue Study of Malathion on Apples and Pears|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BJ)

89259 American Cyanamid Company (1955) Removal of Malathion Residues on Broccoli in a Commercial Freezing Plant by Washing. (Unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BK)

89260 American Cyanamid Company (1956) ?Residue Study of Malathion on Broccoli and Various Other Vegetables|. (Compilation; unpublished study received Jun 1, 1955 under PP0019; CDL:090018-BL)

89521 American Cyanamid Company (1963) ?Malathion Residues in Forage Crops, Alfalfa, Meat and Dairy Products|. (Compilation; unpub- lished study, including published data and report no.s C-33 and C-34, received Jun 1, 1964 under PP0407; CDL:090023-F)

89562 American Cyanamid Company (1957) ?Residue Study of Malathion in Milk|. (Compilation; unpublished study received Oct 15, 1957 under PP0150; CDL:090002-C)

89593 American Cyanamid Company (1958) ?Analyses for Residues of Malathion in Figs|. (Compilation; unpublished study received Mar 28, 1958 under PP0187; CDL:090215-A)

89808 American Cyanamid Company (1957) ?Residues of Insecticides--Grain|. (Compilation; unpublished study received Apr 10, 1957 under PP0136; CDL:090164-B)

96676 Interregional Research Project Number 4 (1982) Malathion and Ma- laoxon Residues Found in Sunflower Seeds or Hulls Treated with Malathion.(Compilation; unpublished study received Mar 17, 1982 under 2E2658; CDL:070717-A)

98775 Paulin, H.J. (1971) Final Report: Determination of Pesticide Residues in Hog Tissue. (Unpublished study received on unknown date under 3E1367; prepared by TRW, Inc., submitted by American Seed Trade Association, Inc., Kalamazoo, Mich.; CDL:093649-K)

100020 American Cyanamid Co. (1966) Malathion Residues on Various Vegetable, Berry and Tobacco Crops|. (Compilation; unpublished study received Jul 19, 1966 under unknown admin. no.; CDL: 124480-A)

101150 Painter, R.; Kilgore, W.; Ough, C. (19??) Distribution of pesticides in fermentation products obtained from artificially fortified grape musts. ?Source unknown| p.342-346. (Also In unpublished submission received Oct 7, 1964 under 100-460; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL;101158-D)

102291 Walker, R.; Yeomans, A.; Fahey, J.; et al. (1965) Comparative Studies of Ultra Low-volume Sprays and Conventional Emulsion Sprays of Malathion and Methyl Parathion Applied to Cotton for Insect Control. (U.S. Agricultural Research Service, Entomology Research Div., Analytical Investigations, Aerosol Investigations, Biological Investigations and Plant Pest Control Div.; unpublished study; CDL:005066-B)

102376 Peterson, R.; Pasarela, N. (1969) Malathion and Methyl Parathion Residues in Ground Undelinted Cottonseeds: Report No. C-181. (Unpublished study received Feb 19, 1969 under 241-EX-49; submitted by American Cyanamid Co., Princeton, NJ; CDL:123158-G)

103342 Kim, D.; Gagne, J. (1982) Pay-Off Flucythrinate (CL 222,705/2.5EC),Cythion Malathion (CL 6,601/ULV): Residues of CL 222,705 and CL 6,601 in Cottonseeds (AER; LA, 1981) (C-0181, C-0261 and C-1593): Report No. C-1993. (Unpublished study received Jun 7, 1982 under 241-110; submitted by American Cyanamid Co., Prince- ton, NJ; CDL:247650-A)

103343 Kim, D.; Gagne, J. (1982) Pay-Off Flucythrinate (CL 222,705/2.5EC), Cythion Malathion (CL 6,601/ULV): Residues of CL 222,705 and CL 6,601 in Cottonseeds (AER; GA, 1981) (C-0181, C-0261 and C-1593): Report No. C-2027. (Unpublished study received Jun 7, 1982 under 241-110; submitted by American Cyanamid Co., Prince- ton, NJ; CDL:247650-B)

104631 IR-4 Project (1975) (Efficacy of Malathion on Almonds and Other Crops). (Compilation; unpublished study received Aug 21, 1978 under 8E2114; CDL:097309-C)

105387 Storherr, R.; Roberts, J. (1958) Insecticide Residues on Georgia Crops. (Unpublished study received Nov 1, 1970 under unknown admin. no.; prepared by Univ. of Georgia, Experiment Station, submitted by Hercules, Inc., Agricultural Chemicals, Wilmington, DE; CDL:005105-E)

108941 American Cyanamid Co. (1968) Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Malathion. (Compilation; unpublished study received on unknown date under 8F0634; CDL:090122-B)

108942 March, R.; Fukuto, T.; Metcalf, R.; et al. (1956) Fate of P32-labeled malathion in the laying hen, white mouse, and American cockroach. Journal of Economic Entomology 49(2):185-195. (Also In unpublished submission received Aug 8, 1967 under 8F0634; submitted by American Cyanamid Co., Princeton, NJ; CDL:090122-E)

108949 American Cyanamid Co. (1957) ?Analyses for Residues of Malathion in Black Raspberry Fruit and Other Products|. (Compilation; unpublished study received on unknown date under PP0089; CDL: 090131-A)

113095 American Cyanamid Co. (1973) ?Residues of Malathion in Raisins|. (Compilation; unpublished study received Feb 15, 1974 under 241-208; CDL:026767-A)

113097 American Cyanamid Co. (1967) ?Residues of Malathion in Cottonseed|. (Compilation; unpublished study received Aug 4, 1967 under 241-186; CDL:026906-B)

113099 American Cyanamid Co. (1973) Residue Data: Malathion|. (Compilation; unpublished study received May 20, 1974 under 241-110; CDL:026910-B)

113099 American Cyanamid Co. (1973) Residue Data: Malathion|. (Compilation; unpublished study received May 20, 1974 under 241-110; CDL:026910-B)

113100 Orloski, E.; Whalen, R. (1964) Malathion Residues in Macadamia Nuts: Report No. C-62. (Unpublished study received Jul 15, 1964 under 241-30; submitted by American Cyanamid Co., Prince- ton, NJ; CDL:026952-A)

113101 Orloski, E.; Whalen, R.; Adkins, T.; et al. (1964) Malathion Residues in Milk: Report No. C-51. (Unpublished study received Apr 3, 1964 under 241-30; submitted by American Cyanamid Co., Princeton, NJ; CDL:026954-A)

113116 American Cyanamid Co. (1954) The Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used:(Malathion). (Compilation; unpublished study received Jul 1, 1955 under PP0019; CDL:090774-L)

113118 Legault, R.; Cone, W. (1968) The Results of Tests on the Amount of Malathion Residue Remaining on Hops, Including a Description of the Analytical Method Used. (Unpublished study received May 4, 1970 under 0E0891; prepared by Washington State Univ., Dept. of Agricultural Chemistry, submitted by Interregional Research Project No. 4, New Brunswick, NJ; CDL:091534-A)

113120 American Cyanamid Co. (1960) The Results of Tests on the Amount of Residues Remaining; A Description of the Analytical Method Used: Malathion|. (Compilation, unpublished study received Apr 22, 1960 under PP0252;CDL:091560-B)

113121 American Cyanamid Co. (1969) Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Malathion. (Compilation; unpublished study received Jul 22, 1970 under 0F0942; CDL:091610-A)

113134 Dogger, J. (1969) Letter sent to W. Stokes dated Aug 1, 1969: Petition for temporary tolerance for malathion in unprocessed shelled almonds.(U.S. Agricultural Research Service, Market Quality Research Div., Stored-Product Insects Research Branch; unpublished study; CDL:093161-A)

113135 Interregional Research Project No. 4 (19??) Procedure for Deter- mining Malathion in Hop Cones. (Unpublished study received Sep 29, 1969 under 0E0891; CDL:093188-A)

113137 Interregional Research Project No. 4 (1978) The Results of Tests on the Amount of Malathion Residues Remaining in or on Flax (Seed, Straw, Meal) Including a Description of the Analytical Method Used. (Compilation; unpublished study received Aug 16, 1979 under 9E2248; CDL:098913-A)

113138 American Cyanamid Co. (1955) Colorimetric Method for the Determination of Malathion in Milled Wheat Products. (Unpublished study received Apr 10, 1957 under PP0136; CDL:092417-A)

113139 American Cyanamid Co. (1958) Study: Malathion Efficacy against Keds, Lice, and Ticks on Sheep & Goats|. (Compilation; unpublished study received on unknown date under PP0187; CDL: 092463-A)

113140 American Cyanamid Co. (1960) Study: Malathion Efficacy on Pea- nuts|. (Compilation; unpublished study received Oct 6, 1960 under PP0275; CDL:092554-A)

113141 American Cyanamid Co. (1960) Malathion Recovery Studies on Peanut Products: Exp. No. 9. (Unpublished study received Oct 6, 1960 under PP0275; CDL:092554-B)

113142 Spitler, G. (1966) Evaluation of Malathion as an Insect Protectant for Inshell Almonds Stored under Commercial Conditions in Chico, Calif. (U.S. Agricultural Research Service, Market Quality Re- search Div.; unpublished study; CDL:092829-A)

113143 Interregional Research Project No. 4 (1976) (Determination of Malathion and Malaoxon Residues in Various Crops). (Compilation; unpublished study received Oct 27, 1976 under 7E1881; CDL: 097770-A)

113144 Interregional Research Project No. 4 (1976) (Efficacy of Malathion Used to Control Wild Rice Worm, Apamia apamiformis). (Compilation; unpublished study received Oct 27, 1976 under 7E1881; CDL: 097770-B)

113147 Higham, J.; Dunn, J.; Blalock, J.; et al. (1974) Cythion ULV: Cythion ..., DEF ..., and Folex ... Residues in Cottonseed Treated with Cythion-DEF and Cythion-Folex Tank Mixtures (South Carolina, Tennessee, and Texas): C-467. (Unpublished study received Jul 18, 1974 under 241-208; prepared in cooperation with State Univ.--Oswego, Lake Ontario Environmental Laboratory and Mobil Chemical Co., submitted by American Cyanamid Co., Princeton, NJ; CDL:100867-A)

113148 McNerney, J.; Levinskas, G.; Morici, I.; et al. (1966) Report on Proban Cythioate: Joint Toxic Action with Other Organic Phosphates and Phenothiazine Tranquilizers: Report No. 66-83. (Un- published study received Sep 23, 1966 under 241-190; submitted by American Cyanamid Co., Princeton, NJ; CDL:101045-A)

113149 American Cyanamid Co. (1965) Determination of Residues of Malathion in Lettuce|. (Compilation; unpublished study received Dec 8, 1965 under 241-30; CDL:101275-A)

113150 American Cyanamid Co. (1965) Malathion Residues on Tomatoes. (Un- published study received Aug 26, 1968 under 241-47; CDL: 101276-A)

113165 Marucci, P. (1960) Letter sent to H. Scott dated Oct 10, 1960 Request for 0-day label for use of malathion on blueberries|. (Unpublished study received Oct 25, 1960 under unknown admin. no.; prepared by Rutgers Univ., Agricultural Experiment Station, Dept. of Horticulture, Cranberry and Blueberry Research Laboratory, submitted by American Cyanamid Co., Princeton, NJ; CDL: 119963-A)

