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Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

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January 2001

Interim Reregistration Eligibility Decision for Fenthion

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-00-011 January 2001

Fenthion Facts

EPA has assessed the risks of fenthion and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. Provided that risk mitigation measures are adopted, fenthion fits into its own "risk cup"-- its individual, aggregate risks are within acceptable levels. Fenthion is not eligible for reregistration at this time but may be pending a decision by the Agency on appropriate mitigation after consultation with stakeholders.

Used as an adult mosquiticide in Florida only, fenthion residues in food and drinking water do not pose risk concerns**.** With mitigation limiting homeowners' and children's exposure via home lawns and other turf, fenthion fits into its own "risk cup." With other mitigation measures, fenthion's worker and ecological risks also would be below levels of concern for reregistration. The Agency is seeking input from stakeholders at a January 17, 2001, meeting on what mitigation measures to impose. EPA will then announce a final determination on the risk mitigation it believes must be adopted in order for products containing fenthion to remain eligible for reregistration.

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

The OP Pilot Public Participation Process

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

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

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

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

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

The fenthion interim decision is being made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk assessments and risk management decisions. EPA continues to work extensively with affected parties to address the risks discussed in this interim decision document, which concludes the OP pilot process for fenthion.

Uses

- An insecticide, fenthion is used to control adult mosquitos in Florida only and dragonfly larvae in contained ornamental fish production ponds in Arkansas, Florida, and Missouri only.

- Annual domestic use is low-- use data from 1990 to 1998 indicate an average of about 246,100 a.i. was used domestically per year (up to 343,100 lbs a.i./year maximum). The average amount used for mosquito control was about 96,500 lbs a.i./year (up to 118.600 lbs a.i./year maximum).

Health Effects

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

Ecological Effects

- Fenthion is very highly toxic to birds and highly toxic to estuarine/marine invertebrates and non-target organisms. The mosquito adulticide use of fenthion has been implicated in several bird kill incidents, including recent bird kills on Marco Island, Florida. These kills on Macro Island are currently under investigation by the US Fish and Wildlife Service.

Risks

- Dietary exposures from eating food crops exposed to fenthion are above the level of concern for the entire U.S. population, including infants and children. However, these uses are being voluntarily cancelled by the registrant, and the Agency will not refine the fenthion dietary exposure analyses. Drinking water is not a significant source of exposure.

- Although there are no homeowner uses for fenthion, residential exposure to adults and children can occur because fenthion is used in mosquito control operations that involve wide area adulticide applications to residential areas in Florida. Risks are of concern for homeowners performing yard work and playing or performing other recreational activities (i.e., golfing) on the treated areas. Risks are also of concern for children engaging in activities in areas not limited to their residence (i.e., parks) treated with fenthion.

- EPA also has risk concerns for workers who mix, load, and/or apply fenthion for both aerial and ground mosquito adulticide applications.

- There are potential risk concerns for acute dietary risks to birds, freshwater invertebrates and estuarine/marine invertebrates at maximum aerial and/or ground applications.

Risk Mitigation

In order to support a reregistration eligibility decision for fenthion, the following risk mitigation measures are being considered and will be discussed at the upcoming stakeholder meeting:

- To mitigate risks to workers who mix, load and apply fenthion for ground and aerial applications:
  - require generic mixer/loader/applicator exposure data for all mosquito pesticide applications;
  - handlers must use closed systems only. The current labels give protective clothing statements for both closed system and non-closed systems. The Agency believes that requiring closed systems for all types of mosquito control applications will result in less exposure to workers;
  - add a prohibition of human flaggers to the label;
  - change the use rate on the label to allow the highest rate only for public health use (i.e., with confirmation of mosquito-vectored diseases).

- To mitigate risks from aquaculture use:
  - eliminate the backpack sprayer method of application;
  - require a handwand sprayer.

- To mitigate risks to residential bystanders:
  - require chemical-specific deposition and turf transferrable residue studies to refine the risk assessment;
  - require a developmental neurotoxicity study;
  - change the use rate on the label to allow the highest rate only for public health use (i.e., with confirmation of mosquito-vectored diseases).

- To mitigate ecological risks:
  - require avian reproduction studies for the northern bobwhite and the mallard to refine the risk assessment;
  - require three acute toxicity studies for the mysid shrimp: one using a formulation, one using the sulfoxide degradate, and one using the suflone degradate.

- restrict the use of fenthion to mosquito control districts in Florida that have developed a plan to identify critical/sensitive bird habitats and endangered species in their counties and have addressed ways to avoid exposure to those areas;
- change the use rate on the label to allow the highest rate only for public health use (i.e., with confirmation of mosquito-vectored diseases);
- require buffer zones to protect aquatic organisms, especially invertebrates;
- require certain label changes to improve applications and lessen risk to non-target organisms.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The fenthion IRED therefore is issued in final (see www.epa.gov/REDs/ or www.epa.gov/pesticides/op) without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.

- The Agency is sponsoring a public stakeholder meeting to gather information and hear concerns and comments about risks and possible risk mitigation for fenthion. This meeting will be held on January 17, 2001, from 9:00 am to 5:00 pm at the Embassy Suites, 8978 International Drive, Orlando, Florida 32819.

- The Agency will revoke all fenthion tolerances because the registrant has agreed to cancel all food uses. When the cumulative risk assessment for all organophosphate pesticides is completed, EPA may need to pursue further risk management for fenthion.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide fenthion. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on October 21, 1999. Additionally, the American Mosquito Control Association sponsored a Stakeholder Meeting in Orlando, Florida on October 13, 1999, where the Agency presented the results of the revised human health and environmental effects risk assessments to the general public. This Stakeholder Meeting concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on October 21, 1999, and closed on December 21, 1999.

Based on its review, EPA believes that the current use of fenthion poses unreasonable adverse effects to human health and the environment, unless steps are taken to mitigate these risks. For fenthion, the Agency is issuing its interim decision on reregistration eligibility, tolerance reassessment, and risk management in two phases. First, EPA is publishing its interim decision on tolerance reassesment for fenthion, which addresses risks from exposure to fenthion-treated livestock food items. Second, EPA is also publishing its proposed strategy to manage the remaining risks from fenthion use (occupational, residential, and environmental), which provides for an additional stakeholder involvement process to begin in the near future. The Agency believes this risk management strategy will support an interim decision on the reregistration eligibility of fenthion. EPA's risk management strategy outlines the Agency's proposal on risk mitigation, then provides for a stakeholder involvement process that will begin shortly -- this public process will provide an opportunity for stakeholders to discuss the Agency's proposed risk mitigation measures and determine the best methods for reducing the risks associated with fenthion. Following this process, EPA will announce the specific risk mitigation measures that will need to be implemented in order for fenthion to be eligible for reregistration. The enclosed “Interim

Reregistration Eligibility Decision for Fenthion" which was approved on September 29, 2000, contains the Agency's decision on the individual chemical fenthion. The reregistration eligibility decision will be finalized once the cumulative assessment for all of the organophosphate pesticides is completed because of exposure to children from the mosquito use.

A Notice of Availability for this Interim Reregistration Eligibility Decision for Fenthion is published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502C), USEPA, Ariel Rios Buliding, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the interim RED and all supporting documents are available on the Internet. See http:www.epa.gov/REDs.

The interim RED is based on the updated technical information found in the fenthion public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for fenthion (revised as of October 13, 1999)**,** and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For fenthion, a proposal was submitted by Bayer Corporation Agriculture Division, the technical registrant. Comments on mitigation or mitigation suggestions were submitted by various mosquito control districts in Florida, Florida Department of Agriculture & Consumer Services, Florida Department of Environmental Protection, Florida Mosquito Control Association, American Mosquito Control Association, Health Canada-Pest Management Regulatory Agency, American Bird Conservancy, other bird conservation organizations, and private citizens.

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

Please note that the fenthion risk assessment and the attached interim RED concern only this particular organophosphate. All food uses of fenthion will be cancelled and therefore, the final tolerance assessment is included in this document. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of fenthion. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a

common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing the risk assessments for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks that have already been attributed to current uses of fenthion.

The Agency believes that currently registered uses of fenthion pose unreasonable adverse effects to human health and the environment, and that mitigation measures are necessary. The Agency will conduct a public process in the near future to identify the best ways to reduce the risks associated with fenthion exposure. The process will include a public comment period on the risk mitigation proposed in this interim RED, as well as a stakeholder meeting. At the conclusion of this process, the Agency will announce a final determination on the risk mitigation it believes must be adopted in order for products containing fenthion to remain eligible for reregistration. Also, if new information comes to the Agency's attention, or if data requirements for registration (or the guidelines for generating such data) change during this time, EPA may take appropriate regulatory action and/or require the submission of additional data to support the reregistration of fenthion products.

This document contains a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. For product-specific DCIs, the first set of required responses is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI. Note that a generic DCI is not being issued at this time. Generic data requirements for fenthion will be called in after the public stakeholder meeting has been held.

If you have questions regarding this document, please contact the Chemical Review Manager, Tracy Truesdale at (703) 308-8073. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Jane Mitchell at (703) 308-8061.

Lois A. Rossi, Director
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Reregistration Division

Attachment

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for
Fenthion

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
:g/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its interim decisions on reregistration eligibility, tolerance reassessment, and risk management for fenthion. The decisions outlined in this document include the final tolerance reassessment decision for fenthion because the registrant has agreed to cancel all food uses for the chemical, and thus, all fenthion tolerances will be revoked. The Agency may need to pursue further risk management for fenthion, however, once the cumulative assessment of the organophosphate pesticides is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on fenthion. After considering the revised risks, as well as mitigation proposed by Bayer Corporation Agriculture Division, the technical registrant of fenthion, and comments and mitigation suggestions from other interested parties including various mosquito control districts in Florida, Florida Department of Agriculture & Consumer Services, Florida Department of Environmental Protection, Florida Mosquito Control Association, American Mosquito Control Association, Health Canada-Pest Management Regulatory Agency, American Bird Conservancy, other bird conservation organizations, and private citizens, EPA developed its risk management strategy for uses of fenthion that pose risks of concern. This strategy is discussed fully in this document.

The Agency believes that certain uses of fenthion, as specified in this document pose unreasonable adverse effects on human health and the environment, and will be ineligible for reregistration, unless measures are taken to mitigate these risks. Accordingly, the Agency will conduct a public involvement process to discuss and identify the best ways to reduce the risks associated with the use of fenthion. This document outlines EPA's risk management strategy, which includes its own proposal on risk mitigation, to be followed by a public comment period and stakeholder meeting in the near future. Following the conclusion of this public process, the Agency will announce its final determination on the risk mitigation measures it believes must be adopted to support a final reregistration eligibility decision.

Fenthion is an organophosphate insecticide used as a mosquito adulticide in the state of Florida. There were also registrations for three granular mosquito larvicide products; however, these were recently voluntarily cancelled by the registrant, Amvac. Fenthion is also used to control lice, flies, and ticks on cattle and swine. As a result of this reregistration process, these livestock products were voluntarily cancelled (by Bayer) and will be phased out over the next two years. Special Local Need registrations exist for the states of Florida, Arkansas, and Missouri to control dragonfly larvae in contained ornamental fish production ponds (i.e., aquaculture). There was also an avicide product (Rid-A-Bird Perch) which was cancelled in 1998. Use data from 1990 to 1998 indicate an average of about 246,100 lb a.i. was used domestically per year (up to 343,100 lb a.i./year maximum). The average amount used for mosquito control was about 96,500 lb a.i./year (up to 118,600 lbs a.i./year maximum).

Overall Risk Summary

EPA's human health risk assessment for fenthion indicates some risk concerns. Both acute and chronic dietary risks were of concern; however, as stated above, all livestock products have been voluntarily cancelled, which eliminates all dietary exposure. The Agency does not have risk concerns about the exposure of adults and children to fenthion from drinking water because of the conservative nature of the screening-level models, and the fact that only minor exposure to surface water is possible due to the application rate and method of the chemical. Applications of fenthion are typically ULV (ultra low volume) and very little of the chemical is deposited on the ground. Because fenthion is applied as a wide area mosquito adulticide, the Agency conducted a residential post-application risk assessment. This assessment indicates a slight risk to toddlers for intermediate-term exposures at the maximum use rate. The Agency also has concern for workers who mix, load, and apply fenthion for mosquito control and for aquaculture. Ecologically, the Agency has concerns for risk to birds and aquatic invertebrates from the use of fenthion.

To mitigate risks of concern posed by the uses of fenthion, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties. Given the high toxicity of fenthion and potential risks posed to workers, residential bystanders, birds and aquatic invertebrates, a number of mitigation measures are proposed by the Agency. However, since fenthion has significant public health benefits and there are few alternatives available, the Agency believes it is important that a broad stakeholder process be conducted to discuss the risk mitigation measures outlined in this interim RED and/or develop other workable mitigation measures that adequately protect those at risk. The proposals outlined in this document are the Agency's ideas on the best ways to reduce the risks of concern identified. These measures will be discussed as a part of the public comment and stakeholder meeting mentioned above.