113166 Kiigemagi, U.; Crowell, H. (19??) Determination of Malathion on Green Beans. (Unpublished study received Apr 4, 1957 under un- known admin. no.; prepared by Oregon State College, Ag Chem. Dept., and Entomology Dept., submitted by American Cyanamid Co., Princeton, NJ; CDL:119976-A)

113170 American Cyanamid Co. (1964) Determination of Malathion Residues in Blueberries|. (Compilation; unpublished study received Feb 27, 1964 under unknown admin. no.; CDL:119980-A)

113171 American Cyanamid Co. (1965) Malation Residues in Lettuce|. (Compilation; unpublished study received Dec 8, 1965 under unknown admin. no.; CDL:119981-A)

113173 Mitchell, M.; Russell; Cleveland, R.; et al. (1971) Cygard 630: Malathion, Methyl Parathion and Methyl Paraoxon Residues in Undelinted Cottonseed: Report No. C-261. (Unpublished study re- ceived Mar 8, 1971 under unknown admin. no.; prepared in cooperation with Syracuse Univ. Research Corp., submitted by American Cyanamid Co., Princeton, NJ; CDL:120007-A)

113175 American Cyanamid Co. (1959) Malathion Residues on Beef and Diary Cattle. (Compilation; unpublished study received Feb 20, 1959 under unknown admin. no.; CDL:120011-A) MRID: 113176
Citation: American Cyanamid Co. (1961) Malathion on Blueberries. (Unpublished study received May 21, 1962 under unknown admin. no.; CDL:120035-A)

113182 Ohinata, K.; Seo, S.; Steiner, L. (1958) Data on Residues of Malathion on Several Different Fruits and Vegetables. (U.S. Agricultural Research Service, Entomology Research Div.; unpublished study; CDL:124454-A)

113186 Getz, M.; Skinner, F.; Beroza, M. (1966) Report of Residue Analysis: Malathion: Report No. PCB-66-12. (U.S. Agricultural Re- search Service, Entomology Research Div., Pesticide Chemicals Research Branch; unpublished study; CDL:124468-A)

113188 Maitlen, J.; McDonough, L.; Esvelt, S. (1966) Report of Residue Analysis: Malathion: Report No. PCY-66-1. (U.S. Agricultural Research Service, Entomology Research Div., Pesticide Chemicals Research Branch; unpublished study; CDL:124471-A)

113191 Pasarela, N.; Brown, R.; Shaffer, C. (1962) Feeding of malathion to cattle: Residue analyses of milk and tissue. Agricultural and Food Chemistry 10(1):7-9. (Also In unpublished submission received Feb 19, 1962 under unknown admin. no.; submitted by American Cyanamid Co., Princeton, NJ; CDL:124485-A)

113193 American Cyanamid Co. (1963) Residues of Malathion in Blueberries. (Compilation; unpublished study received Mar 18, 1964 under unknown admin. no.; CDL:124588-A)

113203 Anon. (1962) Methods for Determining the Amounts of Malathion in Bagged Citrus Pulp: The Amounts There of and Removal. (Compilation; unpublished study received on unknown date under unknown admin. no.; submitted by ?; CDL:221558-B)

113205 Anon. (1963) A Description of the Practicable Methods to Determine the Amount of Malathion in or on Grapes (Raisins). (Compilation; unpublished study received Jan 10, 1964 under H1331; submitted by ?; CDL:221595-B)

113206 American Cyanamid Co. (1969) Study: Malathion Residue on Raisins|. (Compilation; unpublished study received Sep 15, 1971 under 2H2669; CDL:221731-A)

113212 American Cyanamid Co. (1951) Determination of Residues of Insecticide #4049 on Fruits, Vegetables, etc. (Compilation; unpublished study received on unknown date under unknown admin. no.; CDL:222410-C)

113214 American Cyanamid Co. (1952) Malathon Residues--Tomato. (Unpublished study received Nov 19, 1952 under unknown admin. no.; CDL:222470-A)

113223 American Cyanamid Co. (1957) Residues of Malathion in Blueberries. (Compilation; unpublished study received Oct 25, 1960 under unknown admin. no.; CDL:222490-A)

113229 American Cyanamid Co. (1963) Residues of Malathion in Blueberries and Other Crops|. (Compilation; unpublished study received May 24, 1963 under unknown admin. no.; CDL:223807-A)

113230 American Cyanamid Co. (1962) Residues of Malathion in Safflower and Other Crops|. (Compilation; unpublished study received Jul 13, 1962 under 241-30; CDL:223808-A)

113234 Raun, E. (1956) Chicken louse and mite control with malathion formulations. ?Source unknown| (Oct):628-629. (Also In unpubished submission received Jul 13, 1978 under 3770-277; submitted by Economy Products, Omaha, NE; CDL:234368-E)

113236 Harding, W.; Quigley, G. (1956) Litter treatment with malathion to control the chicken body louse. Journal of Economic Ento- mology 49(6):806-807. (Also In unpublished submission received Jul 13, 1978 under 3770-277; submitted by Economy Products, Omaha, NE; CDL:234368-H)

115967 Office of Commissioner (1968) ?Study: Pesticide Residues in Selected Crops|. (Compilation; unpublished study received Feb 21, 1969 under 7E0598; CDL:090766-A)

116023 Interregional Research Project No. 4 (1967) The Results of Tests on the Amount of DDT Residue Remaining on Chestnuts and Walnuts Including a Description of the Analytical Method Used. (Compilation; unpublished study received on unknown date under 1E1097; CDL:090857-A)

120105 American Cyanamid Co. (1956) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Method Used: (Malathion). (Compilation; unpublished study received Jul 22, 1966 under PP0089; CDL:090680-K)

122714 American Cyanamid Co. (1981) Residue Reports: Malathion. (Compilation; unpublished study received Dec 17, 1982 under 241-110; CDL:071295-A)

138431 U.S. Dept. of Agriculture, European Corn Borer Research Laboratory (1956) Corn-Malathion Residues. (Extract; unpublished study; CDL:124484-A)

145201 American Cyanamid Co. (1984) Residue Studies [PAY-OFF Insecticide on Soybeans]. Unpublished compilation. 22 p.

152569 Siglin, J. (1985) A Teratology Study with AC 6,601 in Rabbits: FDRL Study No. 8171. Unpublished study prepared by Food and Drug Research Laboratories. 204 p.

153985 Coffin, D. (1966) Oxidative metabolism and persistence of parathion and malathion on field-sprayed lettuce. Journal of the A.O.A.C. 49(5):1018-1021.

153987 Dorough, H.; Randolph, N. (1967) Comparative residual nature of certain insecticides applied as low volume concentrate and water emulsion sprays. Bulletin of Environmental Contamination & Toxicology 2(6):340-348.

159270 Anon. (19??) Residues of Malathion from Sprays and Dusts on Vegetables and Berries. Unpublished study.

159876 Kynoch, S. (1986) Acute Oral Toxicity to Rats of Malathion (Fyfanon) Technical: 851341D/CHV 33/AC. Unpublished study pre- pared by Huntingdon Research Centre Ltd.

159877 Kynoch, S. (1986) Acute Dermal Toxicity to Rats of Malathion (Fyfanon) Technical: 851330D/CHV 34/AC. Unpublished study pre- pared by Huntingdon Research Centre Ltd.

159878 Jackson, G.; Hardy, C.; Gopinath, G.; et al. (1986) Fyfanon (Malathion) 96/98% Technical: Acute Inhalation Toxicity Study in Rats 4-hour Exposure: CHV 28/8640. Unpublished study pre- pared by Huntingdon Research Centre Ltd. 38 p.

159879 Liggett, M.; Parcell, B. (1985) Irritant Effects on Rabbit Skin of Malathion (Fyfanon) Technical: 851221D/CHV 35/SE. Unpublished study prepared by Huntingdon Research Centre Ltd. 6 p.

159880 Liggett, M.; Parcell, B. (1985) Irritant Effects on the Rabbit Eye of Malathion (Fyfanon) Technical: 851214D/CHV 36/SE. Unpublished study prepared by Huntingdon Research Centre Ltd. 7 p.

159881 Kynoch, S.; Smith, P. (1986) Delayed Contact Hypersensitivity in the Guinea-pig with Malathion (Fyfanon) Technical: 8666D/CHV 37/ SS. Unpublished study prepared by Huntingdon Research Centre Ltd. 12 p.

160000 Hudson, R.H., R.K. Tucker and M.A. Haegele. 1984. Handbook of toxicity of pesticides to wildlife. USDI Resource Publication No. 153. Washington, DC.

5001991 Reference: Stevenson, J.H. (1978) The acute toxicity of unformulated pesticides to worker honey bees (~Apis mellifera~L_). Plant Pathology 27(1):38-40. Author: Stevenson, J.H.

5004003 Davies, R.A.H., McLaren, I.W. (1977) Tolerance of Aphytis melinus DeBach (Hymenoptera; Aphelinidae) to 20 orchard chemical treatments in relation to integrated control of red scale, Aonidiella aurantii (Maskell) (Homoptera:Disaspididae). Australian Journal of Experimental Agriculture and Animal Husbandry 17(85).

5004151 Stevenson, J.H. (1968). Laboratory studies on the acute contact and oral toxicities of insecticides to honeybees. Annals of Applied Biology 61 (3).

5006630 Oehler, D.D.; Eschle, J.L.; Miller, J.A.; Claborn, H.V.; Ivey, M.C. (1969) Residues in milk resulting from ultra-low-volume sprays of malathion, methoxychlor, coumaphos, ronnel, or Gardona for control of the horn fly. Journal of Economic Entomology 62(6):1481-1483.

40098001 Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Inter- pretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Publication 160. 579 p. Author: Mayer, F. Ellersieck, M.

40188501 Tegeris Laboratories, Inc. (1987) One-year Oral Toxicity Study in Purebred Beagle Dogs with AC 6,601: Lab Number: 85010. Un- published study. 778 p.

40397101 Watts, R.; Storherr, R. (1967) Sweep co-distillation cleanup of milk for determination of organophosphate and chlorinated hydro- carbon pesticides. J. of the A.O.A.C. 50(3):581-585.

40397102 Rowlands, D. (1964) The degradation of Malathion on stored maize and wheat grains. J. of the Science of Food and Agriculture 15 (12):824-829.

40397103 Anderegg, B.; Madisen, L. (1983) Effect of insecticide distribution and storage time on the degradation of [Carbon 14] Malathion in stored wheat. J. of Economic Entomology 76(5):1009-1013.

40397104 Norris, M.; Kuchar, E. (1959) Colorimetric estimation of Malathion residues in cottonseed. Agricultural and Food Chemistry 7 (July):488-489.

40397105 Norris, M.; Easter, E.; Fuller, L.; et al. (1958) Colorimetric estimation of Malathion residues in animal products. J. of Agricultural and Food Chemistry 6(2):111-114.

40415701 O'Brien, R.; Dauterman, W. (1961) The metabolism of orally adminis- tered malathion by a lactating cow. Journal of Agr. and Food Chemistry 9(1): 39-42.

40658009 Ruzo, L. (1988) Soil Surface Photolysis of Carbon 14-Trichloro- methyl| Captan in Natural Sunlight: Laboratory Project ID: 231. Unpublished study prepared by Pharmacology and Toxicology Re- search Laboratory. 117 p.

40812001 Siglin, J. (1985) A Teratology Study with AC 6,601 in Rabbits: including Appendix III|: Laboratory Report No. 8171. Unpublished study prepared by Food & Drug Research Laboratories, Inc. 152 p.

40939301 Fletcher, D. (1988) 42-dAY Neurotoxicity Study with AC 6,601 Technical in Mature White Leghorn Hens: Report No. BLAL 87 DN 109. Unpublished study prepared by Bio-Life Associates, Ltd. 69 p.

40939302 Traul, K. (1987) Evaluation of CL 6601 In the Bacterial/Microsome Mutagenicity Test: Study No. 114. Unpublished study prepared by American Cyanamid Co. 32 p.

40941201 Teeter, D. (1988) Malathion (AC 6,601): Hydrolysis: Lab. Rept. No. PD-M 25-59. Unpublished study prepared by American Cyanamid Co.

40944103 Barton, J. (1988) Pesticide Assessment Guidelines Subdivision D: Product Chemistry Requirements for the Manufacturing-use Product, Malathion Insecticide...Physical and Chemical Characteristics: CHDV Volume 28 Report No. 15. Unpublished study prepared by American Cyanamid Co.

40944104 Barton, J. (1988) Pesticide Assessment Guidelines Subdivision D: Product Chemistry Requirements for the Manufacturing-use Product, Cythion Insecticide, The Premium Grade Malathion, AC 6,601...Physical and Chemical Characteristics: CHDV Volume 28 Report No. 18. Unpublished study prepared by American Cyanamid Co. 41 p.

40944106 Drabb, T. (1987) Malathion Solubility. Unpublished study prepared by American Cyanamid Co. 3 p.

40966603 A/S Cheminova (1988) Product Chemistry - Fyfanon Technical: Study No. MVF/00.01.89-Fyfanon. Unpublished updated version of MRID 79251 and 79318. 21 p.

40969301 Miller, G. (1988) Vapor Phase Photolysis of Malathion: Laboratory Report No. PD-M-25-60. Unpublished study prepared by American Cyanamid Co. 17 p.

41029701 Citation Reference: Burgess, D. (1989) Acute Flow-through Toxicity of Cythion 57% EC to Daphnia magna: Report No. 37394. Unpublished study prepared by Analytical Bio-Chemistry Labs Inc. 197 p. Author: Burgess, D.

41054201 Moreno, O. (1989) 21-Day Dermal Toxicity Study with AC 6,601 in Rabbits: Laboratory Report No. MB 88-9191. Unpublished study prepared by MB Research Laboratories, Inc. 155 p.

41126201 Kabler, K. (1989) Determination of Aqueous Solubility of Carbon - 14|-Malathion in Pure Water: ABC Final Report No. 37573. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 160 p.

41160901 Lochry, E. (1989) A Development Toxicity Study with AC 6,601 in Rats: Argus Research Laboratories Protocol 101-005. Unpublished study prepare by Argus Research Laboratories, Inc. p.222

41174301 Bowman, J. (1989) Acute Flow-Through Toxicity of Cythion Technical to Sheepshead Minnow (Cyprinodon variegatus): Report No. 37397. Unpublished study prepared by Analytical Bio-chemistry Laboratories, Inc. 205 p.

41208001 Hoxter, K.; Jaber, M. (1989) Cythion Insecticide (6601 57% EC): Honey Bee Toxicity of Residues of Foliage: Report No. 130-145. Unpublished study prepared by Wildlife International Ltd. 55 p.

41252101 Bowman, J. (1989) Acute Flow-Through Toxicity of Cythion 57% to Sheepshead Minow (Cyprinodon variegatus): Report No. 37396. Un- published study prepared by Analytical Bio-Chemistry Laborato- ries, Inc. 245 p.

41284701 Sweeney, R. (1989) Addendum 1: Cythion Insecticide (AAC6601 57% EC) Honey Bee Toxicity of Residues on Foliage - Malathion...and Malaoxon... in Alfalfa Green Forage and Analysis of Spray Solutions: Lab Project Number: 38212. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 230 p.

41345201 Blumhorst, M. (1989) Adsorption/Desorption Studies-Batch Equilibrum for Malathion: Lab Project Number: 135-001. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 145 p.

41367701 Reddy, V.; Freeman, T.; Cannon, M. (1989) Disposition and Metabolism of Carbon 14|-labelled Malathion in Rats (Preliminary and Definitive Study): MRI Project No. 9354-B; JCSF Study No. 56. Unpublished study prepared by Midwest Research Institute. 117 p.

41389301 Pant, K. (1990) Test for Chemical Induction of Unscheduled DNA Syn- thesis in Rat Primary Hepatocyte Cultures by Autoradiography wi- th AC 6,601: Lab Project Number: 0125-5100. Unpublished study prepared by Sitek Research Laboratories. 41 p.

41422401 Cohle, P. (1989) Early Life Stage Toxicity of Cythion to Rainbow Trout (Oncorhynchus mykiss) in a Flow-through System: Lab Report Number: 37400. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 1068 p.

41451201 Gudi, R. (1990) Acute Test for Chemical Induction of Chromosome Aberration in Rat Bone Marrow Cells in vivo with AC 6,601: Lab Report Number: 0125-1531. Unpublished study prepared by Sitek Research Laboratories. 55 p.

41474501 Forbis, A. (1990) Acute Flow-through Toxicity of Cythion Technical to Mysid Shrimp (Mysidopsis bahia): Lab Project Number: 38414. Unpublished study prepared by Analytical Bio-chemistry Laboratories, Inc. 184 p.

41583401 Schroeder, R. (1990) A Two-generation (Two-litters) Reproduction Study with AC 6,601 to Rats: Laboratory Report No.: 87-3243. Unpublished study prepared by Bio/dynamics, Inc. 2025 p.

41673001 Carpenter, M. (1990) Determination of the Photolysis Rate of (Carbon 14)-Malathion in pH-4 Aqueous Solution: Lab Project No.: 37574. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 535 p.

41695501 Dykes, J.; Kabler, K.; Allen, B. (1990) Determination of the Photolysis Rate on the Surface of Soil with Malathion: Lab Project Number: 37575. Unpublished study prepared by Analytical Bio- Chemistry Labs. 952 p.

41718401 Blakemore, G.; Burgess, D. (1990) Chronic Toxicity of Cythion to Daphnia magna Under Flow-through Test Conditions: Lab Project Number: 37399. Unpublished study prepared by Analytical Bio- Chemistry Laboratories, Inc. 391 p.

41721701 Blumhorst, M. (1990) Aerobic Soil Metabolism Study of Malathion: Lab Project Number: 135-004. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 211 p.

41727701 Rice, F.; Jacobson, B.; Lochhaas, C. (1990) Terrestrial Field Dissipation For Malathion in Cotton (California): Lab Project Number: 38003. Unpublished study prepared by Analytical Bio- Chemistry Laboratories, Inc. 241

41748901 Rice, F.; Jacobson, B.; Lochhaas, C. (1990) Terrestrial Field Dissipation for Malathion in Cotton (Georgia): Lab Project Number 38005. Unpublished study prepared by Analytical Bio- chemistry Laboratories, Inc. 259

41842401 Seely, J. (1991) Histopathologic Evaluation: "The Evaluation of the Chronic Effects of AC 6,601 Administered in the Diet to Sprague- Dawley Rats for 24 Consecutive Months": Lab Project Number: 90- 78. Unpublished study prepared by Pathco, Inc. 888 p.

42015201 Spare, W.; Cutchin, W. (1991) The Volatilization of Malathion from Soil (A Laboratory Study): Lab Project Number: 2901. Unpublished study prepared by Agrisearch, Inc. 163 p.

42058401 Judy, D.; Jacobson, B.; Lochhaas, C. (1991) Combined Aquatic Sedim- ent Field Dissipation and Irrigated Crop Accumulation Study with Malathion (CA): Lab Project Number: 38004. Unpublished study prepared by ABC Labs, Inc. and Pan-Agriculteral Labs. 368 p.

42058402 Judy, D.; Jacobson, B.; Lochhaas, C. (1991) Combined Aquatic Sediment Field Dissipation and Irrigated Crop Accumulation Study with Malathion (MO): Lab Project Number: 38006. Unpublished study prepared by ABC Labs, Inc. and Pan-Agriculteral Labs. 335 p.

42216301 Blumhorst, M. (1991) Anaerobic Aquatic Metabolism Study of Malathion: Lab Project Number: 135-002. Unpublished study prepared by EPL Bio-Analytical Services, Inc. (EPL-BAS). 179 p.

42249901 Wade, B.; Wisk, J. (1992) Effect of Cythion Insecticide 57 Percent EC on New Shell Growth in the Eastern Oyster under Flow-through Conditions: Lab Project Number: 3913032-0200-3140. Unpublished study prepared by ESE, Inc. 52 p.

42271601 Blumhorst, M. (1991) Aerobic Aquatic Metabolism Study of Malathion: Lab Project Number: 135-003. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 155 p.

42317401 Wootton, M.; Johnson, T. (1992) Metabolic Fate and Distribution of (Carbon 14)-malathion in Alfalfa: Lab Project Nos. 420; 1412. Unpublished study prepared by PTRL East, Inc. 221

42482601 Wootton, M.; Johnson, T. (1992) Metabolic Fate and Distribution of (carbon-14) Malathion: Lab Project Number: 421: 1442. Unpublished study prepared by PTRL East, Inc. 250 p.

42538901 Wootton, M.; Johnson, T. (1992) Metabolic Fate and Distribution of ?carbon 14|-Malathion in Lettuce: Lab Project Number: 517: 1482. Unpublished study prepared by PTRL East, Inc.

42581401 Cannon, J.; Murrill, E.; Reddy, V. (1992) Meat and Milk Metabolism Study with (carbon 14)-Malathion in Dairy Goats: Final Report: Lab Project Number: 89 GM 4: 9660-F. Unpublished study prepared by Bio-Life Associates, Ltd. and Midwest Research Institute.

42583401 Wootton, M.; Johnson, T. (1992) Metabolic Fate and Distribution of (carbon 14)-Malathion in Cotton: Lab Project Number: 419: 1379. Unpublished study prepared by PTRL East, Inc.

42715401 Cannon, J.; Murrill, E.; Reddy, V. (1993) Meat and Egg Metabolism Study with (carbon 14)-Malathion in White Leghorn Chickens: Lab Project Number: 89 EM 12: 9660-F: F/R9660.CH. Unpublished study prepared by Bio-Life Associates, Ltd. and Midwest Research Institute.

42744401 Cannon, J.; Murrill, E. (1993) Supplemental Report Meat and Egg Metabolism Study with (carbon 14) Malathion in White Leghorn Chickens: Final Supplemental Report: Lab Project Number: 9660-F. Unpublished study prepared by Midwest Research Institute. 29 p.