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water exceed the Agency’s level of concern for the general U.S. population and all population subgroups, including infants and children. For acute risk, the most highly exposed subgroup is children 1-6 years at 800% aPAD (at the 99.9th percentile). For chronic risk, the most highly exposed subgroup is children 1-6 years at 270% cPAD. On July 13, 2000, the technical registrant (Bayer) requested a phased voluntary cancellation of all five of their livestock products. Two products will be cancelled immediately, both with a 1-year existing stocks provision. The other three products will be cancelled effective December 31, 2000, each with a 1 year existing stocks provision. Therefore, this is essentially a 2-year phase out of all fenthion livestock products. The Agency feels that allowing a 2-year phase out is justified because of the conservative nature of the risk assessment.

Residential Post-Application Risk

Although there are no homeowner uses, residential exposure assessments were conducted to permit risk calculations reflecting the use of fenthion as a residential wide area mosquito adulticide. There are no risk concerns for exposure of adults associated with any treatment scenario. For toddlers, the combined intermediate-term risk from dermal, hand-to-mouth, object-to-mouth, and ingestion exposures resulting from aerial mosquito control applications results in an MOE of 257 (where the level of concern is 300). Even though this number slightly exceeds the Agency's level of concern, the Agency does not have serious concerns for this scenario for the following reasons. The Agency believes that the inputs and approaches used to calculate the exposures for each scenario result in worst case estimates of exposure. The Agency also believes that adding together individual exposure values that are thought to be conservative results in a very conservative estimate of aggregate exposure. In addition, information from mosquito control districts in Florida indicates that the maximum use rate is only used under situations of heavy pest infestation and a lower (typical) rate is generally used. Restricted Entry Intervals (REIs) are not appropriate for a residential exposure situation. Deposition studies and chemical-specific turf transferrable residue studies will be required in a generic mosquito pesticide DCI. In addition, the Agency proposes to lower the use rate, except for situations of public health emergency.

Occupational Risk

Occupational exposure to fenthion is of concern to the Agency. For the mosquito control use of fenthion, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern (i.e., MOEs are less than 100 for short-term exposures and less than 300 for intermediate-term exposures). The Agency does not have worker exposure data which is specific to mosquito applications. Because this type of application varies greatly from agriculture type situations, the Agency is requiring generic mixer/loader/applicator exposure data to be submitted for all mosquito pesticide applications. To further mitigate risk to handlers for mosquito adulticide applications of fenthion the Agency proposes that handlers use closed systems at all times. The Agency proposes to lower the application rate, except for situations of public health emergency. In addition, the use of fenthion in aquaculture exceeds the Agency's level of concern. To mitigate risk to handlers for aquaculture applications, the Agency proposes that the backpack sprayer method of application be eliminated.

Ecological Risk

Ecological risks are also of concern to the Agency. Fenthion is very highly toxic to birds and highly toxic to estuarine/marine invertebrates. Based on previous bird kill incidents and a recent report of bird kills from Florida, the Agency proposes the following actions to protect birds from fenthion: restrict the use of fenthion to certain mosquito control districts in Florida that have developed a plan to identify critical/sensitive bird habitats and endangered species in their counties and address ways to avoid exposure to these areas; only allow the highest use rate for public health use; require certain label

changes to improve applications and lessen risk to non-target organisms; and require buffer zones to protect aquatic organisms, especially invertebrates.

Also, the Agency is requiring the following ecological effects studies to be submitted for fenthion: avian reproduction studies with the northern bobwhite and the mallard, and 3 acute toxicity studies with the mysid shrimp: 1 testing a formulation, 1 testing the sulfoxide degradate, and 1 testing the sulfone degradate.

Summary of Benefits of Fenthion Use - Public Health

Fenthion is considered to be a public health pesticide. The Food Quality Protection Act (FQPA) defines a public health pesticide as a minor use pesticide used predominantly in public health programs for vector control or other health protection uses. FQPA requires EPA to weigh the risks of a public health pesticide against the health risk of the disease to be controlled. FQPA also amends the definition of unreasonable adverse effects on the environment by specifying that the risks and benefits of public health pesticides be considered separate from the risks and benefits of other pesticides. EPA is also required to consult with the Department of Health and Human Services (DHHS) before suspending or cancelling a public health pesticide for failure to provide data or meet conditions of registration, if requested by a registrant of any other interested party.

The threat of spread of mosquito-vectored diseases is particularly great in Florida because the mild climate supports year-round mosquito populations. Targeted species include nuisance salt marsh mosquitoes and the vectors of St Louis Encephalitis, Venezuelan Equine Encephalitis, Eastern Equine Encephalitis, Malaria, Yellow fever, West Nile Virus, and Dengue. Monitoring programs for the above vectors and diseases are in place. Fenthion is particularly effective against salt marsh mosquitoes which are nuisance and Venezuelan Equine Encephalitis vectoring pests over most parts of the state, and the vector for St. Louis Encephalitis which is also widespread. The last widespread epidemic of St. Louis Encephalitis in Florida occurred in 1990, with 223 human cases and 11 deaths.

The Agency is issuing this interim Reregistration Eligibility Document (IRED) for fenthion, as announced in a Notice of Availability published in the *Federal Register*. To further discuss risk mitigation for fenthion, a stakeholder meeting process will be held in the near future. Tolerance reassessment for fenthion is included in this document because all food uses have been cancelled; however, the reregistration eligibility decision for fenthion cannot be considered final until the cumulative risk assessment for all organophosphate pesticides is complete because of exposure to children from the mosquito use. The cumulative assessment may result in further risk mitigation measures for fenthion.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

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

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

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments

- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

In addition to the policy issues that resulted from the TRAC process, the Agency issued on September 29, 2000, a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's baseline approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides, and the Agency expects that other types of chemicals will be handled similarly. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals will be necessary for most uses where current risk assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this interim RED are consistent with the Pesticide Registration Notice.

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

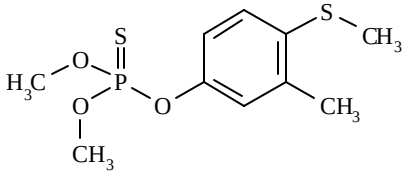
II. Chemical Overview

A. Regulatory History

Fenthion was first registered in the United States in 1965 as a contact and systemic organophosphate insecticide/acaricide for mosquito and insect control on swamps, standing water, recreation areas, alfalfa, pasture grass, forests, barns, poultry houses, nonfood areas of commercial buildings, restaurants, and homes; for lice control on cattle (beef and non-lactating dairy) and hogs; for control of ants, mites, leafhoppers, and aphids on ornamentals and flowers; for bird control; and for use on rice to control mosquitoes (in the State of California only). A Registration Standard was issued in June1988. In the Registration Standard, the Agency classified all fenthion end-use products as Restricted Use pesticides based on avian, fish and aquatic invertebrate toxicity. The avicide product (Rid-A-Bird) was cancelled in March 1999. All other uses except the mosquito adulticide use in Florida and direct livestock treatment were voluntarily cancelled by the registrant in response to the Registration Standard.

B. Chemical Identification

FENTHION:



- **Common Name:** Fenthion
- **Chemical Name:** *O,O*-dimethyl *O*-(4-(methylthio)-*m*-tolyl)phosphorothioate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 55-38-9
- **OPP Chemical Code:** 053301
- **Empirical Formula:** $C_{10}H_{15}O_3PS_2$
- **Molecular Weight:** 278.3g/mole
- **Trade and Other Names:** Baytex
- **Basic Manufacturer:** Bayer Corporation Agriculture Division

Pure fenthion is a yellow-tan liquid with a slight garlic odor. The melting point is <-25° and the boiling point is 105°C at 0.01 mm Hg. Fenthion is practically insoluble in water, and is soluble in methanol, ethanol, ether, acetone, and many other organic solvents (especially chlorinated hydrocarbons). Fenthion is stable up to 210°C, and resistant to alkali up to pH 9.0.

C. Use Profile

The following information is based on the currently registered uses of fenthion, including those that have been voluntarily cancelled as a result of the recent risk assessments. Risk assessments for the recent cancelled uses will be presented in this document.

Type of Pesticide: Insecticide.

Summary of Use Sites:

Food: Livestock lice/fly/tick control: As a result of the recent risk assessment, this use has been voluntarily cancelled. Fenthion was registered to control lice, horn and face flies, and Gulf Coast ticks on cattle and swine.

Public Health: Fenthion is registered for use as a mosquito adulticide in Florida only. Fenthion is only registered for use in Florida due to a marketing decision made several years ago by the registrant, Bayer. Three granular mosquito larvicide products were recently voluntarily cancelled; these products were rarely used in the U.S.

Residential: Although there are no homeowner uses, residential post-application exposure is expected from use of fenthion as a residential wide area mosquito adulticide.

Other Non-food: State Local Need registrations exist in Florida, Arkansas, and Missouri to control dragonfly larvae in baitfish culture and ornamental tropical fish aquaculture.

Target Pests: adult mosquitoes (specifically *Culex nigripalpus* and *Aedes sp.*), mosquito larvae, cattle lice, horn and face flies, Gulf Coast ticks, and dragonfly larvae.

Formulation Types Registered: One technical product and one soluble concentrate are currently registered for adult mosquito control in Florida. The remaining products, a technical for livestock products, 3 granulars, 2 ready-to-use products, 1 soluble concentrate, and 1 impregnated ear tag have been voluntarily cancelled.

Method and Rates of Application:

Mosquito Control Applications:

Equipment: Aerial or ground-based Ultra-Low Volume (ULV) mosquito adulticide applications account for a vast majority of the mosquito control applications. Aerial thermal foggers are also used for adulticide applications. Aerial and ground-based applications of granulars as a larvicide have been voluntarily cancelled.

Rates: Aerial ULV application rates range from 0.05 to 0.10 lb ai/acre. The ground-based ULV maximum application rate is 0.03 lb ai/A. The aerial thermal fogging application rate is also 0.03 lb ai/acre. Aerial ULV applications require that between 0.66 and 1.3 oz formulation/A be applied while ground ULV application volumes rage from 1.2 oz/minute to 3.6 oz/minute depending on the selected sprayer groundspeed. Aerial thermal fogging applications require that 0.4 oz formulation/A be applied in conjunction with up to 0.8 quarts of fuel oil.

Both aerial and ground applications of granular materials for mosquito control were at a rate of 0.1 lb ai/A. Granular applications required that from 5 to 10 pounds of formulated product be applied aerially or by ground for mosquito control depending upon the product selected. As stated above, the granular products have been cancelled.

Direct Animal Treatments: As stated previously, these uses have been voluntarily cancelled and will be phased out over a 2 year period.

Applications: Applications for pest control on food animals are made by pouring or otherwise directly ladelling solutions onto the backs of the target animals (i.e., ready-to-use or prepared aqueous application solutions). Impregnated ear tags are also used.

Rates: Application rates for the ready-to-use formulations on livestock range up to 0.089 oz (0.0014 lb ai)/100 lb on cattle. Using the average cattle weight of 600 pounds per animal, the maximum application rate for the ready-to-use formulation is 0.0084 lb ai/animal (calculated using 2 lb ai/gallon in formulation). The pour-on specifies a dilution of 0.5 gallons formulation for every 4.5 gallons dilute solution prepared where each such dilution can treat up to 258 animals depending upon size. The maximum application rate for the ladel-on formulation, which equates to the use of 1 oz of dilute solution per 100 cattle pounds, is (0.00067 lb ai)/100 lb. Again, using an average cattle weight of 600 pounds per animal, the application rate for the ladel-on formulation is 0.004 lb ai/animal (calculated using 0.77 lb ai/gallon in

formulation). Each impregnated ear tag weighs 15 grams and contains 20 percent fenthion. Each animal is treated using two ear tags. As such, the application rate is 6 grams ai or 0.013 lb ai per animal.

Aquaculture Treatments:

Applications: Applications in aquaculture are intended for the control of larval dragonflies in commercially operated freshwater ponds. The use is only for ornamental fish or baitfish. Applications are made prior to stocking ornamental fish such as koi carp, goldfish, comets, shubunkins, fantails, and baitfish such as shiners and minnows. The only labels for this use are Section 24C (Special Local Need (SLN)). The concentration of fenthion in each labelled product is 95 percent active ingredient. The material is diluted and applied by handheld equipment to obtain an even distribution in the treated ponds. For risk assessment purposes, the Agency has completed calculations using low pressure handwand and backpack sprayers as the method of application.

Rate: The application rate is based on achieving a water concentration of 0.1 ppm. If a 5 acre pond that is 3 feet deep is treated, a total of 52.5 ounces of formulation in sufficient water to enable uniform application to the pond is needed to complete the application (i.e., 4 pounds of active ingredient). Single applications are allowed 2 to 4 days prior to stocking.

Use Classification: Fenthion is a restricted-use organophosphate insecticide.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of fenthion, based on available pesticide usage information for 1990 through 1998. A full listing of all uses of fenthion, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Usage Analysis" document, which is available in the public docket. Approximately 246,100 lb. a.i. of fenthion are used annually with a maximum annual use of 343,100 lb. a.i.