42782101 Pederson, C.; Fletcher, D. (1993) AC 6,601 Technnical: Toxicity and Reproduction Study in Mallard Ducks: Lab Project Number: 90 DR 39. Unpublished study prepared by Bio-Life Assocs.

42894601 Barker, W.; Prohonic, K. (1993) Accountability Study of the Proposed Method for the Determination of Malathion (0,0-Dimethyl Phosphorodithioate of Diethyl Mercaptosuccinate) and its Metabolite, Malaoxon, in/on Alfalfa Hay Treated with (Carbon 14)-Radiolabeled Malathion: Final Report: Lab Project Number: 92-0106. Unpublished study prepared by EN-CAS Analytical Lab. 98 p.

43042402 Jacobson, B. (1992) Supplement to: Terrestrial Field Dissipation for Malathion in Cotton: Lab Project Number: 38003: FA-890210. Unpublished study prepared by ABC Labs, Inc. 124 p.

43078702 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Sweet Cherries Harvested After Ground and Aerial Treatment: Lab Project Number: AA920128: 92-0040. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Environmental Labs, Inc. 596 p.

43106401 Forbis, A.; Leak, T. (1994) Uptake Depuration, and Bioconcentration of (carbon 14)-Malathion by Bluegill Sunfish (Lepomis macrochirus) under Flow-Through Test Conditions: Lab Project Number: 40542: XBL-92151. Unpublished study prepared by ABC Labs, Inc. and XenoBiotic Labs, Inc. 96 p.

43106402 Forbis, A.; Leak, T. (1994) Raw Data Report for: Uptake Depuration, and Bioconcentration of (carbon 14)-Malathion by Bluegill Sunfish (Lepomis macrochirus) under Flow-Through Test Conditions: Lab Project Number: 40542R: XBL-92151. Unpublished study prepared by ABC Labs, Inc. and XenoBiotic Labs, Inc. 1096 p.

43107601 Schwab, D.; Lochhaas, C. (1993) Magnitude of Malathion 25WP Residue in Apples: Final Report: Lab Project Number: 40195. Unpublished study prepared by ABC Laboratories, Inc. 84 p.

43107602 Schwab, D.; Lochhaas, C. (1993) Magnitude of Malathion 5-E Residue in Melons: Final Report: Lab Project Number: 40191. Unpublished study prepared by ABC Laboratories, Inc. 101 p.

43107603 Schwab, D.; Lochhaas, C. (1993) Magnitude of Malathion 5-E Residue in Apples: Final Report: Lab Project Number: 40190. Unpublished study prepared by ABC Laboratory.

43108201 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Tart Cherries Harvested after Ground and Aerial Treatment: Lab Project Number: AA920106: 92-053. Unpublished study prepared by EN-CAS Analytical Labs, Inc.

43146701 Lamb, I. (1994) An Acute Neurotoxicity Study of Malathion in Rats: Final Report: Lab Project Number: WIL/206005. Unpublished study prepared by WIL Research Labs, Inc.

43166301 Severn, D. (1993) Overview of the Environmental Behavior of Malathion and Response to EPA's Reviews of Malathion Environmental Fate Studies: Lab Project Number: 38003-29: 38003-28: 38003-27. Unpublished study prepared by Jellinek, Schwartz & Connolly, Inc.

43175501 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Bell Peppers Harvested after Ground Treatment: Lab Project Number: AA920118: 92-0032: 92-0038. Unpublished study prepared by American Agricultural Serv., Inc.; EN-CAS Analytical Labs., Inc.; and Pan-Agricultural Labs, Inc.

43266601 Beattie, G. (1994) A 13-Week Toxicity Study of Aerosolized Malathion Administered by Whole Body Inhalation Exposure to the Albino Rat: Lab Project Number: 90729. Unpublished study prepared by Product Safety Assessment, Bio-Research Labs, Ltd.

43269501 Lamb, I. (1994) A Subchronic (13-Week) Neurotoxicity study of Malathion in Rats: Final Report: Lab Project Number: WIL-206006. Unpublished study prepared by WIL Research Labs.

43340301 Kammerer, R.; Robinson, R. (1994) Procedure for Flow-Through Bluegill Bioconcentration Studies with Radiolabeled Test Substances (Test Substance: (carbon 14)-Malathion): Lab Project Number: XBL92151: RPT00179: 40542. Unpublished study prepared by ABC Laboratories, Inc. and XenoBiotic Laboratories, Inc.

43350401 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Bulb Onions Harvested After Ground Treatment: Lab Project Number: AA920115: 92-0043. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs, Inc.

43350402 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Winter Wheat Raw Agricultural Commodities Harvested After Ground and Aerial Treatment: Lab Project Number: AA920127: 92-0053. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs, Inc.

43360001 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Sorghum Grain Harvested After Ground and Aerial Treatment: Lab Project Number: AA920121: 92-0032. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43360401 Bookbinder, M. (1994) Magnitude of the Residues of Malathion and its Metabolite Malaoxon in/on Potatoes Harvested after Ground Treatment: Lab Project Number: AA920119: 92-0050. Unpublished study prepared by American Agriculture Services, Inc. and EN-CAS Analytical Labs.

43361101 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Sweet Corn Raw Agricultural Commodities Harvested After Ground and Aerial Treatment: Lab Project Number: AA920109: 92-0052. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43362501 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Head Lettuce Harvested After Ground Treatment: Lab Project Number: AA920126: 92-0048. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43362601 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Grass Raw Agricultural Commodities Harvested After Ground and Aerial Treatment: Lab Project Number: AA920113: 92-0058. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43367201 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Leaf Lettuce Harvested after Ground Treatment: Lab Project Number: AA920114: 92/0050. Unpublished study prepared by EN-CAS Analytical Laboratories. 554 p.

43368301 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Strawberries Harvested after Ground Treatment: Lab Project Number: AA920122: 92/0059. Unpublished study prepared by EN-CAS Analytical Laboratories.

43370601 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Cucumbers Harvested after Ground Treatment: Lab Project Number: AA920111: 92/0045. Unpublished study prepared by En-Cas Analytical Lab., American Agricultural Services, Inc.

43372601 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Blueberries Harvested after Ground and Aerial Treatment: Lab Project Number: AA920105: 92/0032. Unpublished study prepared by EN-CAS Analytical Laboratories and American Agricultural Services, Inc.

43372701 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Lima Beans Harvested after Aerial Treatment: Lab Project Number: AA920125: 92/0037. Unpublished study prepared by EN-CAS Analytical Laboratories and American Agricultural Services, Inc.

43372901 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Tomatoes Harvested after Ground Treatment: Lab Project Number: AA920123: 92/0042. Unpublished study prepared by EN-CAS Analytical Laboratories, Inc. and American Agricultural Servicies, Inc.

43376801 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Snap Beans Harvested After Aerial Treatment: Lab Project Number: AA920103: 92-0035. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43383301 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Green Onions Harvested After Ground Treatment: Lab Project Number: AA920116: 92-0035. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs. 568 p.

43383401 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Grapes Harvested After Ground Treatment: Lab Project Number: AA920112: 92-0047. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43383501 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Avocados Harvested After Ground Treatment: Lab Project Number: AA920102: 92-0057. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43414901 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Spring Wheat Raw Agricultural Commodities Harvested After Ground and Aerial Treatment: Lab Project Number: AA920124: 92-0060. Unpublished study prepared by American Agricultural Services, Inc. and En-Cas Analytical Labs.

43417601 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Dry Bean Seeds Harvested After Aerial Treatment: Lab Project Number: AA920104: 92-0034. Unpublished study prepared by American Agricultural Services and EN-CAS Analytical Labs.

43451701 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in Orange Processed Commodities: Lab Project Number: AA920129: 92-0074. Unpublished study prepared by American Agricultural Services, Inc.; EN-CAS Analytical Labs; and The National Food Laboratory, Inc.

43468101 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Rice Raw Agricultural Commodities Harvested After Ground and Aerial Treatment: Amended Report: Lab Project Numbers: AA920120: 92-0039. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43468201 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Field Corn Raw Agricultural Commodities Harvested After Ground and Aerial Treatment: Lab Project Numbers: AA920108: 92-0046: AA920108.IA. Unpublished study prepared by American Agricultural Services, Inc.; and EN-CAS Anlaytical Labs.

43499901 Bookbinder, M. (1994) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Tomato Processed Commodities: Lab Project Number: AA920135: 92-0079. Unpublished study prepared by American Agricultural Services, Inc.; The National Food Lab, Inc.; and EN-CAS Analytical Labs.

43501501 Beavers, J.; Haberlein, D.; Mitchell, L.; et al. (1995) Malathion: A One-generation Reproduction Study with the Northern Bobwhite (Colinus virginianus): Lab Project Number: 232-112A. Unpublished study prepared by Wildlife International, Ltd.

43510501 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Winter Wheat Processed Commodities: Lab Project Number: 92-0080: AA920136: EL6110. Unpublished study prepared by American Agricultural Services, Inc.; EN-CAS Analytical Labs; and Texas A&M University.

43524101 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Potato Processed Commodities: Lab Project Number: AA920138: 92/0075. Unpublished study prepared by American Agricultural Services, Inc., Wm. J. Englar & Associates, Inc., and EN-CAS Analytical Laboratories.

43545201 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and its Metabolite Maloxon in/on Clover Raw Agricultural Commodities Harvested after Ground and Aerial Treatment: Lab Project Number: AA920107: 94-0044. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43546101 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Alfalfa Raw Agricultural Commodities Harvested after Ground and Aerial Treatment: Lab Project Number: AA920101: 92-0031: AA920101.CA1. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs.

43548401 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Grape Processed Commodities: Lab Project Number: 92-0073: AA920133: AA920133.CA1. Unpublished study prepared by American Agricultural Services, Inc.; The National Food Lab, Inc.; and EN-CAS Analytical Labs.

43549001 Clayton, B. (1995) Stability of Malathion and Malaoxon in Various Raw Agricultural Crop Commodities During Six Months of Frozen Storage: (Final Report): Lab Project Number: 93-0038A. Unpublished study prepared by EN-CAS Analytical Labs.

43562301 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Rice Processed Commodities: Lab Project Numbers: AA920137: 92-0077: AA920137.LA1. Unpublished study prepared by American Agricultural Services, Inc.; Texas A&M University; and EN-CAS Analytical Labs.

43577401 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Field Corn Processed Commodities: Lab Project Number: AA920132: 92-0072: AA920132.TX1. Unpublished study prepared by American Agricultural Service, Inc.; Texas A&M University; and EN-CAS Analytical Labs.

43585301 Bookbinder, R. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Cottonseed Processed Commodities: Lab Project Number: AA920131: 92-0071: AA920131.MS1. Unpublished study prepared by American Agricultural Services, Inc.; EN-CAS Analytical Labs; and Texas A&M University. 555 p.

43596601 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Cottonseed Harvested after Ground and Aerial Treatment: Lab Project Number: 92-0033: AA920110: AA920110.AZ1. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Anaytical Labs.