Annual Poundage:	**Average**	**Maximum**
Total:	246,100 lb. a.i.	343,100 lb. a.i.
Mosquito control:	96,500 lb. a.i.	118,600 lb. a.i.
Livestock:	148,000 lb. a.i.	222,100 lb. a.i.
Pour-on:	136,600 lb. a.i.	204,900 lb. a.i.
Ear tag:	11,400 lb. a.i.	17,200 lb. a.i.

Fenthion is used for adult mosquito control in the state of Florida only. Ten out of 52 mosquito control districts in Florida used fenthion in 1998. Only seven districts used fenthion in 1999. Maximum annual percent livestock treated numbers are: 12% beef cattle (9.5% pour-on and 2.5% ear tags), 4% dairy cattle (ear tag only), and 9% swine (pour-on).

The sources of usage data for fenthion are: 1) American Mosquito Control Association (AMCA) 1998 Survey; 2) Florida Coordinating Council on Mosquito control ("Florida Mosquito Control", 1998 white paper); 3) Registrants; 4) various Florida Mosquito Control Districts; 5) Certified/Commercial Pesticide Application Survey 1993; and 6) EPA internal & proprietary data.

III. Summary of Fenthion Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide fenthion, as fully presented in the documents, "Human Health Risk Assessment: *Fenthion*," dated October 13, 1999, and "Transmittal of EFED RED for the list A Chemical Fenthion,"dated May 1, 1996 (and addenda thereto). The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

These risk assessments for fenthion were presented at an October 13, 1999 Stakeholder Meeting in Orlando, Florida, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's interim risk management decision for fenthion only; the Agency must complete a cumulative assessment of the risks of all the organophosphate pesticides before other final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for fenthion in August, 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. The only revision that was made based on public comment was the correction of the typical use rate. All other revisions were made as a result of further internal review or policy changes. Major revisions to the human health risk assessment are listed below:

- **Human Study Issue:** The body of fenthion toxicology data includes a 28-day human study. It is current Agency policy to make no final regulatory decision based on a human study until a new policy has been developed to ensure that such studies meet the highest scientific and ethical standards. This new policy is not yet in place, so the Agency has selected doses and endpoints to calculate dietary and non-dietary risk based solely on animal studies. In the preliminary fenthion human health risk assessment, released before the current Agency policy was articulated, this study provided the endpoint from which the

Reference Doses (RfDs) and Population Adjusted Doses (PADs) were calculated. In the refined fenthion risk assessment presented here, this study and its role in the assessment have been reconsidered.

S **Dermal Absorption Factor**: The dermal absorption factor was changed from 20% to 3%. The following discussion provides a rationale for the use of a 3% dermal absorption factor for risk assessment purposes.

The fenthion database does not contain a dermal absorption study and therefore a dermal absorption factor had to be calculated. Based on the toxicity data available for fenthion, the use of the default 100% dermal absorption factor is not appropriate because it substantially overestimates the toxicity of this compound via the dermal route. In a special study conducted in the rat, a comparison of the extent of cholinesterase inhibition after a single dose of fenthion via either the dermal or the oral route was evaluated. Here, an absorption factor of 20% was calculated by using an oral LOAEL of 5 mg/kg (NOAEL = 1 mg/kg) and a dermal LOAEL of 25 mg/kg (NOAEL = 5 mg/kg). However, this estimate is not adequate for use in short or intermediate term risk assessment due to the duration of the treatment (single dose) in this study, in contrast to the multiple day exposure scenarios assessed in the risk assessment.

The dermal risk assessments are based on oral NOAELs established in a study conducted in monkeys. Since oral NOAELs were selected, the 20% dermal absorption factor would be used for route-to-route extrapolation. Use of this dermal absorption factor yields dermal equivalent doses which are unrealistically low and are not consistent with the toxicity profile seen for fenthion or other related OPs.

During the September 16, 1999 HIARC meeting, a 3% dermal absorption factor was calculated based on the comparison of the oral developmental LOAEL in a rabbit study and the LOAEL in a 21-day dermal toxicity study in rabbits using the technical grade compound based on the common endpoint of cholinesterase inhibition. Though it is recognized that the use of a 21-day dermal toxicity study in rabbit is not optimal for deriving a dermal absorption factor, given the currently available data it was found to yield a more realistic estimate of dermal absorption.

More information on the dermal absorption factor can be found in the document entitled "Fenthion- Extrapolation of dermal absorption factor for use in risk assessment" dated July 26, 2000.

S **Unit Exposure Values**: EPA has corrected inconsistencies in unit exposure values and exposure scenarios noted in the previous risk assessment for handlers. The 1998 risk assessment considered handler exposures using three different levels of personal protection including: baseline (applicators wearing long-pants and long-sleeved shirt); using

maximum PPE (applicators at baseline with coveralls, gloves, and a respirator); and with the use of engineering controls (e.g., closed cabs, etc.). In this assessment, additional levels of personal protection were considered ranging from a baseline level of protection through the use of engineering controls in every aspect of the application process. Fenthion labels typically require the use of long-pants, long-sleeved shirts, double layer clothing, gloves, and respiratory protection (dust/mist masks with a protection factor of 5). In some cases, however, lower levels of personal protection are allowed such as when a closed loading system is used or for pilots/applicators in enclosed cabs and cockpits.

S **PHED Data**: PHED data for mixer/loaders of liquids were extrapolated to estimate ready-to-use pour on applications to animals. Also, airblast application data were used to extrapolate to an applicator during ground ULV mosquito control applications.

S **The AgDRIFT Model**: The AgDRIFT model was used to predict deposition after aerial mosquito control applications. AgDRIFT is a product of the SDTF (Spray Drift Task Force) which is a FIFRA task force comprised of pesticide manufacturers, formed to address the spray drift issue generically.

S **Residential SOPs**: Several changes were made as a result of the September 21, 1999 FIFRA SAP meeting on Residential SOPs. The following changes were made to the fenthion assessment:

- The value for estimating initial turf transferable residues was lowered from 20% to 5%;
- The turf transfer coefficient was changed from 43,000 cm^2/hr (8,700 cm^2/hr for kids) to 14,500 cm^2/hr (5,200 cm^2/hr for kids) per hour when addressing short-term endpoints and 7,300 cm^2/hr (2,600 cm^2/hr for kids) per hour for intermediate-term endpoints;
- The number of times for toddler hand-to-mouth exposure was changed from 1.56 events per hour coupled with 350 cm^2 (per event) to 20 events per hour x 20 cm^2 (per event) where 1 hand-to-mouth event (20 cm^2) represents the palmar surface area of 3 fingers;
- The amount of extraction from the hand by saliva was lowered from a quantitative transfer level of 100% to 50% extraction by saliva per mouthing event.

– **Revised Percent Livestock Treated Figures**: Maximum annual percent livestock treated numbers were incorporated: 12% beef cattle (9.5% pour-on/spot and 2.5% ear tags), 4% dairy cattle (ear tag only), and 9% swine (pour-on/spot).

– **DEEM™** : The Dietary Exposure Evaluation Model was used to generate acute and chronic dietary risk figures. This is a means of assessing dietary exposure which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes

by Individuals (CSFII), 1989-1992. For chronic dietary risk assessments, the three-day average of consumption for each subpopulation is combined with residues in commodities to determine average exposure in mg/kg/day. For refined acute dietary risk assessments, the entire distribution of consumption events for individuals is multiplied by a distribution of residues (probabilistic analysis, referred to as "Monte Carlo" or probabilistic assessment; risk at 99.9th percentile of exposure reported) to obtain a distribution of exposures in mg/kg/day.

– **Revised Application Rates**: Typical residential risks from mosquito control use were calculated using the corrected average aerial application rate of 0.056 lb a.i./acre. No correction was necessary at the maximum label rate.

1. Dietary Risk from Food. In this section, the Agency has chosen to describe the dietary risk from food even though all food uses of fenthion have been recently voluntarily cancelled. The dietary risk from food is high; however, this is considered to be an overestimate based on the limited data available. Had the food uses not been voluntarily cancelled, residue data would be needed to further refine the risk.

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of fenthion can be found in the October 13, 1999 Human Health Risk Assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 1 in this document.

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1.

c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of fenthion, the FQPA safety factor is 1; therefore, the acute or chronic RfD equals the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

Table 1. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Fenthion

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	PAD
Acute Dietary	NOAEL = 0.07 mg/kg/day	Lack of plasma ChE inhibition at week 1	Chronic-monkey (MRID No. 00147245)	100[a]	1X	0.0007 mg/kg/day
Chronic Dietary	NOAEL/LOAEL = 0.02 mg/kg/day (threshold dose)	Plasma ChE inhibition	Chronic-monkey (MRID No. 00147245)	300[b]	1X	0.00007 mg/kg/day

[a] 10x for interspecies, 10x for intraspecies.

[b] 10x for interspecies, 10x for intraspecies, 3x for lack of a true NOAEL.

Fenthion is one of the more potent cholinesterase inhibitors, having an acute No Observed Adverse Effect Level (NOAEL) of 0.07 mg/kg/day in a 2-year oral monkey study. This study is useful for both acute dietary and short-term dermal/inhalation risk assessment because there was a lack of plasma and red blood cell cholinesterase (ChE) inhibition at the NOAEL during the first week of the study. The monkey is considered to be the most sensitive species. A lack of cholinesterase inhibition at week 1 indicates that there would be no cholinesterase inhibition during the entire first week of dosing. The short-term/acute Lowest Observed Adverse Effect Level (LOAEL) from the monkey study was 0.2 mg/kg/day based on observed plasma and red blood cell ChE inhibition.

d. Exposure Assumptions

Fenthion uses that can result in dietary exposure are limited to ear tag use, pour-on applications, and the veterinary feed-through uses for cattle and swine. Anticipated upper bound residue levels in livestock commodities were calculated using the limited available data. Upper bound estimates of fenthion residues in milk, beef, and pork commodities were described in detail in the C. Olinger memo dated 9/30/97. No new data have been submitted.

Anticipated residues (ARs) for beef and milk were extrapolated from existing livestock dermal treatment studies since no data were available at the maximum use rate and 21 day pre-slaughter interval (PSI). These ARs are higher than current tolerance levels for cattle tissues. While these ARs represent a best estimate using the limited data available, they are an overestimate. ARs are at the

tolerance level for pork based on an appropriate dermal treatment study, and below tolerance level for milk. The ARs for milk are considered reasonable since ear tags are the only dairy cattle use and residues are not expected to be detectable as a result of that use. Residue data are needed for cattle reflecting the maximum application rate and minimum (21 days). All types of treatments (including ear tag treatment) would need to be represented by adequate residue data. The Agency believes that residues in cattle tissue and milk from the ear tag use would be small compared to residues resulting from the dermal application.

Fenthion residues in milk were monitored by USDA/PDP in 1996 and 1997; a total of 1,297 samples were analyzed with no detections. The limit of detection (LOD) for fenthion was 0.001 ppm for all USDA/PDP laboratories. The milk monitoring data and the 21-day PSI residue estimates were used in the acute and chronic analyses.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concerns. The fenthion acute and chronic dietary risks from food exceed the Agency's level of concern for the general U.S. population and various population subgroups, including infants and children. The most highly exposed subgroup is children 1-6 years, with approximately 800% of the acute PAD (at the 99.9th percentile of exposure) and 270% of the chronic PAD consumed.

In the chronic analysis, infants were the only population subgroup for which chronic dietary risk was below the level of concern, at approximately 60% of the chronic PAD. Detailed results are shown in Table 2. The acute critical exposure contribution and the chronic critical commodity analyses demonstrate that estimated dietary risk is due largely to potential residues in beef meat and fat and that milk is a minor contributor to acute and chronic dietary risk.

Available USDA monitoring data on beef liver did not include all fenthion residues of concern, but qualitatively support the results of the dietary exposure analyses conducted using livestock direct treatment study data.

The chronic and acute analyses do not take into consideration the potential for reduction of fenthion residues in cooked/canned/processed livestock commodities, since there are no chemical-specific cooking studies and for this reason likely overestimate dietary exposure. The Agency will not refine the fenthion dietary exposure analyses further since this use is being cancelled.

Table 2. Acute and Chronic Dietary Exposure/Risk Estimates for Fenthion

Population Subgroup	Acute Assessment (99.9th %-ile)		Chronic Assessment	
	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%cPAD
General US Population	0.003274	470	0.000094	130
All Infants (<1 yr)	0.004124	590	0.000040	57
Nursing Infants (<1 year old)	0.003312	470	0.000036	51
Non-Nursing Infants (<1 yr)	0.004350	620	0.000042	60
Children (1-6)	0.005627	800	0.000187	270
Children (7-12 years)	0.003709	530	0.000135	190
Females (13-19 years)	0.002893	410	0.000087	120
Females (13-50 years)	0.002390	340	0.000073	100
Males (13-19 years)	0.002772	400	0.000116	170
Males (20+ years)	0.002509	360	0.000088	130

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment and provides a high-end estimate of risk. In the case of fenthion, the only use that could potentially cause contamination of drinking water is the mosquito use which involves aerial applications and/or ground applications in Florida. For the livestock use, fenthion is either contained within an ear tag or is spot treated to livestock. These uses are not expected to result in significant exposures to drinking water sources. Limited groundwater monitoring data are available for fenthion, but the utility of these data are limited by the fact that only the parent compound was analyzed. No surface water monitoring data were available; therefore, modeling was used to estimate drinking water risks from the mosquito adulticide use.