43630301 Humble, G.; Herzig, R. (1995) Independent Laboratory Validation of the Pesticide Analytical Method for Malathion and Malaoxon: Final Report: Lab Project Number: RES9533: ENC-22/94: AA/920117. Unpublished study prepared by AGVISE Labs, Inc. 376 p.

43661401 Rice, F.; Williams, B. (1995) Magnitude of the Malathion and Malaoxon Residues in or on Stored Wheat Grain and Aspirated Grain Fractions: Lab Project Numbers: 41701: FS-41701.SG: ABC 41701. Unpublished study prepared by ABC Labs., Inc.

43666801 Rice, F. (1995) Magnitude of the Malathion and Malaoxon Residues in or on Stored Corn Grain and Processed Commodities: Final Report: Lab Project Number: 41702: FS-41702. Unpublished study prepared by ABC Labs Inc.

43684801 Clayton, B. (1995) Stability of Malathion and Malaoxon in Various Processed Commodities During Six Months of Frozen Storage: Lab Project Number: 93-0038B. Unpublished study prepared by EN-CAS Analytical Labs.

43868601 Nixon, W. (1995) Column Leaching of (carbon 14)-Malathion in Four Soil Types Following Aerobic Aging: Lab Project Number: 951: 1842. Unpublished study prepared by PTRL East, Inc. 163 p.

43910901 Clayton, B. (1996) Stability of Malathion and Malaoxon in Various Raw Agricultural and Processed Commodities During Twelve Months of Frozen Storage: Lab Project Number: 93-0038C. Unpublished study prepared by EN-CAS Analytical Labs.

43942901 Daly, I. (1996) A 24-Month Oral Toxicity/Oncogenicity Study of Malathion in the Rat via Dietary Administration: Final Report: Lab Project Number: 90-3641: J-11 90-3641. Unpublished study prepared by Huntingdon Life Sciences.

43975201 Daly, I. (1996) A 24-Month Oral Toxicity/Oncogenicity Study of Malaoxon in the Rat via Dietary Administration: Final Report: Lab Project Number: 93-2234. Unpublished study prepared by Huntingdon Life Sciences. Relates to L0000076 and 3469901.

43991401 Samoil, K. (1996) Magnitude of Residue: Malathion on Flax: Lab Project Number: 04795: 04795.94-ND02: 4795.94-NDR03. Unpublished study prepared by North Dakota State University, Pesticide Analytical Lab and Dept. of Entomology.

44001101 Samoil, K. (1996) Magnitude of Residue: Malathion on Mushroom: Lab Project Number: PR 4816: 04816: PR 04816. Unpublished study prepared by Interregional Research Project No. 4.

44009601 Samoil, K. (1996) Magnitude of Residue: Malathion on Apple: Lab Project Number: 04768: 04768.94-CA77: 04827.94-CA79. Unpublished study prepared by Interregional Research Project No. 4.

44013701 Samoil, K. (1996) Magnitude of Residue: Malathion on Pear: (Final Report): Lab Project Number: 04827: 04827.94-CAR29: 04827.94-CA79. Unpublished study prepared by Interregional Research Project No. 4.

44016001 Samoil, K. (1996) Magnitude of Residue: Malathion on Peach: Lab Project Number: PR 04826: 04826.90-GA20: 04826.92-MI11. Unpublished study prepared by Interregional Research Project No. 4.

44061201 Samoil, K. (1996) Magnitude of Residue: Malathion on Fig: Lab Project Number: 4793: 04793: 4793.92-CA 118. Unpublished study prepared by IR-4.

44076801 Samoil, K. (1996) Magnitude of Residue: Malathion on Macadamia: (Final Report): Lab Project Number: 04812: PR04812: 92-HI04. Unpublished study prepared by University of Hawaii at Manoa. 287 p.

44094401 Samoil, K. (1996) Magnitude of Residue: Malathion on Strawberry: (Final Report): Lab Project Number: 05152: 5152.92-CAR02: M-1788. Unpublished study prepared by New Jersey Agricultural Experiment Station.

44094801 Samoil, K. (1996) Magnitude of Residue: Malathion on Watercress: (Final Report): Lab Project Number: 04852: PR#04852: 92-FL82. Unpublished study prepared by University of Hawaii at Manoa.

44098401 Samoil, K. (1996) Magnitude of Residue: Malathion on Melon: (Final Report): Lab Project Number: 04815: 4853.92-GA11: 92-TIR08. Unpublished study prepared by New Jersey Agricultural Experiment Station.

44120001 Samoil, K. (1996) Magnitude of Residue: Malathion on Apricot: Lab Project Number: PR 04769: 04769.93-CA48: 04769.93-CAR16. Unpublished study prepared by Interregional Research Project No. 4.

44124801 Samoil, K. (1996) Magnitude of Residue: Malathion on Mint: Lab Project Number: PR 04829: 4829.93-WI19: 4829.93-CAR09. Unpublished study prepared by Interregional Research Project No. 4.

44203901 Samoil, K. (1997) Magnitude of Residue: Malathion on Broccoli: (Final Report): Lab Project Number: 04776: PR 04776: 4776.92-WA28. Unpublished study prepared by Interregional Research Project No. 4.

44205901 Samoil, K. (1997) Magnitude of Residue: Malathion on Pea (Succulent): Lab Project Number: 04823: 92-WI03: 92-CA22. Unpublished study prepared by USDA-ARS and University of Wisconsin.

44232601 Samoil, K. (1996) Magnitude of Residue: Malathion on Cabbage: (Final Report): Lab Project Number: 04778: 91-FL48: 92-NY21. Unpublished study prepared by University of Florida.

44232701 Samoil, K. (1997) Magnitude of Residue: Malathion on Okra: Lab Project Number: 04820: 4820.92-TX15: 4820.94-SC10. Unpublished study prepared by Interregional Research Project No. 4.

44266401 Samoil, K. (1997) Magnitude of Residue: Malathion on Turnip: Lab Project Number: 04847: 4847.92-WA27: 4847.92-OH18. Unpublished study prepared by Interregional Research Project No. 4.

44271101 MSamoil, K. (1997) Magnitude of Residue: Malathion on Mustard Greens: Lab Project Number: 04817: 4817.92-AZ02: 4817.92-SC05. Unpublished study prepared by Interregional Research Project No. 4.

44272401 Samoil, K. (1997) Magnitude of Residue: Malathion on Spinach: Lab Project Number: 04842: 4842.92-NJ02: 4842.93-TX01. Unpublished study prepared by Interregional Research Project No. 4. {OPPTS 860.1500}

44282101 Samoil, K. (1997) Magnitude of Residue: Malathion on Raspberry: (Amended Draft Report): Lab Project Number: 4835.92-WA39: 4835.92-WA40: 04835. Unpublished study prepared by USDA-ARS and Washington State University. {OPPTS 860.1500}

44282201 Samoil, K. (1997) Magnitude of Residue: Malathion on Blackberry: (Amended Draft Report): Lab Project Number: 04774: 4774.92-OR14: 4774.92-OR18. Unpublished study prepared by USDA-ARS; University of California; and Oregon State University. {OPPTS 860.1500}

44331001 Samoil, K. (1997) Magnitude of Residue: Malathion on Papaya: Lab Project Number: 03727: 3727.93-HI02: 3727.93-FL07. Unpublished study prepared by Interregional Research Project No. 4. 562 p.

44383301 Samoil, K. (1997) Magnitude of Residue: Malathion on Walnut: (Final Report): Lab Project Number: 04851: 04851.95-CA71: 4851.92-CA109. Unpublished study prepared by Rutgers University and University of California.

44391501 Samoil, K. (1997) Magnitude of Residue: Malathion on Guava: Lab Project Number: 04799: 4799.93-FL21: 4799.93-HI01. Unpublished study prepared by Interregional Research Project No. 4. {OPPTS 860.1500}

44436101 Samoil, K. (1997) Magnitude of Residue: Malathion on Asparagus: Lab Project Number: 04770: 04770.94.CA80: 94.200. Unpublished study prepared by IR-4 & Rutgers University.

44441601 Samoil, K. (1997) Magnitude of Residue: Malathion on Carrot: Lab Project Number: 04779. Unpublished study prepared by Univ. of California. {OPPTS 860.1500}

44472801 Samoil, K. (1998) Magnitude of Residue: Malathion on Passionfruit: Lab Project Number: A3726: 95-HIO1: 95-FL10. Unpublished study prepared by University of Florida, Tropical Research & Education Center and University of Hawai'i at Manoa.

44478401 Samoil, K. (1998) Magnitude of Residue: Malathion on Chestnut: Lab Project Number: A4783: A4783.95-FLR05. Unpublished study prepared by University of Florida.

44479301 Auletta, C. (1997) Supplemental Information for MRID 43975201: Statistical Analysis of Survivorship and Tumor Incidence Data for Rats from a 24-Month Oral Toxicity and Oncogenicity Study with Malaoxon: Lab Project Number: 93-2234. Unpublished study prepared by Huntingdon Life Sciences.

44480301 Samoil, K. (1998) Magnitude of Residue: Malathion on Mango: Lab Project Number: B4814: B4814.95-FLR16: B4814.94-FLR16. Unpublished study prepared by Univ. of Florida.

44554301 Beattie, G. (1993) A 2-Week Toxicity Study of Aerosolized Malathion Administered Whole-Body Inhalation Exposure to the Albino Rat: Lab Project Number: 90557. Unpublished study prepared by Bio-Research Laboratories Ltd.

44613801 Samoil, K. (1998) Magnitude of Residue: Malathion on Pineapple: Lab Project Number: 04830: 4830.93-VPI02: VPI0009. Unpublished study prepared by Virginia Polytechnic Institute.

45045001 Ehrich, M.; Shell, L.; Rozum, M. et al. (1993) Short-Term clinical and neuropathologic effects of cholinesterase inhibitors in rats. Journal of the American College of Toxicology 12(1).

45046301 Mendoza, C. (1975) Toxicity and Effects of Malathion on Esterases of Suckling Albino Rats. Toxicology and Applied Pharmacology 35.

45554501 Edwards, C. (2001) Malathion Technical In Vitro Mammalian Cell Gene Mutation Test Performed with Mouse Lymphoma Cells: Lab Project Number: 40413. Unpublished study prepared by Scantox.

45566201 Fulcher, S. (2001) Malathion: Effects on Cholinesterase in the CD Rat (Adult and Juvenile) by Oral Gavage Administration: Lab Project Number: CHV067/012452. Unpublished study prepared by Huntingdon Life Sciences, Ltd. Relates to L0000617 and L0000634.

45626801 Robinson, K. (2002) Evaluation of the Embryo-Lethal Potential of Malathion in the Rabbit. Unpublished study prepared by ClinTrials BioResearch,Ltd. {OPPTS 870.3700}

45627001 Fulcher, S. (2002) Malathion: Dose Finding Study in CD Rats by Oral Gavage Administration Preliminary to Developmental Neurotoxicity Study: Lab Project Number: CHV/062. Unpublished study prepared by Huntingdon Life Sciences, Ltd. Relates to L0000581, L0000598, L0000617, and L0000634.

45642901 Desi, I.; Dura, G.; Gonczi, L.; et al. (1976) Toxicity of Malathion to Mammals, Aquatic Organisms and Tissue Culture Cells. Archives of Environmental Contamination and Toxicology 3:410-425.

45642902 Kurtz, P. (1977) Dissociated Behavioral and Cholinesterase Decrements Following Malathion Exposure. Toxicology and Applied Pharamacology 42:589-594.

45646401 Fulcher, S. (2002) Malathion Developmental Neurotoxicity Study in the CD Rat by Oral Gavage Administration: Lab Project Number: CHV006/013331: CHV/066. Unpublished study prepared by Huntingdon Life Sciences Ltd. Relates to L0000813. {OPPTS 870.6300}

45686901 Blasiak, J.; Kowalik, J. (1999) Protective Action of Sodium Ascorbate Against the DNA-Damaging Effect of Malaoxon. Pesticide Biochemistry and Physiology 65:110-118.

45686902 Blasiak, J.; Jaloszynski, P.; Trzeciak, A.; et al. (1998) In Vitro Studies on the Genotoxicity of the Organophosphorus Insecticide Malathion and Its Two Analogues. Mutation Research 445:275-283.

46755601 Citation: Reiss, R. (2006) Estimation of Benchmark Doses for Cholinesterase Inhibition after Dermal Exposure to Malathion: (Rabbit). Unpublished study prepared by Sciences International, Inc.

46790501 Barnett, J. (2006) Percutaneous Repeated Dose 21-Day Toxicity Study of Malathion in Rabbits: Final Report. Project Number: TQC00016. Unpublished study prepared by Charles River Laboratories.

46821701 Reiss, R. (2006) Amended Report for MRID 46755601: Estimation of Benchmark Doses for Red Blood Cell Cholinesterase for Dermal Exposures to Malathion: (Rabbit). Unpublished study prepared by Sciences International, Inc.

Citation References

Ecological Fate and Effect References

Ali Fouad, A.F. and Fukuto, T.R. (1982). Toxicity of O,O,S-trialkyl phosphorothioates to the rat. *J Agric Food Chem* **30**, 126-130.

Aldridge, W.N., Miles, J.W., Mount, D.L., and Verschoyle, R.D. (1979). The toxicological properties of impurities in malathion. *Arch Toxicol* **42**. 95-106.

Bourquin , A.W. (1977). Effects of malathion on microorganisms of and artificial salt-marsh environment. J. Environ. Qual. **4.** 373-378.

Chukwudebe, A., March, R.B., Othman, M., and Fukuto, T.R. (1989). Formation of trialkyl phosphorothioate esters from organophosphorus insecticides after exposure to either ultraviolet light or sunlight. *J Agric Food Chem*. 37. 539-545.

Eichelberger, J.W. and Lichtenberg, J.J. (1971). Persistence of pesticides in river water. *EnvironSci Technol* 5. 541.

Fukuto, T.R. (1983). Toxicological properties of trialkyl phosphorothioate and dialkyl alkyl- and arylphosphonothioate esters. *J Environ Sci Health* B18. 89-117.

Guerrant, G.O., Fetzer, L.E. Jr., and Miles, J.W. (1970). Pesticide residues in Hale County, Texas, before and after ultra-low volume aerial application of malathion. *Pesticides Monitoring Journal* 4. 14-20.

Handbook of Environmental Fate and Exposure Data for Organic Chemicals[1] volume 3. P.H. Howard, Ed., Lewis Publishers. 1991.

Howard, P.H. ed. *Handbook of Environmental Fate and Exposure Data for Organic Chemicals* Volume 3. Lewis Publishers Chelsea Michigan. 1991.

Kearney, P.C., Plimmer, J.R., and Helling, C.S. 1969. Encyc. Chem. Technol. 18. 515 as reported in Matsumura, Fumio. *Toxicology of Insecticides.* Second Edition. Plenum Press, New York. 1985.

Lichtenstein, E.P. and Schulz, K.R. (1964). The effects of moisture and microorganisms on the persistence and metabolism of some organophosphorus insecticides in soil with special emphasis on parathion. *J Econ Entomol* **57**, 618.

Matsumura, Fumio. Toxicology of Insecticides. Second Edition. Plenum Press, New York. 1985.

Miles, C.J. and Takashima, S., 1991. Fate of malathion and O,O,S-trimethyl phosphorothioate by-product in Hawaiian soil and water. *Arch Env Contam and Toxicol*. 20. 325-329.

Mulla, M.S., Mian, L.S., and Kawecki, J.A. (1981). "Distribution, transport, and fate of the insecticides malathion and parathion in the environment" in *Residue Reviews* volume 81. Gunther, F.A. and Gunther, J.D. eds., Springer-Verlag New York.

Muhlman, V.R. and Shrader, G. (1957). Hydrolse der insektiziden phosphorsauresster. *Z. Naturf.* 12. 196-208.

Paschal, D.C., and M.E. Neville. (1976) Chemical and microbial degradation of malaoxon in an Illinois soil. J. Environ. Qual**.** 5:441-443.

Penn State. Study of Off-Site Deposition of Malathion Using Operational Procedures for the Southeastern Cotton Boll Weevil Eradication Program. Aerial Application Technology Laboratory. Department of Entomology. December 1993.

Roberts, J.E., Chisholm, R.D., and Koblitsky, L. (1962). Persistence of insecticides in soil and their effects on cotton in Georgia. *J Econ Entomol* **55**. 153.

State of California Department of Food and Agriculture; Division of Pest Management, Environmental Protection and Worker Safety; Environmental Monitoring and Pest Management Branch (1991). Environmental Monitoring of Malathion Aerial Application Used to Eradicate Mediterranean Fruit Flies in Southern California, 1990. EH 91-3.

State of California Environmental Protection Agency. A Characterization of Sequential Aerial Malathion Applications in the Santa Clara Valley of California. California Department of Food and Agriculture (presently CalEPA). Division of Pest Management, Environmental Protection and Worker Safety. EH-82-01. 1981.

State of California Environmental Protection Agency. Environmental Monitoring Results of the Mediterranean Fruit Fly Eradication Program, Riverside County 1994. Department of Pesticide Regulation. Environmental Hazards Assessment Program. September 1996.

State of California Environmental Protection Agency. *Environmental Monitoring Results of the Mediterranean Fruit Fly Eradication Program, Riverside County 1994*. Department of Pesticide Regulation. Environmental Hazards Assessment Program. September 1996.

State of California Environmental Protection Agency. *Assessment of Malathion and Malaoxon Concentrations and Persistence in Water, Sand, Soil and Plant Matrices Under Controlled Exposure Conditions.* Department of Pesticide Regulation. Environmental Hazards Assessment Program. (Report EH 93-03) February 1993.

Toia, R.F., March, R.B. Umetsu, N., Mallipudi, N.M., Allahyari, R., and Fukuto, T.R. (1980). Identification and toxicological evaluation of impurities in technical malathion and fenthion. *J Agric Food Chem* **28**. 599-604.

U.S. Department of Agriculture. National Boll Weevil Cooperative Control Program: Final Environmental Impact Statement-1991 volume 1. Animal Plant Health Inspection Service. 1991.

U.S. Department of Agriculture. Environmental Monitoring Report: Boll Weevil Cooperative Eradication Program: Texas Lower Rio Grande Valley. Animal Plant Health Inspection Service. 1995.

U.S. Department of Agriculture. Environmental Monitoring Report: Southern Rolling Plains Boll Weevil Eradication Program Animal Plant Health Inspection Service. 1994-1995.

U.S. Department of Agriculture. Environmental Monitoring Report: Texas High Plains Boll Weevil Diapause Control Program. Animal Plant Health Inspection Service. 1995.

U.S. Department of Agriculture. Environmental Monitoring Report: Southeast Boll Weevil Eradication Program. Animal Plant Health Inspection Service. 1993.

U.S. Department of Agriculture. Environmental Monitoring Report: Southeast Boll Weevil Eradication Program. Animal Plant Health Inspection Service. 1996.

U.S. Department of Agriculture. Environmental Monitoring Report: Southeast Boll Weevil Eradication Program Sensitive Sites. Animal Plant Health Inspection Service. 1997.

U.S. Department of Agriculture. Environmental Monitoring Report: Cooperative Medfly Project Florida. Animal Plant Health Inspection Service. 1997.

U.S. Environmental Protection Agency. Pesticides in Ground Water Database - A Compilation of Monitoring Studies:1971- 1991. Office of Prevention, Pesticides, and Toxic Substances, EPA 734-12-92-001, September 1992.

U.S. Environmental Protection Agency. GENEEC: A Screening Model for Pesticide Environmental Exposure Assessment. The International Symposium on Water Quality Monitoring, April 2-5 1995. American Society of Agricultural Engineers. p 485. 1995.

U.S. Environmental Protection Agency. PRZM-3, A Model for Predicting Pesticide and Nitrogen Fate in the Crop Root and Unsaturated Soil Zones: Users Manual for Release 3.0. R.F. Carsel, J.C. Imhoff, P.R. Hummel, J.M. Cheplick, and A.S. Donigian, Jr. National Exposure Research Laboratory, U.S. Environmental Protection Agency, Athens, GA 30605-2720. AQUA TERRA Consultants, Mountain View, CA 94043. Waterborne Environmental, Inc. Leesburg, VA 22075. 1997.

U.S. Environmental Protection Agency. EXPOSURE ANALYSIS MODELING SYSTEM (EXAMS II) User's Guide for version 97.2 Lawrence A. Burns, Ph.D., Research Ecologist, Ecosystems Research Division, National Exposure Research Laboratory, Athens, Georgia. 1997.

U.S. Geological Survey. Pesticides in Surface and Ground Water of the United States: Preliminary Results of the National Water Quality Assessment Program. Pesticides National Synthesis Project. National Water Quality Assessment. 1997.

Umetsu N., Grose, F.H., Allahyari, R., Abu-El-Haj, S., Fukuto, T.R. (1977). Effect of impurities on the mammalian toxicity of technical malathion and acephate. *J Agric Food Chem* **25.** 946-955.

Wang, T.C., Lenahan, R.A., and Tucker, J.W. 1987. Deposition and persistence of aerially-applied fenthion in a Florida estuary. Bull Environ Contam Toxicol. 38. 226-231

Willis and McDowell, 1987. Pesticide Persistance on Foliage. Reviews of Environmental Contamination and Toxicology, Vol. 100.

Bender, Michael E., 1969. The Toxicity of the Hydrolysis and Breakdown Products of Malathion to Fathead minnow - University of Michigan.

Bender, Michael E. 1969. Uptake and Retention of Malathion by the Carp. University of Michigan.

Bender, Michael E. 1976. The Toxicity of Malathion and its Hydrolysis Products to Eastern Mudminnow *Umbra pygmaea* , Virginia Institute of Marine Science.

Beyers, P. & P.Sikoski, 1993. Acetylcholinesterase Inhibition in Federally Endangered Colorado Squawfish exposed to Carbaryl and Malathion.