The environmental fate data base for fenthion is incomplete. However, it is clear that fenthion degrades by aerobic microbial metabolism with a half-life of <1 day in aerobic soil and 11 days under anaerobic aquatic conditions. Although no clear degradation rates are available, fenthion also probably degrades by photolysis in water. No mobility studies with unaged fenthion have been submitted; however, since fenthion degrades rapidly and thermal fogs and ULV are the only terrestrial uses of fenthion, there probably would be no serious groundwater contamination from the parent compound.

a. Surface Water

Since fenthion is either contained within an ear tag or is spot treated to livestock; these uses are not expected to result in significant exposures to drinking water sources. However, the use of fenthion

as a mosquito adulticide requires the active ingredient to remain suspended in air for a period of time, rather than quickly depositing on the ground. This application technique facilitates drift, reduces deposition, and widens the area of deposition. Therefore, there is potential for this use to result in surface water exposure from spray drift.

A conservative screening level estimate of potential fenthion residues in surface water was generated using the GENEEC model. These Estimated Environmental Concentrations (EECs) were developed for a 1 hectare (ha) by 2 meter (m) deep pond adjacent to a 10 ha treated area. Inputs to GENEEC included an assumption of 12 applications at 7 day intervals at a rate of 0.1 lb ai/acre, an assumed aerial spray drift of 5%, an assumed soil half-life of 3 days, a K_{oc} value of 1500, and an assumed aquatic half-life of 6 days. Over a 3-year period from 1993-1996, fenthion was applied in Lee County, FL an average of approximately 4 times/month.

The EECs thus generated are to be used for determining potential drinking water exposure and risk. The peak concentration for determination of acute exposure and risk is 1.33 ppb and the 56-day average concentration for determination of chronic exposure and risk is 0.19 ppb.

As a means of estimating the relative magnitude of potential risk associated with fenthion in drinking water compared to food and residential sources, these EECs were compared to the PADs. Conservatively modeled fenthion exposure estimates due to drinking water alone (i.e., without considering food sources) indicate that a small amount of the aPAD and cPAD could maximally be utilized by residues in drinking water alone. There is little concern for adults and children from exposure to fenthion in drinking water because: (i) the EECs utilized in these calculations were derived from conservative, screening-level models; and (ii) only minor exposure to surface water is possible due to the application rate (ULV) and method (low deposition).

b. Ground Water

Limited groundwater monitoring data are available for fenthion but the utility of these data are limited by the fact that only the parent compound was analyzed; fenthion is not as persistent as the five regulated metabolites of toxicological concern. In addition, Florida was not tested (Florida is the only state in which fenthion is used as a mosquito adulticide). There are no terrestrial agricultural uses of fenthion and since these uses represent the primary drinking water source of exposure, the potential for drinking water exposure is very low. The Agency believes that the only use that could potentially cause contamination of drinking water is the mosquito use which involves aerial applications and/or ground applications in Florida.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food

(and if appropriate, residential uses) then determines a "drinking water level of comparison"(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

Because the dietary risks exceeded the Agency's level of concern, DWLOCs were not calculated for fenthion.

3. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to fenthion by entering or performing other activities on treated areas. Occupational handlers of fenthion include: mixers/loaders, applicators, and flaggers for mosquito control uses; applicators for livestock use; and applicators for the aquaculture use. Although there are no homeowner uses of fenthion, residential exposure to adults and children can occur from the use of fenthion as a wide area mosquito adulticide. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern. However, in the case of fenthion, 300 is the target MOE for intermediate exposure because of a lack of a definitive NOAEL in the 2-year oral monkey study.

a. Toxicity

The toxicity of fenthion is integral to assessing the occupational and residential risk. All risk calculations are based on the most current toxicity information available for fenthion.

A 21-day dermal toxicity study in rats is not available in the fenthion database. Generally, it is this study that is preferred to assess the potential dermal toxicity of a chemical. For fenthion, two acceptable dermal toxicity studies in the rabbit are available; however, these studies are not considered to accurately represent the potential dermal toxicity of fenthion to humans. Data available in the rat indicates that organophosphates, like fenthion, are activated in the liver. However, this process does not occur to the same extent in the rabbit due to the high levels of arylesterases (which quickly detoxify OPs before they reach the liver) present in the rabbit bloodstream. Therefore, the 21-day dermal toxicity studies in the rabbit were not used for endpoint selection.

At present, the dermal risk assessments are based on oral NOAELs established in a study conducted in monkeys. In this study, the monkeys were orally dosed with fenthion at 0.02, 0.07 and 0.20 mg/kg/day. No inhibition of plasma cholinesterase activity was seen at 0.02 or 0.07 mg/kg/day at the week 1 measurement. Upon longer exposures, plasma ChE was frequently inhibited at 0.02

mg/kg/day such that this level was deemed to be a threshold level. Therefore, the threshold NOAEL/LOAEL for plasma ChE inhibition was 0.02 mg/kg/day and a NOAEL of 0.07 mg/kg/day was chosen due to the lack of plasma ChE inhibition during the first week of the study.

Table 3a. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessments for Fenthion

Assessment	**Dose**	**Endpoint**	**Study**	**Absorption factor**
Short-Term Dermal	NOAEL=0.07 mg/kg/day	Lack of plasma ChE inhibition at week 1	2-year feeding study -monkey (MRID 00147245)	3% [a]
Intermediate- Term Dermal	Threshold NOAEL/LOAEL = 0.02 mg/kg/day	Plasma ChE inhibition	2-year feeding study -monkey (MRID 00147245)	3% [a]
Short-Term Inhalation	NOAEL=0.07 mg/kg/day	Lack of plasma ChE inhibition at week 1	2-year feeding study -monkey (MRID 00147245)	100% [b]
Intermediate-Term Inhalation	Threshold NOAEL/LOAEL = 0.02 mg/kg/day	Plasma ChE inhibition	2-year feeding study -monkey (MRID 00147245)	100% [b]

[a] 3% based on a comparison of LOAELs in a rabbit developmental study (MRID 40462701) and a 21-day dermal toxicity study in rabbits (MRID 40329501).

[b] 100% in lieu of any data to indicate otherwise.

Fenthion is classified as Toxicity Category II for acute oral, dermal, and inhalation toxicity. This chemical was classified as Toxicity Category III for eye irritation and Category IV for dermal irritation. Acute toxicity studies did not reveal any gender bias in the toxicity profile of fenthion. In the acute dermal study for fenthion, the LD_{50} for both sexes combined was 963 mg/kg/day. In the case of the acute inhalation study the LC_{50} was 0.507 mg/L and 0.454 mg/L for males and females, respectively. Refer to Table 3b for acute toxicity of fenthion.

Table 3b. Acute Toxicity Profile for Occupational Exposure for Fenthion

Study	**MRID**	**Results**	**Toxicity Category**
81-1. Acute Oral-rats	40186704	LD_{50} = 405 (302-681) mg/kg, males = 586 (461-791) mg/kg females	II
81-2. Acute Dermal - rabbits.	40186705	LD_{50} = 963 (744-1162) mg/kg for both sexes combined	II
81-3. Acute Inhalation - rats.	40186706	LC_{50} = 0.507 (0.409 - 0.695) mg/L, males = 0.454 (0.349- 0.658) mg/L, females Deaths in females and tremors and ataxia (both sexes) at lowest doses (0.209 mg/L).	II
81-4. Primary Ocular Irritation - rabbits.	40186708	No cornea or iris irritation was noted. Discharge, redness and swelling were noted in the conjunctiva in all rabbits that were reversed after two days.	III
81-5. Primary Dermal Irritation - rabbits.	40186709	PII = 0	IV
81-6. Dermal Sensitization - guinea pigs	40186710	Not a sensitizer in the Magnusson-Kligman maximization study	NA--

b. Occupational Exposure and Risk

(1) Occupational Exposure

Chemical-specific exposure data were not available for fenthion, so exposures and risks to fenthion handlers were assessed using data from the *Pesticide Handlers Exposure Database (PHED)*, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc. The data and exposure factors utilized represent the best information currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from fenthion labels and typical use information if available. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but all are the best available data. The quality of the data used for each scenario assessed is discussed in the document "The ORE aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Fenthion" dated October 1, 1999 which is available in the public docket and on the internet

Anticipated use patterns, application methods and range of application rates were derived from current labeling. Application rates specified on fenthion labels range from 0.03 to 0.10 lb ai/acre for mosquito control applications (allowable maximum depends upon the method of application). Animal and aquaculture maximum use rates were defined based on the size of the animal or of the ponds. For these scenarios, the Agency defined a likely maximum based on estimates of what is likely to be treated (i.e., number of cattle and pond size were defined for risk assessment purposes). Wherever available, both maximum and average (typical) application rates are used in each assessment.

The following assumptions and factors were used in order to complete this exposure assessment:

- An average occupational work day interval is 8 hours per workday. The values used by the Agency to represent the amount of acres that can be treated in a day (or application volumes as appropriate) for each scenario include:

  (1a) mixing/loading liquids for mosquito control fixed-wing aerial applications to 7500 acres per day (see further explanation below);
  (1b) mixing/loading liquids for mosquito control ground-fogger applications to 3000 acres per day (see further explanation below);
  (2) loading granular materials for mosquito control fixed-wing aerial applications to 80 or 800 acres per day (see further explanation below);
  (3) applying liquids using aerial equipment (includes both ULV and thermal fogger) for mosquito control applications to 7500 acres per day (see further explanation below);
  (4) applying liquids using ULV ground-fogger equipment for mosquito control to 3000 acres per day (see further explanation below);

(5) applying granulars using aerial equipment for mosquito control applications to 80 or 800 acres per day (see further explanation below);
(6) applying the ready-to-use solutions to livestock (cattle and swine) to 200 animals per day;
(7) applying cattle ear tags to 200 animals per day;
(8) mixing/loading/applying liquids to livestock via ladeling to 200 animals per day;
(9) loading/applying granulars for ground-based mosquito larvicide control applications to 5 acres per day;
(10) mixing/loading/applying liquids for aquaculture using low pressure handwand sprayers to a single 2.5 or 5 acre pond per day;
(11) mixing/loading/applying liquids for aquaculture using backpack sprayers to a single 2.5 or 5 acre pond per day;
(12) flagging during aerial application of liquids to 7500 acres per day (see further explanation below); and
(13) flagging during aerial application of granulars to 80 or 800 acres per day (see further explanation below).

- The Agency typically uses a maximum of 1200 acres per day for assessing risks to aerial applicators in agricultural scenarios. Mosquito control applications, however, are distinctly different from the typical agricultural scenario. For the liquid mosquito control formulation, aerial applications are either Ultra-Low Volume (ULV) or thermal fog. Similarly, ground-based applications are ULV. According to *The Use of Aircraft in Agriculture* (Ackeson and Yates, FAO/UN 1974), the number of acres treated using aerial ULV techniques can reach as high as 5000 acres per hour for fixed-wing aircraft and 1500 acres per hour for helicopters. The average number of acres per day that were treated by air in Florida was defined as 6600 acres per day using 1993 to 1995 data. Since the exposure scenarios of concern are short- or intermediate-term, a value of 7500 acres per day per individual was selected for the aerial application of liquids exposure scenario. Likewise, for ground-based ULV applications, the techniques and number of acres that can be treated per day are distinctly different from typical agricultural scenarios. Based on the liquid mosquito control label application parameters, approximately 3000 acres per day can be treated. For granular application, the Agency estimated that 800 acres can be treated per day.

- The animal assessments were based on cattle since they are larger than swine and the unit application rates were higher for cattle. Treated cattle were assumed to weigh 600 pounds. No scenario-specific data are available to the Agency with which to assess the cattle pour-on uses. As such, the Agency has used data for the open mixing of liquids to calculate the exposures for this scenario because it appears to be the best data available with which to assess this scenario. The Agency did not use these data for the ladel-on scenario because that process also involves additional activities that are not thought to be represented by the mixing/loading data for liquids.

- Average body weight of an adult handler is 70 kg. This body weight is used in all assessments since the endpoints of concern are not sex-specific (i.e., the cholinesterase inhibition could be assumed to occur in males or females).

- All handler calculations were completed using typical (if available) and maximum labeled application rates for each scenario.

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

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical resistant gloves and a dust/mist respirator with a protection factor of 5.
- Maximum PPE: Baseline + coveralls, chemical resistant gloves, and an air purifying respirator with a protection factor of 10.
- Engineering controls: Engineering controls such as a closed cab airplane or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods; there are no known devices that can be used to routinely lower the exposures for these methods.

These were combined to result in 8 different combinations of PPE.

The Agency has completed two distinct risk assessments for fenthion handlers; short-term duration (1-7 days) and intermediate-term duration (>7 days). The rationale behind this approach is that an insufficient use and usage data set is available to establish that intermediate-term exposures do not occur. In fact, for many situations with fenthion, the Agency was able to develop several plausible scenarios for which intermediate-term exposures can occur (i.e., data from Lee County mosquito control district indicate that application events occur 50 to 60 times per year). MOEs for all short- and intermediate-term scenarios may be found in the October 13, 1999 Human Health Risk Assessment for Fenthion. There are currently no products containing fenthion for which the Agency believes that occupational post-application exposures would be of concern.