Beyers, P. 1993. Acetylcholinesterase Inhibition in Federally Endangered Bonytail Chub Exposed to Carbaryl and Malathion.

Bookhout, Cazlyn G. and John D. Costlow Jr., 1976. Effects of Mirex, Methoxychlor and Malathion on Development of Crabs., Duke University and Gulfbreeze Laboratory (USEPA) Pg. 53-69.

Bourke, J.B. et al , 1968. Comparative Metabolism of Malathion - C_{14} in Plants and Animals. New York State Agricultural Experiment Station, Cornell University.

Bourquin, Al W. 1975. Microbial-Malathion Interaction in Artificial Saltmarsh Ecosystems. Gulfbreeze Laboratory, USEPA.

California-Administrative Report 82-2, 1982. Monitored aquatic incidents during broadscale aerial application over San Francisco, Bay area ,1981., Dept. Of Fish and Game, Environmental Services Branch.

Cook, Gary H. and James C. Moore, 1976. Determination of Malathion, Malaoxon, and Mono- and Dicarboxylic Acids of Malathion in Fish, Oyster,and Shrimp Tissue. USEPA Gulfbreeze Laboratory.

Conte, Fred S. and Jack C. Parker, 1975. Effect of Aerially Applied Malathion on Juvenile Brown and White Shrimp, *Penaeus aztecus* and *Penaeus setiferus*. - Texas A&M University (Am. Fisheries Society).

Coppage, D et al 1975. Brain Acetylcholinesterase Inhibition in fish as a Diagnosis of Environmental Poisoning by Malathion. Gulfbreeze Environmental Research Lab.

Coppage, D.L. and T. W. Duke, 1971. Effects of Pesticides in Estuaries Along the Gulf and Southeast Atlantic Coasts. USEPA, Gulfbreeze Laboratory.

Dahlsten, Donald L. 1983. Effects of Malathion Bait Spray for Mediterranean Fruit Fly on Non-target Organisms on Urban Trees in Northern California., University of California.

Darsie, Richard and Coraiden, F. Eugene, 1958. Malathion Toxicity to Killifish in Delaware. Delaware Agricultural Research Station.

Desi, I. et al , 1976. Toxicity of Malathion to Mammals, Aquatic Organism and Tissue Culture Cells. Division of Hygienic Biology, Budapest, Hungary.

Dieter, Michael P., 1975. Use of Enzyme Profiles to Monitor Residues in Wildlife.USFWS, Patuxent Wildlife Research Center.

De Llamas, Monica C. *et al*, 1985. Cholinesterase Activities in Developing Amphibian Embryos Following Exposure to the Insecticides Dieldrin and Malathion. Departmento de Quimica, Facultad de Ingenieria, Universidad Nacional del Comahue, Buenos Aires, Argentina. Achives of Environmental Contamination and Toxicology. Volume 14, 161-166.

Dunachie and Fletcher, 1969.

Eaton, John G., 1970. Chronic Toxicity of Malathion to the Bluegill (*Lepomis macrochirus*). Duluth EPA Lab., Duluth Minnesota.

Engbring, John. 1989. Fluctuations in Bird Populations on the Island of Bota as Related to an Experimental Program to Control The Melon Fly. U.S. Fish and Wildlife Service, Honolulu, Hawaii.

Finlayson, B.J., G. Faggella, H. Jong, E. Littrell, and T.Lew , 1981. Impact on Fish and Wildlife From Broadscale Aerial Malathion Applications in South San Francisco Bay Region, , Pesticide Investigation Unit, Water Pollution Control Laboratory, California Fish and Game Department.

Gary, Norman E. and Eric C., Mussen. 1984. Impact of Mediterranean Fruit Fly Malathion Bait Spray on Honeybees. Dept. of Entomology, Univ. of California, Davis.

Giles, S. and Robert H., Jr., 1970. The Ecology of a Small Forested Watershed Treated with the Insecticide Malathion S^{35}., Published by the Wildlife Society.

Greenburg, J. and. N. Latham, 1968. Malathion - Induced Teratisms in the Developing Chick. University of Ottawa.

Gusey, William F. And Z. Maturgo, 1973. Wildlife Utilization of Croplands. Dept. Of Environmental Affairs, Shell Oil Company.

Hall R.J. and D.R. Clark, 1982. Responses of the Iguanid Lizard, *Anolis caroleninsus* to Four Organophosphorous Pesticides, Environmental Pollution (Ser. A) 28:45-52

Hill, Elwood F. et al., 1971. Effects of Ultra-Low Volume Applications of Malathion in Hale County Texas. Journal of Med Entomology.

Hoff, James and Westman, James, 1965. Dibrom/Malathion Formulation Use as a Piscicide.

Holland, H.T. and Jack Lowe , 1966. Malathion, Chronic Effects on Estuarine Fish -, Gulfbreeze Biological Laboratory.

Jensen, Loren D. and Anden R. Gaufin. 1964. Effects of Ten Organic Insecticides on Two Species of Stonefly Naiads. , Dept. Zoology, University of Utah. (MRID 00065497)

Johansen, C.A. et al. 1965. Bee Poisoning Hazard of Undiluted Malathion Applied to Alfalfa in Bloom. Washington State University College of Agriculture.

Johnson, C.R. 1977. Effects of Field Applied Rates of Five Organophosphorous Insecticides on Thermal Tolerance, Orientation and Survival of *Gambusia affinis*.

Keller, Anne E. , 1995. Toxicity of Malathion to Native Freshwater Mussels.National Biological Survey Laboratory, Gainesville, Florida.

Kennedy, Harry D. and David Walsh. 1970. Effects of Malathion on Two Warmwater Fishes and Aquatic Invertebrates in Ponds. USFWS, Fish Pesticide Research Laboratory, Columbia, Mo.,

Kucera, Emil.1987. Brain Cholinesterase Activity in Birds After a City-Wide Aerial Application of Malathion. Manitoba Dept. of Environment and Workplace Safety and Health.

Kuhajda, B.R. et al 1996. Impact of Malathion on Fish and Aquatic Invertebrate Communities and on Acetylcholinesterase Activity in Fishes in Stewart Creek, Fayette County, Alabama. , Dept. Of Biological Sciences, University of Alabama,

Marliac and Mutchler, 1963. In other studies where malathion was injected into eggs at 50 mg/egg chicks showed shortening of legs and bleaching of feathers .

McEwen, Lowell and Robert L. Brown. 1966. Acute Toxicity of Dieldrin and Malathion to Wild Sharp-tailed Grouse.Journal of Wildlife management. Vol. 30, No. 3, July 1966. MRID 113233

Mehrotra, K. N. et al, 1966. Physiological Effects of Malathion on the House Sparrow *Passer domesticus*.Indian Agricultural Research Institute Delhi, India.

Mitchell and Yutema, 1973. Teratogenic Effects of Malathion and Captan in the Embryo of Common Snapping Turtle.

Mount, Donald I. and Charles Stephan, 1967. A Method for Establishing Acceptable Toxicant Limits for Fish - Malathion and Butoxyethanol Ester of 2, 4-D -U.S. Dept of Interior.

Oshima, R. S. 1982 California Medfly Report.

Parkhurst, Zell and Harlan Johnson. 1955. Toxicity of Malathion 500 to fall Chinook Salmon Fingerlings. USFWS, (Progressive Fish Culturist) .

Parrish, Patrick R., et al., 1977. Chronic Toxicity of Methoxychlor, Malathion, and Carbofuran to Sheepshead Minnow (Cyprinodon variegatus), EG & G Bionomics Marine Research Laboratory, Pensacola, Fla. EPA-600/3-77-059. May 1977.

Parsons, Jack K. and Billy Don Davis, 1971. The Effects on Quail, Migratory Birds and Non-Game Birds from Application of Malathion and Other Insecticides. Texas Parks and Wildlife Dept., Study conducted from 1964 to 1968.

Pawar, Keshore R., *et al*, 1983. Effect of Malathion on Embryonic Development of the Frog *Microhyla ornata* (Dumeril and Bibron). Department of Zoology, University of Poona, India. Bulletin of Environmental Contamination and Toxicology, Volume 31. 170-176.

Post, George and Robert Leasure. , 1974. Sublethal Effects of Malathion to Three Salmonid Species. Colorado State University .

Proctor, Raphael R. Jr., Jane P. Corliss, and Donald Lightner 1966. Mortality of Post larval and Juvenile Shrimp Caused by Exposure to Malathion -A Laboratory and Field Study. National Marine Fisheries Service, Galveston Laboratory.

Rosenbaum, E.A. *et al.* 1988. Early Biochemical Changes Produced by Malathion on Developing Toad Embryos. Archives of Environmental Contamination and Toxicology. Volume 17 831-835.

Rong, Suriyam, Y. et al, 1968. Effects of Insecticides on Feeding Activity of the Guppy, a Mosquito-eating Fish in Thailand - World Health Organization.

Tagatz, M.E., 1974. Effects of Ground Application of Malathion on Saltmarsh Environments In Northwestern Florida. USEPA Gulfbreeze, Environmental Research Laboratory, Gulfbreeze, Florida.

USDA, Environmental Monitoring report. Cooperative Medfly Project Florida, 1997. Spray Operations Hillsborough Area. USDA Report.

Weis, Peddrick and Judith Weiss, 1975.Abnormal Locomotion Associated with Skeletal Malformations in Sheepshead minnow. Rutgers University and New York Ocean Science Laboratory, Montauk, New York.

Walker, W.W. and Stojanovic, B.J., 1974. Malathion degradation by an *Arthrobacter* species. *J. Environ Quality*. **3**. 4-10.

Walker, W.W. and Stojanovic, B.J., 1973. Microbial versus chemical degradation of malathion in soil. *J. Environ Quality*. **2**. 229-232.

Woodward, Dan F., , 1969. Sport Fisheries Research USFWS, Publication 77.

Author Anonymous, 1967. Quarterly Report - USFWS Research Laboratory, Columbia, Mo..

Author Anonymous, 1970. USFWS Sport Fisheries Research Report Publication 106, Wash. DC.

Bender, Michael E., 1969. The Toxicity of the Hydrolysis and Breakdown Products of Malathion to Fathead minnow - University of Michigan.

Bender, Michael E. 1969. Uptake and Retention of Malathion by the Carp. University of Michigan.

Bender, Michael E. 1976. The Toxicity of Malathion and its Hydrolysis Products to Eastern Mudminnow *Umbra pygmaea* , Virginia Institute of Marine Science.

Beyers, P. & P.Sikoski, 1993. Acetylcholinesterase Inhibition in Federally Endangered Colorado Squawfish exposed to Carbaryl and Malathion.

Beyers, P. 1993. Acetylcholinesterase Inhibition in Federally Endangered Bonytail Chub Exposed to Carbaryl and Malathion.

Bookhout, Cazlyn G. and John D. Costlow Jr., 1976. Effects of Mirex, Methoxychlor and Malathion on Development of Crabs., Duke University and Gulfbreeze Laboratory (USEPA) Pg. 53-69.

Bourke, J.B. et al , 1968. Comparative Metabolism of Malathion - C_{14} in Plants and Animals. New York State Agricultural Experiment Station, Cornell University.