(2) Occupational Risk Summary

In the revised assessment, risks for handlers were assessed using the same endpoints for both dermal and inhalation exposures. The resulting risks (MOE values) were then added in order to obtain

an overall risk for each applicator that accounted for both dermal and inhalation exposures for each exposure duration considered. Dermal and inhalation risks are mitigated using different types of protective equipment, so it may be acceptable to add a pair of gloves and not a respirator, and vice versa. All of the risk calculations for handlers completed in this assessment are included in Appendix A of the document "The ORE aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Fenthion" (i.e., ORE chapter) dated October 1, 1999.

For occupational use of fenthion during wide area mosquito adulticide ULV applications, five different exposure scenarios were assessed. Two exposure scenarios were assessed for occupational use during aquaculture applications. There are no fenthion products labelled for homeowner use; therefore, risks to residential handlers were not assessed. Although the granular mosquito larvicide products and all livestock uses of fenthion were recently cancelled, the risks for these uses will be identified in this document. In the risk tables that follow, the cancelled uses and corresponding MOEs will be shown in italics. Four exposure scenarios were assessed for occupational use during mosquito larvicide applications. Three exposure scenarios were assessed for occupational use during applications to food animals in agriculture. Within each of the scenarios, further analyses were conducted to determine the MOE at typical and maximum application rates, and at maximum and typical acreage, where applicable. Each of these analyses is included in Appendix A, Tables 1-10 of the ORE chapter. Tables 1 through 6 of Appendix A in the ORE chapter illustrate how the calculations were performed to define the MOEs for handlers in this risk assessment. Tables 7 and 8 provide summaries of the MOE values calculated for each route of exposure, dermal and inhalation, respectively, in the risk assessment. Tables 9 and 10 provide the information that is key to interpreting the overall results of the risk assessment because they contain the overall risks calculated using several combinations of personal protection. The reader is referred to these tables for more information on this comprehensive assessment.

The following tables summarize the risk concerns after all assessments were revised using the most current data and assumptions for occupational handlers, based on combined dermal and inhalation exposures. The tables presented in this summary document outline the risks that remain of concern at the highest possible level of protection depending upon the feasibility (i.e., those scenarios that have MOEs < 100 for short-term exposures and MOEs < 300 for intermediate-term exposures). Note that the scenarios that are not of concern at the highest level of protection (i.e., MOEs > 100 or MOEs > 300) are not reported in this document, but may be found in the comprehensive worker risk tables in Appendix A of the ORE chapter.

(a) Occupational Handler Risks

The scenario numbers listed below correspond to scenario numbers detailed and discussed in Appendix A of the ORE chapter.

i) Mosquito Control

For the mosquito control uses of fenthion, 32 combinations of differing rates, acreages, and application methods for short-term and intermediate-term exposures were assessed; of these, 7 have remaining risk concerns for short-term and intermediate-term exposures. All MOEs in the tables below are based on combined dermal and inhalation risks. The mosquito control scenarios with remaining risk concerns at the highest feasible level of protection are:

(1a) mixing/loading (M/L) liquids for aerial application (at both maximum and typical application rates). (Concern for both short-term and intermediate-term exposures);
(1b) mixing/loading liquids for ground fogger application (at both maximum and typical application rates). (Concern for intermediate-term exposures only).
(3) aerial application of liquid sprays (at both maximum and typical application rates). (Concern for both short-term and intermediate-term exposures);
(4) ground fogger application (at the maximum rate only for short-term exposures, at both the maximum and typical rate for intermediate-term exposures);
(5) aerial application of granulars (at the maximum and typical application rates). (Concern for both short-term and intermediate term exposures);
(9) ground-based granular application (at the maximum application rate). (Concern for both short-term and intermediate-term exposures);
(12) flagging for aerial application of liquid sprays (at both maximum and typical application rates). (Concern for intermediate-term exposures only).

ii) Livestock Applications

For the livestock use, scenarios with risks of concern at baseline, once all refinements were made, are reported below, along with the risk estimates with increasing levels of protection. The scenarios that do not have risks of concern (i.e., MOEs > 100 for short-term exposures and MOEs >300 for intermediate-term exposures) are not reported here, but can be found in the comprehensive tables in Appendix A of the ORE chapter. The scenario numbers listed below correspond to scenario numbers detailed and discussed in Appendix A of the ORE chapter. For these livestock uses of fenthion, the Agency assessed 6 combinations of rates, gallons used, and application methods for short-term and intermediate-term exposures. Each combination was assessed at baseline, and with a single layer of clothing and gloves. A quantitative risk assessment was completed for application of cattle ear tags and for mixing/loading/applying liquids to livestock via ladeling because appropriate exposure data were not available. For short-term and intermediate-term exposures, the ready-to-use products have risks of concern at the baseline level of protection. With the addition of a single layer of clothing and gloves, the MOEs are well above the Agency's level of concern. Fenthion livestock labels do not contain protective clothing requirements.

The exposure scenarios are:

(6) applying the ready-to-use solutions to livestock;;
(7) applying cattle ear tags;
(8) mixing/loading/applying liquids to livestock via ladeling.

iii) Aquaculture Applications

As with the livestock scenarios reported above, the aquaculture exposure scenarios with risks of concern at the highest level of protection feasible are reported below. The level of concern for short-term exposures is 100 and for intermediate-term exposures is 300.

The exposure scenarios are:

(10) mixing/loading/applying liquids for aquaculture using low pressure handwand sprayers;
(11) mixing/loading/applying liquids for aquaculture using backpack sprayers.

TABLE 4. Remaining Risk Concerns for Occupational Handlers: Combined Short-Term Dermal and Inhalation MOEs

Scenario	??		Summary MOEs for Combinations of Dermal and Inhalation Protective Measures							
	Rates	Acres	Baseline	Single Layer, Gloves & No Respirator	Single Layer, Gloves & Pf 5 Respirator	Single Layer, Gloves & Pf 10 Respirator	Double Layer, Gloves & No Respirator	Double Layer, Gloves & Pf 5 Respirator	Double Layer, Gloves & Pf 10 Respirator	Eng. Controls
(1a) Mixing/loading Liquids for Aerial Application	??	??	0.1	3.5	2.8	8.1	3.8	8.7	10.4	2.8
	??	??	0.1	6.2	5.0	14.4	6.8	15.6	18.5	5.0
(3) Aerial Application of Liquid Sprays	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
(4) Ground Fogger Application	??	??	3.6	4.7	3.0	7.1	4.9	7.3	7.7	3.0
	??	??	6.7	8.7	5.6	13.3	9.2	13.6	14.5	5.6
(5) Aerial Application of Granulars	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
(6) Ready-to-Use Package For Livestock	??	??	33.1	1543.2	1246.4	3600.8	1705.7	3888.9	4629.6	Not Feasible
(7) Ear Tags For Cattle	??	??	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible
(8) Ladel On For Livestock	??	??	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible
(9) Ground-based Granular Application	??	??	27.1	28.7	23.9	34.4	42.0	53.3	55.2	Not Feasible

Scenario	??		Summary MOEs for Combinations of Dermal and Inhalation Protective Measures							
	Rates	Acres	Baseline	Single Layer, Gloves & No Respirator	Single Layer, Gloves & Pf 5 Respirator	Single Layer, Gloves & Pf 10 Respirator	Double Layer, Gloves & No Respirator	Double Layer, Gloves & Pf 5 Respirator	Double Layer, Gloves & Pf 10 Respirator	Eng. Controls
(10) Low Pressure Handwand Application of 95% Liquid	??	??	0.4	28.6	22.2	77.0	29.8	71.6	86.9	Not Feasible
	??	??	0.8	57.1	44.4	154.1	59.6	143.3	173.8	Not Feasible
(11) Backpack Application of 95% Liquid	??	??	No Data	11.7	9.5	15.7	15.7	22.7	24.0	Not Feasible
	??	??	No Data	23.3	19.0	31.4	31.4	45.4	48.0	Not Feasible
(12) Flagging For Aerial Application of Liquid Sprays	0.1	7500	9.6	9.2	15.2	16.5	9.6	16.3	17.9	480.4
	0.056	7500	17.2	16.4	27.1	29.5	17.2	29.2	32.0	857.8

Table 5. Remaining Risk Concerns for Occupational Handlers: Combined Intermediate-Term Dermal and Inhalation MOEs

Scenario	??		Summary MOEs for Combinations of Dermal and Inhalation Protective Measures							
	Rate	Acres	Baseline	Single Layer, Gloves & No Respirator	Single Layer, Gloves & PF 5 Respirator	Single Layer, Gloves & PF 10 Respirator	Double Layer, Gloves & No Respirator	Double Layer, Gloves & PF 5 Respirator	Double Layer, Gloves & PF 10 Respirator	Eng. Controls
(1a) Mixing/loading Liquids for Aerial Application	??	??	0.02	1.0	ERR	2.3	1.1	2.5	3.0	??
	??	??	0.04	1.8	ERR	4.1	1.9	4.4	5.3	??
(1b) Mixing/loading Liquids for Ground Fogger Application	??	??	0.18	8.2	ERR	19.2	9.1	20.7	24.7	??
	??	??	0.33	15.4	ERR	36.0	17.1	38.9	46.3	??
(3) Aerial Application of Liquid Sprays	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
(4) Ground Fogger Application	??	??	1.02	1.3	ERR	2.0	1.4	2.1	2.2	??
	??	??	1.91	2.5	ERR	3.8	2.6	3.9	4.1	??
(5) Aerial Application of Granulars	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??
	??	??	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	Not Feasible	??

Scenario	??		Summary MOEs for Combinations of Dermal and Inhalation Protective Measures							
	Rate	Acres	Baseline	Single Layer, Gloves & No Respirator	Single Layer, Gloves & PF 5 Respirator	Single Layer, Gloves & PF 10 Respirator	Double Layer, Gloves & No Respirator	Double Layer, Gloves & PF 5 Respirator	Double Layer, Gloves & PF 10 Respirator	Eng. Controls
(6) Ready-to-Use Package For Livestock	??	??	9.45	440.9	??	1028.8	487.3	1111.1	1322.8	Not Feasible
(7) Ear Tags For Cattle	??	??	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible
(8) Ladel On For Livestock	??	??	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible
(9) Ground-based Granular Application	??	??	7.73	8.2	??	9.8	12.0	15.2	15.8	Not Feasible
(10) Low Pressure Handwand Application of 95% Liquid	??	??	0.12	8.2	??	22.0	8.5	20.5	24.8	Not Feasible
	??	??	0.23	16.3	??	44.0	17.0	40.9	49.6	Not Feasible
(11) Backpack Application of 95% Liquid	??	??	No Data	3.3	??	4.5	4.5	6.5	6.9	Not Feasible
	??	??	No Data	6.7	??	9.0	9.0	13.0	13.7	Not Feasible
(12) Flagging For Aerial Application of Liquid Sprays	??	??	2.75	2.6	ERR	4.7	2.7	4.7	5.1	??
	??	??	4.90	4.7	ERR	8.4	4.9	8.3	9.1	??
(13) Flagging For Aerial Application of Granulars	??	??	74.79	88.4	ERR	277.8	97.2	291.7	388.9	??
	??	??	133.55	157.8	ERR	496.0	173.6	520.8	694.4	??

iv) Post-Application Occupational Risk

Occupational post-application risks were not assessed because the Agency believes there are no applicable fenthion product use patterns. Mosquito control applications are addressed in the residential post-application risk assessment summarized below and livestock pest control applications are not considered an occupational post-application risk assessment required by the Agency.

c. Post-Application Residential Exposure and Risk

(1) Residential Exposure

Although there are no homeowner uses of fenthion, residential exposure can occur because fenthion is used in mosquito control operations that involve wide area adulticide applications to residential areas. This exposure scenario has been selected because it is likely that people will spend time outdoors following mosquito control adulticide applications and come in contact with fenthion deposited on turf. The Agency conducted risk assessments for both adults and children who are exposed as follows:

Mosquito control applications are the only post-application concern for residential settings and the general population. The animal treatments in agriculture or uses in aquaculture are not thought to lead to significant post-application exposures.

Residential (homeowner) Adults: these individuals are members of the general population that are exposed to chemicals by engaging in activities at their residences and also in areas not limited to their residence (e.g., golf courses or parks) previously treated with a pesticide. These kinds of exposures are attributable to a variety of activities and usually addressed by the Agency in risk assessments by considering a representative activity that results in a conservative exposure calculation.

Residential Children: children are members of the general population that are exposed to chemicals by engaging in activities in areas not limited to their residence (e.g., parks) previously treated with a pesticide. These kinds of exposures are attributable to a variety of activities and usually addressed by the Agency in risk assessments by considering a representative activity that results in a conservative exposure calculation. Toddlers have been selected as the most sensitive exposure population for the assessment.

The Agency's *Standard Operating Procedures For Residential Exposure Assessment* was used to predict the amount of transferrable residues available on treated turf because no chemical- and scenario-specific data were available to complete this assessment. Special considerations were also given to the methods of application in this assessment in order to account for the fact that the objective of a mosquito control adulticide application (to create smaller droplets) is antithetical to a normal agricultural application of a pesticide (to minimize drift). The Agency evaluated post-application

residential risks by first calculating the amount of fenthion that deposits in areas after mosquito control applications and then calculating the exposure to both adults and children in those environments. The Agency used the Spray Drift Task Force model for predicting deposition from aerial applications (i.e., AgDRIFT) to determine how much material deposits in residential areas after aerial applications and published data to determine how much material deposits in residential areas after ground-fogger applications. After these values were determined, the risks for adults and toddlers were calculated using guidance included in the Agency's Residential SOPs and guidance provided at the September 21, 1999 meeting of the FIFRA Science Advisory Panel on residential exposure issues.

At the FIFRA SAP meeting on September 21, 1999, several changes to the Residential SOPs were proposed. The following proposed changes were incorporated into the fenthion exposure assessment: The turf transferable residues were reduced from 20% to 5%; the turf transfer coefficient was reduced from 43,000 cm^2/hr (8,700 cm^2/hr for kids) to 14,500 cm^2/hr (5,200 cm^2/hr for kids) per hour when addressing short-term endpoints and 7,300 cm^2/hr (2,600 cm^2/hr for kids) per hour for intermediate-term endpoints. Duration for both endpoints is 2 hours; the number of hand-to-mouth events was changed from 1.56 events per hour x 350 cm^2 (per event) to 20 events per hour x 20 cm^2 (per event) - one hand-to-mouth event (20 cm^2) represents the palmar surface area of 3 fingers; and the percent of pesticide extracted from saliva was reduced from 100% to 50% extraction from the hand by saliva.

The Agency considered both low exposure (e.g., light yard and garden work) and high exposure (e.g., heavy yard work) activities for adults in the assessment. In order to consider the risks to children, guidance from the Agency's *SOPs For Residential Exposure Assessment* was used to address the exposures of children from treated turf.

Based on the anticipated fenthion use patterns and current labeling, four major post-application exposure scenarios were modeled using a surrogate approach for each application method (i.e., aerial and ground ULV). Two of these scenarios are assessment of exposure to adults while the remaining two scenarios were assessments of exposures to toddlers. The four scenarios are:

(1) adults involved in a high exposure activity (e.g., heavy yard work) at the typical Florida mosquito control application rate;

(2) adults involved in a high exposure activity (e.g., heavy yard work) at the label maximum mosquito control application rate;

(3) toddlers involved in a high exposure activity (e.g., rolling/playing on lawn) at the typical Florida mosquito control application rate; and

(4) toddlers involved in a high exposure activity (e.g., rolling/playing on lawn) at the label maximum mosquito control application rate.

The Agency believes that fenthion exposures can occur over a single day or up to weeks at a time. This is supported by the length of time fenthion residues take to decline using the standard dissipation model. The toxicology database for fenthion indicates that the Agency needs to separately consider exposures to the skin and exposures via inhalation because the effects and the dose levels at which effects occur differ based on whether it gets on skin or it is inhaled. However, inhalation exposures are minimal in outdoor post-application scenarios because of the low vapor pressure and because existing empirical data have also generally shown post-application inhalation exposures to be negligible. As such, inhalation exposures are not considered in the post-application assessment. Hand-to-mouth exposures are considered in this assessment because toddlers are anticipated to engage in mouthing behaviors.

REIs are not considered a viable regulatory tool for reducing exposures and risks in the residential environment (i.e., for the general population). Therefore, for chemicals used in the residential environment or any other areas where the general population can be exposed, risk management currently considers the risks associated with a chemical on the day it is applied and as part of an aggregate exposure assessment (should the single day risks be of no concern.)

(2) Post-Application Residential Risk

Fenthion is used for wide area mosquito control in residential areas where exposure to adults and children may occur. Exposure may result from performing yard work, and playing or performing other recreational activities (e.g., golfing) on the treated areas. As a result, both toddler and adult risks were considered in the risk assessment.

The use of a Restricted Entry Interval (REI) is not an appropriate method of risk mitigation for residential use chemicals and, essentially, for all exposure scenarios where there is the potential for unrestricted general population exposures. As a result, the approach used to evaluate residential risks is to consider exposures immediately after application as these represent higher exposures and risks which are a concern for acutely toxic compounds like the organophosphates.

The Agency developed exposure scenarios in this residential post-application risk assessment to evaluate exposures to children and adults after both aerial and ground-based wide area mosquito control applications. Different application methods were considered in the assessment because they deposit different amounts of material in surrounding areas and the application rates (both allowable maximum and average) are different for each method (i.e., resulting in different levels of exposure). Risks to adults were assessed only via dermal exposures as outdoor post-application inhalation exposures have been historically shown to be minimal and in this case the outdoor dilution factor is expected to also minimize the potential for inhalation exposure. Adults are expected to have minimal hand-to-mouth activity that would contribute to nondietary ingestion exposure. Dermal as well as nondietary ingestion exposures to toddlers, however, were considered in this assessment to obtain total risk estimates for aggregation purposes as toddlers are likely to be exposed from playing on treated

lawns and from routine mouthing behaviors. Toddlers were selected as the most sentinel population for this assessment because their exposures are expected to be higher than other children because they are more mobile than younger children and they have a greater propensity for mouthing behaviors than older children. In this assessment, the Agency considered hand-to-mouth behavior, object-to-mouth behavior, and soil ingestion. All residential post-application risk calculations completed for adults and children are presented in Appendix C of the ORE chapter.

There are no risk concerns for exposure of adults associated with any treatment scenario. The combined MOEs for toddler exposures also do not exceed the Agency's level of concern for short-term exposures; however, for intermediate-term exposures the MOE is 257 at the maximum aerial application rate (where the Agency's level of concern is 300). MOEs for the intermediate-term assessment were calculated using a dose level that was derived by taking the average of the dose levels from applications occurring on a monthly basis. The MOE at the average application rate is 460 which is not of concern.

4. Aggregate Risk

An aggregate risk assessment considers the combined risk from dietary exposure (food and drinking water pathways) and residential exposure (dermal exposure, inhalation exposure for homeowner applicators, and incidental oral exposure for toddlers from mouthing behavior). Aggregate risk assessments for fenthion were conducted for acute (1-day), short-term (1-7 days), intermediate-term (7 days to several months), and chronic (lifetime) exposure. Generally, all risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency (for fenthion, MOEs greater than 100 are not of concern for short-term exposures and MOEs greater than 300 are not of concern for intermediate-term exposures). Results of the aggregate risk assessment are summarized here.

a. Acute Aggregate Exposure and Risk

The Agency is able to quantitate the food sources of dietary exposure and residential exposure; dietary exposure through drinking water has only been estimated using models. Acute dietary (food only) risks exceed the Agency's level of concern as the most exposed population subgroup, children (1-6 years), has a risk that is 800% of the aPAD based on very conservative exposure estimates. Based on EECs generated via modeling, the potential exists for relatively small additional contributions to the acute aggregate risk from surface water sources of drinking water in Florida. Thus, there is a concern for acute aggregate risk due to fenthion use.

b. Aggregate Short-term and Intermediate-term Exposures and Risks

There are food and water sources of dietary exposure as well as residential exposures to fenthion based on the current use pattern. Chronic dietary risk from food sources exceeds the Agency's level of concern with the most highly exposed population subgroup, again, being children (1-6 years) at 270%

of the cPAD. Drinking water sources could possibly contribute comparatively small levels of additional dietary exposure and, hence, risk in Florida. Combined residential dermal and nondietary ingestion exposures following aerial mosquito adulticide treatments result in intermediate-term risks of concern to toddlers. The Agency is therefore, concerned about intermediate-term aggregate risk associated with the use of fenthion.

c. Chronic Aggregate Exposure and Risk

In the case of chronic aggregate risk, the Agency is able to quantitate only the food sources of dietary exposure as the drinking water residues were estimated from conservative, screening-level models. In the case of the dietary component (food only) of the chronic aggregate assessment, risks were above the Agency's level of concern with the most highly exposed population subgroup, again, being children (1-6 years) at 270% of the cPAD; these risk values were based on highly conservative exposure estimates. Again, based upon conservative modeling, the potential exists for comparatively small amounts of additional dietary exposure via drinking water. Thus, there is concern for chronic aggregate risk resulting from fenthion use.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated May 1, 1996 and the addendum dated July 31, 1996, available in the public docket.

1. Environmental Fate and Transport

The environmental fate data base is incomplete; however, it is clear that fenthion degrades by aerobic microbial metabolism with calculated half-lives of <1 day in an aerobic soil metabolism study and 11 days under anaerobic aquatic conditions. Major degradates were fenthion sulfoxide, 3-methyl-4-methylsulfonyl) phenol, fenthion phenol sulfoxide, fenthion phenol, and 3-methoyl phenol. In both studies, carbon dioxide was a major degradate at the end of the studies.

Although no clear degradation rates are available, fenthion also probably degrades by photolysis in water. Several studies that are unacceptable for various reasons have been submitted; all these flawed studies indicate rapid degradation (half-lives of 1-4 hours) when irradiated with undescribed artificial light sources.

No mobility studies with unaged fenthion have been submitted; however, since fenthion degrades rapidly and thermal fogs and ULV are the only terrestrial uses of fenthion, there probably would be no serious groundwater contamination from the parent compound. The aged column leaching studies showed that fenthion residues (aged 30 days and leached 45 days) were mobile through the column.

Fenthion sulfoxide, fenthion sulfone, fenthion phenol, 3-methoyl-4-methylsulfonyl) phenol, were all recovered from the leachate. From information on other organophosphate insecticides we know that the sulfoxide and sulfone compounds are often very toxic. It is not clear if the fenthion degradates are biologically active, but if they are found to be of toxicological concern, further groundwater/drinking water concerns may be evident.

Fenthion has an octanol water partition coefficient of 69,000, which indicates that it may bioaccumulate in fish and non-target organisms. The laboratory accumulation study in fish indicates that carp exposed to fenthion at 0.01 and 0.1 ppm had bioconcentration factors of approximately 2000x and 2300x, respectively. Depuration occurred with approximately 95% of the residues depurating during 15 days. The study was unacceptable because the results did not distinguish whether the parent or the degradates bioaccumulated and whether the accumulations were in edible or visceral tissues.

2. Risk to Birds and Mammals

a. Birds - Mosquito Adulticide Applications

The potential for acute dietary risk to birds is high at the maximum aerial use rate of 0.1 lb ai/acre. The potential for acute dietary risk to endangered species is high at both the ground and aerial maximum use rates of 0.03 and 0.1 lb ai/acre, respectively. A chronic risk assessment for birds from use of fenthion for mosquito control cannot be completed until chronic toxicity data are submitted.

Published literature and incident reports indicate that spray applications of fenthion present a more serious threat to birds than indicated solely by dietary risk presumptions. The Agency's risk presumptions assume that exposure from spray applications is primarily via ingestion of contaminated food sources (e.g., grass, seeds, insects). However, dermal contact with aerial droplets and contaminated vegetation and inhalation of ULV or thermal-fog mists also are likely routes of exposure for birds. Fenthion is very highly toxic to birds dermally. Fenthion applied aerially by ULV spray is used for lethal control of massive numbers of red-billed quelea (*Quelea quelea*) in Africa, albeit at much higher rates than are used for mosquito control in the U.S. The mortality that results from quelea flying through the ULV spray mist is presumed to be due to both dermal contact and inhalation. Secondary exposure of raptors feeding on dead, exposed birds also is a concern.

Several bird mortality incidents were reported during the 1970's and 1980's resulting from fenthion spraying for mosquito control at single application rates comparable to those currently used. A detailed account of the incidents can be found in the EFED chapter and the addendum to the EFED chapter referred to above.

The US Fish and Wildlife Service (FWS) recently informed OPP of bird kills caused by fenthion sprays for adult mosquito control on Marco Island, Collier County, Florida. FWS reported that dead and/or sick birds were found on at least 12 occasions between October, 1998, and August, 1999. The

incidents occurred after aerial (helicopter) ULV application of Baytex at a rate of 2/3 ounce of Baytex (0.05 lb ai) per acre, which conforms to the label application rate for aerial spraying. According to FWS, sprays were made over the beach early in the morning, and sick and dead birds were observed on the beach within 8-10 hours.

The FWS reports mortality of at least 16 bird species. All are listed migratory species (50 Code of Federal Regulations 10.13 lists those species protected by the Migratory Bird Treaty Act) and one, a piping plover (Charadrius melodus) is a Federally listed endangered species {50 Code of Federal Regulations 17.11(h)} pursuant to the Endangered Species Act. More than 200 dead or sick birds have been found, and it is possible that many more were effected but never found or reported. Other species involved include western sandpiper (*Calidris mauri*), least sandpiper (*C. minutilla*), dunlin (*C. alpina*), sanderling (*C. alba*), short-billed dowitcher (*Limnodromus griseus*), willet (*Catoptrophorus semipalmatus*), snowy plover (*Charadrius alexandrinus*), snowy egret (*Egretta thula*), little blue heron (*E. caerulea*), cattle egret (*Bubulcus ibis*), black skimmer (*Rhynchops niger*), sandwich tern (*Sterna sandvicensis*), fish crow (*Cyanocitta cristata*), ring-billed gull (*Larus delawarensis*), laughing gull (*L. atricilla*), and others not identified. A sample of dead shorebirds was sent to the National Forensics Laboratory in Ashland, Oregon for analysis, and fenthion was detected on legs, feathers, beaks and/or in stomach contents.