Bourquin, Al W. 1975. Microbial-Malathion Interaction in Artificial Saltmarsh Ecosystems. Gulfbreeze Laboratory, USEPA.

California-Administrative Report 82-2, 1982. Monitored aquatic incidents during broadscale aerial application over San Francisco, Bay area ,1981., Dept. Of Fish and Game, Environmental Services Branch.

Cook, Gary H. and James C. Moore, 1976. Determination of Malathion, Malaoxon, and Mono- and Dicarboxylic Acids of Malathion in Fish, Oyster,and Shrimp Tissue. USEPA Gulfbreeze Laboratory.

Conte, Fred S. and Jack C. Parker, 1975. Effect of Aerially Applied Malathion on Juvenile Brown and White Shrimp, *Penaeus aztecus* and *Penaeus setiferus*. - Texas A&M University (Am. Fisheries Society).

Coppage, D et al 1975. Brain Acetylcholinesterase Inhibition in fish as a Diagnosis of Environmental Poisoning by Malathion. Gulfbreeze Environmental Research Lab.

Coppage, D.L. and T. W. Duke, 1971. Effects of Pesticides in Estuaries Along the Gulf and Southeast Atlantic Coasts. USEPA, Gulfbreeze Laboratory.

Dahlsten, Donald L. 1983. Effects of Malathion Bait Spray for Mediterranean Fruit Fly on Non-target Organisms on Urban Trees in Northern California., University of California.

Darsie, Richard and Coraiden, F. Eugene, 1958. Malathion Toxicity to Killifish in Delaware. Delaware Agricultural Research Station.

Desi, I. et al , 1976. Toxicity of Malathion to Mammals, Aquatic Organism and Tissue Culture Cells. Division of Hygienic Biology, Budapest, Hungary.

Dieter, Michael P., 1975 Use of Enzyme Profiles to Monitor Residues in Wildlife.USFWS, Patuxent Wildlife Research Center.

Dunachie and Fletcher, 1969. (Walker (1971)Khera and Lyon(1968)
A number of studies were conducted where malathion or malaoxon were injected into chick embryos,). Malaoxon caused reduced survival of embryos at a concentration of 30 micromoles, and those that did survive had severe abnormalities. Malathion at 30 and 15 micromoles produced less severe abnormalities.

Desi, I. et al 1976. Toxicity of Malathion to Mammals, Aquatic Organism and Tissue Culture .

Eaton, John G., 1970. Chronic Toxicity of Malathion to the Bluegill (*Lepomis macrochirus*). Duluth EPA Lab., Duluth Minnesota.

Engbring, John. 1989. Fluctuations in Bird Populations on the Island of Bota as Related to an Experimental Program to Control The Melon Fly. U.S. Fish and Wildlife Service, Honolulu, Hawaii.

Finlayson, B.J., G. Faggella, H. Jong, E. Littrell, and T.Lew , 1981. Impact on Fish and Wildlife From Broadscale Aerial Malathion Applications in South San Francisco Bay Region, , Pesticide Investigation Unit, Water Pollution Control Laboratory, California Fish and Game Department.

Gary, Norman E. and Eric C., Mussen. 1984. Impact of Mediterranean Fruit Fly Malathion Bait Spray on Honeybees. Dept. of Entomology, Univ. of California, Davis.

Giles, S. and Robert H., Jr., 1970. The Ecology of a Small Forested Watershed Treated with the Insecticide Malathion S^{35}., Published by the Wildlife Society.

Greenburg, J. and. N. Latham, 1968. Malathion - Induced Teratisms in the Developing Chick. University of Ottawa.

Gusey, William F. And Z. Maturgo, 1973. Wildlife Utilization of Croplands. Dept. Of Environmental Affairs, Shell Oil Company.

Hall R.J. and D.R. Clark, 1982. Responses of the Iguanid Lizard, *Anolis caroleninsus* to Four Organophosphorous Pesticides, Environmental Pollution (Ser. A) 28:45-52

Hill, Elwood F. et al., 1971. Effects of Ultra-Low Volume Applications of Malathion in Hale County Texas. Journal of Med Entomology.

Hoff, James and Westman, James, 1965. Dibrom/Malathion Formulation Use as a Piscicide.

Holland, H.T. and Jack Lowe , 1966. Malathion, Chronic Effects on Estuarine Fish -, Gulfbreeze Biological Laboratory.

Jensen, Loren D. and Anden R. Gaufin. 1964. Effects of Ten Organic Insecticides on Two Species of Stonefly Naiads. , Dept. Zoology, University of Utah. (MRID 00065497)

Johansen, C.A. et al. 1965. Bee Poisoning Hazard of Undiluted Malathion Applied to Alfalfa in Bloom. Washington State University College of Agriculture.

Johnson, C.R. 1977. Effects of Field Applied Rates of Five Organophosphorous Insecticides on Thermal Tolerance, Orientation and Survival of *Gambusia affinis*.

Keller, Anne E. , 1995. Toxicity of Malathion to Native Freshwater Mussels.National Biological Survey Laboratory, Gainesville, Florida.

Kennedy, Harry D. and David Walsh. 1970. Effects of Malathion on Two Warmwater Fishes and Aquatic Invertebrates in Ponds. USFWS, Fish Pesticide Research Laboratory, Columbia, Mo.,

Kucera, Emil.1987. Brain Cholinesterase Activity in Birds After a City-Wide Aerial Application of Malathion. Manitoba Dept. of Environment and Workplace Safety and Health.

Kuhajda, B.R. et al 1996. Impact of Malathion on Fish and Aquatic Invertebrate Communities and on Acetylcholinesterase Activity in Fishes in Stewart Creek, Fayette County, Alabama. , Dept. Of Biological Sciences, University of Alabama,

Marliac and Mutchler, 1963. In other studies where malathion was injected into eggs at 50 mg/egg chicks showed shortening of legs and bleaching of feathers.

McEwen, Lowell and Robert L. Brown. 1966. Acute Toxicity of Dieldrin and Malathion to Wild Sharp-tailed Grouse.Journal of Wildlife management. Vol. 30, No. 3, July 1966. MRID 113233

Mehrotra, K. N. et al, 1966. Physiological Effects of Malathion on the House Sparrow *Passer domesticus*.Indian Agricultural Research Institute Delhi, India.

Mitchell and Yutema, 1973. Teratogenic Effects of Malathion and Captan in the Embryo of Common Snapping Turtle.

Mount, Donald I. and Charles Stephan, 1967. A Method for Establishing Acceptable Toxicant Limits for Fish - Malathion and Butoxyethanol Ester of 2, 4-D -U.S. Dept of Interior.

Oshima, R. S. 1982 California Medfly Report.

Parkhurst, Zell and Harlan Johnson. 1955. Toxicity of Malathion 500 to fall Chinook Salmon Fingerlings. USFWS, (Progressive Fish Culturist) .

Parrish, Patrick R., et al., 1977. Chronic Toxicity of Methoxychlor, Malathion, and Carbofuran to Sheepshead Minnow (Cyprinodon variegatus), EG & G Bionomics Marine Research Laboratory, Pensacola, Fla. EPA-600/3-77-059. May 1977.

Parsons, Jack K. and Billy Don Davis, 1971. The Effects on Quail, Migratory Birds and Non-Game Birds from Application of Malathion and Other Insecticides. Texas Parks and Wildlife Dept., Study conducted from 1964 to 1968.

Post, George and Robert Leasure. , 1974. Sublethal Effects of Malathion toThree Salmonid Species. Colorado State University .

Proctor, Raphael R. Jr., Jane P. Corliss, and Donald Lightner 1966. Mortality of Post larval and Juvenile Shrimp Caused by Exposure to Malathion -A Laboratory and Field Study. National Marine Fisheries Service, Galveston Laboratory.

Rong, Suriyam, Y. et al, 1968. Effects of Insecticides on Feeding Activity of the Guppy, a Mosquito-eating Fish in Thailand - World Health Organization.

Tagatz, M.E., 1974. Effects of Ground Application of Malathion on Saltmarsh Environments In Northwestern Florida. USEPA Gulfbreeze, Environmental Research Laboratory, Gulfbreeze, Florida.

USDA, Environmental Monitoring report. Cooperative Medfly Project Florida, 1997. Spray Operations Hillsborough Area. USDA Report.

Weis, Peddrick and Judith Weiss, 1975.Abnormal Locomotion Associated with Skeletal Malformations in Sheepshead minnow. Rutgers University and New York Ocean Science Laboratory, Montauk, New York.

Walker, W.W. and Stojanovic, B.J., 1974. Malathion degradation by an *Arthrobacter* species. *J. Environ Quality*. **3**. 4-10.

Walker, W.W. and Stojanovic, B.J., 1973. Microbial versus chemical degradation of malathion in soil. *J. Environ Quality*. **2**. 229-232.

Woodward, Dan F., 1969. Sport Fisheries Research USFWS, Publication 77.

Author Anonomous,1967. Quarterly Report - USFWS Research Laboratory, Columbia, Mo..

Author Anonomous,1970. USFWS Sport Fisheries Research Report Publication 106, Wash. DC.

Economic and Biologic Analysis References

Biological and Economic Analysis Division, OPPTS/OPP/USEPA. Malathion Quantitative Usage Analysis data prepared in 1997.

Toxicology References

Banerjee, B. D., Pasha, S. T., Hussain, Q. Z., Koner, B. C. and Ray, A. (1998) A comparative evaluation of immunotoxicity of malathion after subchronic exposure in experimental animals. *Indian J. Experimental Biology*, 36, 273-282.

Cabello, G., et al. (2001) A Rat Mammary Tumor Model Induced by the Organophosphorous Pesticides Parathion and Malathion, Possibly through Acetylcholinesterase Inhibition. *Environmental Health Perspectives*, 109(5):471-479.

California Department of Health Services, 1991. *Health Risk Assessment of Aerial Application of Malathion Bait: Summary Report.* February 1991. Available at http://www.oehha.org/pesticides/reports/index.html .

Chanda, SM, TL Lassiter, VC Moser, S Barone, Jr., and S Padilla. 2002. *Tissue carboxylesterases and chlorpyrifos toxicity in the developing rat.* Human and Ecological Risk Assessment (8)(1): 75-90.

Dauterman, W. C. and Main, A. R. (1966). Relationship Between Acute Toxicity and *In Vitro* Inhibition and Hydrolysis of a Series of Carboxy Homologs of Malathion. *Toxicol. Appl. Pharmacol*. 9:408-418.

Rodgers, K. and Xiong, S. (1997) Effect of administration of malathion for 90 days on macrophage function and mast cell degranulation. *Toxicology Letters* 93, 73-82.

Rodgers, K., Amand, K. St., and Xiong, S. (1996) Effects of malathion on humoral immunity and macrophage function in mast cell-deficient mice. *Fundam. Appl. Toxicol*. 31, 252-258.

Rodgers, K. E., Leung, N., Ware, C. F., Devens, B. H., and Imamura, T. (1986) Lack of immunosuppressive effects of acute and subacute administration of malathion on murine cellular and humoral immune responses. *Pestic. Biochem. Physiol*., 25, 358-365.