The situation on Marco Island appears to be somewhat unique. However, repeated sprays of adulticide, principally fenthion, are made on Marco Island because of the continual influx of mosquitoes from the Everglades (where larvicides cannot be applied). Because of the small area involved on Marco Island, application is made by helicopter. The Collier County Mosquito District stated that they sprayed on Marco Island about 175 days during the past three years. In contrast, Lee County mostly sprays larvicides; fenthion is sprayed only occasionally and only in residential areas.

Marco Island is a haven for shorebirds. Parts of the shoreline include Florida Designated Shorebird Nesting Area Critical Habitat. The shoreline currently is being considered for Federal designation as Critical Habitat for wintering piping plover, which may be present eight months of the year. Clearly, mitigation measures are needed to eliminate exposure of shorebirds to fenthion to ensure their protection under the Endangered Species Act and the Migratory Bird Treaty Act.

Insectivorous passerines also are potentially at risk from exposure to fenthion. Tiebout and Brugger (1995) assessed dietary risks of fenthion, naled, and malathion mosquito sprays to birds in Florida. Based solely on ingestion of fenthion-contaminated food, they concluded that insectivorous birds, including as many as 80 passerine species, could be at risk from fenthion applied for mosquito control. A case study for the black-whiskered vireo (*Vireo altiloquus barbatulus*), a species potentially at risk where mosquitoes are controlled in Florida, indicated that 42% of the population could be at risk from a single fenthion application of 0.1 lb ai per acre. In contrast, they predicted that very few species would be at risk from naled and malathion, two alternative adulticide sprays.

Based on the available information and the current incidents in Collier County, the Agency concludes that fenthion spraying, especially when repeated at frequent intervals, may cause mortality in a variety of bird species. Fenthion also is very highly toxic to estuarine invertebrates, which may be at risk from mosquito spraying and may indirectly impact birds by reducing their food supply. The Agency also is concerned about possible reproductive risks to birds exposed to repeated applications of fenthion during and immediately preceding the breeding season. Avian reproduction tests (guidelines 71-4 a, b) are needed to determine if chronic exposure from repeat applications poses a reproductive risk to birds.

b. Birds - Livestock Application

The Agency currently has no method for quantifying exposure to birds from applying a pesticide on livestock. It is possible that such application poses some risk to birds that perch on recently treated livestock or consume contaminated hairs or invertebrates. Dermal contact with fenthion can contaminate a bird's feet and feathers. Although the potential for exposure exists from treatment of livestock, this use of fenthion probably poses the least risk to birds of the currently registered uses. Currently, two bird kill incidences are presumed to be related to livestock use. Information on these incidences can be found in the EFED chapter. Any risk to birds associated with the livestock use is now eliminated with the cancellation of all livestock products.

c. Mammals

Fenthion poses low acute risk to mammals. The potential for chronic risk is slight; however, because fenthion degrades rapidly in the environment, chronic exposure is unlikely.

3. Risk to Aquatic Species

a. Freshwater and Estuarine/Marine Fish - Mosquito Adulticide Applications

Fenthion poses low acute and chronic risk to freshwater fish and estuarine/marine fish at either aerial or ground maximum mosquito adulticide application rates.

b. Freshwater and Estuarine/Marine Invertebrates - Mosquito Adulticide Applications

Potential for acute and chronic risk is high for freshwater invertebrates and estuarine/marine invertebrates at maximum aerial and ground application rates of 0.1 and 0.03 lb ai/acre; however, risk to aquatic organisms cannot be adequately assessed until outstanding data are submitted. An acute estuarine/marine mysid test is required for the two major degradates and the TEP.

IV. Summary of Benefits Assessment

A. Background

Mosquito control in Florida is conducted by 50 mosquito control districts. The districts are governmental agencies that monitor for the presence of mosquito larvae and adults and mosquito-borne diseases. Districts justify their annual budget to an elected committee that is responsive to the public. Pesticide applications are part of overall mosquito IPM programs that include source reduction, use of biocontrol agents such as mosquitofish, public education, rotation of pesticides, and other control methods. The Florida Coordinating Council on Mosquito Control, answering to the Florida Secretary of Agriculture, coordinates matters involving districts and state conservation agencies.

Mosquito control has historically been necessary year-round in most Florida areas. During most years, mosquito-borne disease incidences have not caused a public health emergency, but their appearance has been cyclic and unpredictable. A few isolated cases of St. Louis encephalitis show up annually, with a larger scale outbreak happening less frequently.

B. Disease and Vector Monitoring

Mosquito control is designed to maintain the mosquito population at a level where, if it should begin vectoring a disease, it will have minimal impact on the human population. Vector populations and diseases fluctuate depending on complex environmental and biological circumstances including weather patterns and alternate host populations.

Pesticide applications by mosquito control districts are based on monitoring data. Monitoring is performed on a continuous basis at strategic locations across a district. Monitoring includes trapping and counting adult mosquitos, conducting "bite counts" at designated sampling locations by district personnel, sampling and counting of mosquito larvae, reporting human and animal disease incidence, conducting bioassays of trapped adult mosquitoes for diseases, searching for suitable breeding habitat such as tire dumps or rain pools, and recording complaint calls from citizens. Monitoring is conducted on a daily basis. Bite counts, an important monitoring tool, must reach 25 bites per minute before treatment is undertaken.

Aerial and ground fenthion applications in a district are usually spot treatments corresponding to specific sites where monitoring has shown thresholds have been exceeded. In most areas, preemptive larval treatments prevent adult populations from developing. Large area blanket spraying of residential areas are only done if a widespread problem exists, such as an epidemic of encephalitis or a mosquito population explosion following a hurricane. The application interval would also correspond to need indicated by monitoring. There are provisions to avoid spraying where sensitive individuals live and where there are beekeepers or wildlife refuges. To avoid and record nontarget effects, most districts maintain close communications with park and refuge managers. General announcements are made to

the public before spraying commences and most districts maintain web pages for public education and information.

C. Pests and Diseases Targeted by the Use of Fenthion

Florida has over 70 species of mosquitoes, only 10 of which are generally targeted. Targeted species include potential and actual vectors of St. Louis Encephalitis, Venezuelan Equine Encephalitis, Eastern Equine Encephalitis, Malaria, Yellow fever, West Nile Virus, and Dengue. There is a fair probability that any of the above diseases may show up in the human population during any year.

In the early 20th century, malaria, yellow fever, and dengue were commonly spread by Florida mosquitoes. It was in response to these problems that mosquito control districts were initially formed and the work of the districts is credited with elimination of those diseases from Florida. The CDC has reported that fenthion is particularly effective against salt marsh *Aedes* mosquitoes that vector Venezuelan Equine Encephalitis and *Culex nigripalpus* that vectors St. Louis encephalitis.

The threat of the spread of mosquito-vectored diseases is particularly great in Florida because the frost-free climate supports year-round mosquito populations. The last widespread epidemic of St. Louis Encephalitis in Florida occurred in 1990, with 223 human cases and 11 deaths. Incidences of malaria and dengue have been increasing in Central and South America. Dengue is regularly reported from Puerto Rico and other Caribbean islands adjacent to Florida. While none of the 96 cases of malaria reported from Florida in 1998 were from indigenous sources, there is a threat that local mosquitoes will become infected and begin transmitting it. Because malaria microbes have recently developed resistance to several antimalarial drugs, the hazards of malaria control once it is in the human population have increased. Fifty cases of Eastern Equine Encephalitis have been recorded from Florida in the last thirty years. This disease is of major concern because of its high mortality rate among humans. Fenthion has been successfully used to reduce populations of the vectors of the above diseases.

Two new problems have surfaced in the last several years that are cause for public health concern in Florida: a new pest, the Asian tiger mosquito, that may be a vector for dengue and other diseases, and a new disease, the West Nile Virus. While not yet detected in Florida, West Nile Virus appears to be spreading southward from the northern states and may become established soon. The vectors for West Nile Virus, including various *Culex* and *Aedes* species, are already present in Florida. Fenthion has been used to successfully manage populations of the above vectors in Florida.

D. Usage of Fenthion

Table 6 gives the number of mosquito control districts that used fenthion from 1994 - 1998 and the pounds of the active ingredient used.

Table 6. Usage of Fenthion

Fiscal Year	Districts Using Fenthion		Pounds Active Ingredient	
	Air	Ground	Air	Ground
1994	4	6	59,000	19,000
1995	4	7	43,000	30,000
1996	4	7	150,000	61,000
1997	7	8	70,000	46,000
1998	3	5	66,000	33,000

Seven programs used fenthion in FY98. These were Lee*, Collier*, Osceola*, East Volusia, Duval, Hillsborough, and Pasco (* aerial). During FY97, users were Collier*, Duval*, Lee*, Osceola*, Pasco*, Pinellas*, Glades, Hillsborough, Indian River, and Saint Lucie (* aerial). Malathion, naled, and fenthion are the only adulticides applied aerially in Florida. Aerial adulticiding with fenthion is favored by districts because the targets mainly occur in areas without roads and because more widespread vector populations can be covered more quickly than by ground equipment. Fenthion is amenable to aerial application because it is not as corrosive to equipment as naled and because the formulation is very effective at a lower rate than malathion. Several counties discontinued using fenthion from FY97 to FY98 because of low populations of target mosquitoes, resistance buildup in target populations in some areas, and cost (naled and malathion are less expensive). High usage years corresponded with higher target populations during those years, in part. More pounds of active ingredient of malathion and naled than fenthion are applied annually in Florida. Fenthion is typically applied at lower than label rates for both ground and aerial ULV applications: at 0.02 lb ai per acre ground with a 0.03 lb ai per acre maximum label rate and 0.06 lb ai per acre aerial ULV with a 0.1 lb ai per acre maximum label rate. The maximum rate of 0.03 lb ai per acre label rate is used for thermal fogging. Most districts apply aerially using ULV. According to users, the maximum label rates are sometimes necessary because they are beneficial if there is a severe outbreak over a very large area which may include some resistant populations that are susceptible only to the highest rate.

E. Comparative Efficacy and Resistance Management

Fenthion is not the sole mosquito insecticide used in any district: all districts rotate adulticides to target certain species and for resistance management. They also complement adulticide applications with larvicides and other IPM techniques to make sure adulticides are judiciously applied. Fenthion is considered to be critical in the product rotation to slow mosquito resistance. Additionally, districts tailor ground and aerial spraying and the chemicals to be used to the locality to be sprayed.

The CDC stated that fenthion use is critical for Florida for management of malathion-resistant mosquito species, including *Culex nigripalpus*. Fenthion is particularly effective against *Aedes* salt marsh species which are important over a major area of the state. Malathion is considered to be ineffective at controlling target species in the areas where fenthion is used. That means that if malathion is substituted, it must be used at higher rates and applied more frequently to obtain the same level of

control as is obtained with fenthion. It is notable that in some areas, *Culex nigripalpus* is also resistant to fenthion. In those areas, naled or malathion is used. Because of resistance problems, chlorpyrifos has not been used as an adulticide in Florida in recent years. Overall, fenthion is effective for a broad range of pest species, is compatible with other control methods, and is largely accepted by the Florida public. Fenthion and other OPs have the drawback of taking longer than pyrethroids to knock down adults.

To fully appreciate the benefits of fenthion, it is necessary to consider the constraints of the various alternatives. For aerial application, naled, while as effective as fenthion and without resistance problems, has the constraint of being very corrosive to equipment and having a reputation for causing eye irritation in bystanders. Thus districts with larger urban populations that require spraying, including Collier, Duval, and Lee would favor fenthion over naled for that reason. Because fenthion may be applied ULV at a low rate, large areas may be treated without refilling, saving wear on equipment and exposure to loaders.

Considering pyrethroid and pyrethrin alternatives, for ground application, resmethrin is ineffective against *Aedes* salt marsh mosquitoes. Permethrin, while effective, is more expensive than fenthion and prohibited for aerial application in the state because of concerns over nontarget aquatic organisms. Pyrethrins and sumithrin have the drawback of being significantly more expensive than fenthion. There are no carbamate or other classes of adulticides.

While larvicides and pupicides are alternatives to fenthion, they can't be solely relied upon for control because the habitats for some vectors, notably *Culex nigripalpus* and *Aedes* salt marsh species, are too cryptic or too vast to be reliably treated. Bti, altosid, Bs, and temephos are larvicides used and oil and monomolecular films are the pupicides used by Florida districts.

F. Estimation of Economic Impacts of Switching to Alternatives

During 1998, fenthion was the least expensive active ingredient to apply per acre (average of aerial and ground). Loss of fenthion and replacement with current alternatives would cause increased costs for both aerial and ground mosquito control. For FY97 aerial application, if fenthion were replaced with malathion and naled in proportion to their current usage, overall cost of application would have increased from $1.5 million to $1.8 million, or 16%. This may be an underestimate because aerial applications are more expensive than ground, but aerial estimates alone were not available. Also, benefits of fenthion with respect to naled may be underestimated because of the corrosiveness of naled. A previous Agency estimate stated that cost of replacing equipment due to corrosion would be up to $0.02/acre for aerial applications. For FY 1997-98 ground application, if fenthion were replaced with naled, malathion, pyrethroids, and pyrethrins in proportion to their current usage, cost of application would have increased from $2.17 million to $2.47 million, or 13%. This may be an overestimate because costs of ground applications alone for fenthion were not available.

The research and registration pipeline for new mosquito adulticides is fairly empty. Bendiocarb was recently retained for five years for use as an adulticide, but no products are currently marketed for that use. Spinosad has been suggested as an alternative larvicide, but there is currently no ongoing research. The state of Florida, University of Florida, and USDA Agricultural Research Service, in cooperation with various districts, maintain an active research program in Florida on application technology, reducing effective rates, vector and disease ecology, and mitigating nontarget effects. The rate reduction research through use of new calibrating devices, more sensitive adult monitoring, and development of new spray nozzles shows promise in reducing usage and more accurate vector population targeting.

G. Benefits Conclusions

When consulted, CDC stated that fenthion is critical for resistance management in Florida and for control of the very important *Aedes* salt marsh species and *Culex nigripalpus*. CDC also mentioned that fenthion is very important overseas as a larvicide in vector control programs; a use which could be impacted by loss in the US. Considering that mosquito-vectored diseases are prevalent and increasing throughout the subtropics and tropics, that much of Florida is subtropical, that vectors occur in Florida, and that the vectored diseases have historically occurred in Florida, there is a high probability that large outbreaks could occur without adequate mosquito control. Fenthion has been described by public health authorities as one of the effective tools for controlling adult mosquitoes in Florida and in controlling mosquito-vectored diseases in Florida. The Agency concludes that the current uses of fenthion in Florida have a significant public health benefit.

V. Interim Determination of Reregistration Eligibility, Tolerance Reassessment, and Risk Management

A. Determination of Interim Reregistration Eligibility

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient fenthion, as well as a fenthion-specific dietary risk assessment that has not considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient fenthion, EPA has sufficient information on the human health and ecological effects of fenthion to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under

FIFRA, as amended by FQPA. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of fenthion, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of fenthion and to determine if fenthion can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency has determined that certain uses of fenthion require mitigation of the risks associated with the exposure to fenthion. The Agency will conduct a public process to identify the best ways to reduce the risks associated with fenthion exposure. This process will include a public comment period and a stakeholder meeting. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures that must be adopted in order for products containing fenthion to be eligible for reregistration. Further, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing fenthion, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

Although the Agency has not yet completed its cumulative risk assessment for the organophosphates, the Agency is issuing this interim assessment now in order to initiate a stakeholder process to identify risk reduction measures that are necessary to support the continued use of fenthion. Based on its current evaluation of fenthion alone, the Agency has determined that fenthion products would present risks inconsistent with FIFRA.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. Because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for fenthion after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because all food uses for fenthion have been voluntarily cancelled, this reregistration eligibility decision announces that all existing food residue tolerances for fenthion will be revoked.

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

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. A mitigation proposal was received from Bayer Corporation Agriculture Division; details of this proposal are discussed in the next section. Several other comments on mitigation were also received from various mosquito control districts in Florida, Louisiana, Illinois, and Mississippi, Florida Department of Agriculture & Consumer Services, Florida Department of Environmental Protection, Florida Mosquito Control Association, American Mosquito Control Association, Health Canada-Pest Management Regulatory Agency, American Bird Conservancy, other bird conservation organizations, and private citizens. These comments in their entirety are available in the public docket. A brief summary of the comments and the Agency response is noted here.

1) ***Comment:*** Eighteen comments were received from the mosquito control community including the American Mosquito Control Association, the Florida Mosquito Control Association, and various mosquito control districts in Florida, Illinois, and Louisiana. Their comments focused on the benefits of fenthion and the organophosphate pesticides for use in mosquito control. They emphasized the importance of fenthion in controlling disease (i.e., public health), quality of life for citizens (i.e., nuisance mosquitoes), integrated pest management, resistance management, the fact that there are few alternatives, and that fenthion is safe and effective. They also stated that EPA and HHS must work together on this issue as mandated by FQPA. They emphasized that the risk assessments were based on modeling for agricultural situations which vary greatly from mosquito control applications. Some comments indicated that the high use rate for fenthion is never used or needed; however, others indicted that the high rate is necessary at times for effective control. They also stated that workers are adequately protected if the personal protective equipment is worn as indicated on the current fenthion label. Several mosquito control districts mentioned the fact that they are currently using and/or testing the new high pressure nozzle technology which reduces deposition.

Response: The Agency understands that fenthion is very important in protecting the public from mosquito borne diseases. FQPA requires EPA to weigh the risks of a public health pesticide against the health risk of the disease to be controlled. The threat of spread of mosquito-vectored diseases is particularly great in Florida because the large bodies of water and mild climate supports year-round mosquito populations. Recognizing the importance of this chemical, the Agency has developed a number of mitigation measures which it proposes in order to reduce the risks from the use of fenthion. Because of the significance of this chemical, the Agency believes that an open stakeholder process is necessary to discuss these measures and/or to develop other workable mitigation measures that adequately protect those at risk. The Agency is planning to conduct a public comment and stakeholder process to accomplish this objective.

It is true that the Agency has relied on worker exposure data from PHED, which is generally used for agricultural situations. The Agency does not have worker exposure data which is specific to

mosquito control applications. Because mosquito control applications vary greatly from agriculture type situations, the Agency intends to require generic mixer/loader/applicator exposure data to be submitted for all mosquito pesticide applications. These data requirements will be included in a generic DCI for all mosquito pesticides.

The Agency acknowledges the fact that many mosquito control districts, universities, and others are currently engaged in research and development regarding better mosquito control practices. The Agency believes that this research plays a very important part in improving pesticide use practices; further work in these areas is encouraged.

2) *Comment*: Three comments were received from the Florida Department of Agriculture & Consumer Services. Two were from the Florida Coordinating Council on Mosquito Control and one was from the Division of Agricultural Environmental Services. The Florida Department of Environmental Protection also submitted a comment. These comments were similar in nature to the comments discussed above under comment #1.

3) *Comment:* Health Canada - Pest Management Regulatory Agency

The Head of Health Re-evaluation Section commented on the use of the human study. "The extent to which the human study can be utilized in the modification of the interspecies uncertainty factor should be further considered. This study may be of limited value in the consideration of an acute reference dose due to study limitations including the small group size, testing in one sex and the timing of cholinesterase determinations (24 hours after dosing)."

She also commented on the recalculated dermal absorption factor as follows: "...further consideration of the recalculated dermal absorption factor of 3% may be warranted, particularly given the limitation of the rabbit model in assessing dermal toxicity of certain organophosphates. Additional studies to consider include the acute oral and dermal toxicity studies in the rat and a study by Christenson, 1990 (cited in the 1996 JMPR) which looked at effects of route (oral, dermal, subcutaneous) on cholinesterase activity in the rat following acute administration. The dermal absorption factor estimated from an alternate rabbit study (using the vehicle Cremaphor) was discounted by EPA as the vehicle was thought to enhance dermal absorption and use patterns were reported to be primarily ULV applications with the technical form. Dermal absorption from non-ULV applications may also need to be considered in risk assessment."

Response: The Agency has made a decision not to use human data.

Regarding further consideration of the recalculated dermal absorption factor, the vast majority of mosquito adulticide applications make use of very concentrated formulations and/or ULV equipment. Also, Cremophor is rarely, if ever, used as an intentionally added inert in pesticide formulations. As a result, the Agency is of the opinion that use of the technical material is preferable over fenthion plus Cremophor in a dermal toxicity study. It was determined that rabbits are not an appropriate species

upon which to base hazard endpoint selection because dermal toxicity may be underestimated. However, the relative dermal vs. oral toxicity in the same species, even rabbits, is considered scientifically supportable. There are no appropriate/comparable oral and dermal rat toxicity studies upon which to derive a dermal absorption factor. As far as the W.R. Christenson (1990c) study is concerned, the study summarized in the 1995 JMPR does not appear to be useful for quantitative determination of a dermal absorption factor because RBC and brain cholinesterase were observed at the same dose (LOAEL and NOAEL reported to be 25 and 5 mg/kg BW, respectively) regardless of whether administration was via the oral or the dermal route. In other words, the study is useful only to postulate the relative ease of absorption of fenthion administered by different routes based on the time after administration of the single dose at which maximum cholinesterase inhibition occurred (24 hours for oral and 4 days for dermal).

4) *Comment:* Bayer Corporation - Agriculture Division

Bayer commented that the larvicide products are registered by Amvac and that these products have not been sold for at least 10 years. The technical product only allows for formulation into products used to control adult mosquitoes. Amvac has requested voluntary cancellation of the granular larvicide products. Bayer also reiterated that the Rid-A-Bird perch is cancelled; that no human flaggers are involved in aerial adulticiding operations; and that Bayer will explicitly prohibit human flaggers on the label. They stated that historical exposure monitoring (cholinesterase) conducted by mosquito control districts does not indicate that any consequential occupational exposure occurs in mosquito adulticiding operations. Bayer also indicated that they are open to further discussions on worker safety measures with EPA and the users of fenthion.

Regarding dietary risk, Bayer stated that they believe that the residue estimates are greatly exaggerated, and also that additional studies are needed to refine the assessment. Bayer stated that they are currently evaluating the livestock uses and would like to meet with Agency personnel to discuss possible options.

Regarding the non-dietary residential exposure, Bayer stated that the conservative nature of the assumptions used in this screening type assessment are likely to overestimate exposure. This exposure is unlikely to occur as mosquito applications are most often made shortly before dawn and after sundown, when toddlers would not be expected to spend extended periods of time on lawns. Bayer does not believe that the use of fenthion in adult mosquito control poses unacceptable risk to toddlers from post application exposure. Bayer stated that they would like to meet with the Agency, representatives from mosquito control district(s) in Florida, other interested states, and the Centers for Disease Control (CDC) to discuss additional data requirements. They note that CDC has indicated that they may be able to fund some of the studies necessary to support the reregistration of fenthion. Lastly, Bayer emphasized the importance of fenthion in public heath programs and they indicated that other states, including Louisiana, Georgia, Mississippi and California have expressed interest in using fenthion in their public health programs.

Response: Regarding the Amvac larvicide products, the Agency received a request for voluntary cancellation of these products on March 10, 1999. This voluntary cancellation was published in the Federal Register dated June 14, 2000. The Agency is requiring in this document, a label modification which prohibits human flaggers as Mosquito Abatement Districts do use spotters in some cases and their exposure would likely be similar to flaggers. After discussions with the Agency, Bayer subsequently decided to propose a phased voluntary cancellation of the fenthion livestock products. After consultations with the stakeholders, the Agency accepted this proposal which is outlined in the risk mitigation section of this document. The Agency also believes that the risk assessment for non-dietary exposures is conservative because of a lack of chemical-specific and scenario-specific data. The Agency intends to issue a DCI for all mosquito pesticides to call in worker exposure data specific for mosquito control operations and deposition and turf transferrable residue studies to better estimate post-application residential risk. Two Stakeholder Conference Calls were held on May 16 and May 30, 2000 to discuss possible risk mitigation measures and additional data requirements for fenthion. As stated earlier, a stakeholder process will be held to further discuss risk mitigation for fenthion. It is unlikely at this time that the Agency would allow expansion of the use of fenthion based on the lack of data mentioned above and also because of high toxicity and risk concerns to birds and aquatic invertebrates.

5) ***Comment:*** Forty-four comments were received from bird conservation organizations including Save Our American Raptors (SOAR), Cornell University, Soarin' Hawk Raptor Rehabilitation, Liberty Prairie Conservancy, Black Canyon Audubon Society (Colorado), Agricultural Conservation Programs San Antonio, American Bird Conservancy, WildCare Foundation - Wildlife Rehabilitation, and 35 private citizens.

These comments focused on the toxicity of fenthion to birds. Each commentor requests that the Agency disallow further avicide registration proposals for fenthion, cancel pour-on and spot treatments for livestock uses of fenthion, and restrict the mosquito adulticide use of fenthion to emergency use status only**.**

Response: The "Rid-A-Bird" perch product was cancelled by the Agency in March 1999. The Agency has no plans to register fenthion for this use in the future. The registrant for fenthion, Bayer, has voluntarily cancelled the livestock uses of fenthion which will eliminate risk to birds that land on the backs of cattle. The Agency has developed ecological risk mitigation proposals for fenthion as outlined later in this section. Further risk mitigation for fenthion will be discussed during the comment and stakeholder process.

6) ***Comment*****: American Bird Conservancy**

In addition to the comment listed above, the American Bird Conservancy submitted a second comment regarding the use of fenthion as a mosquito adulticide. Their comment stated the following: concentrated monitoring efforts to search for bird kills after fenthion spraying have not been carried out

in Florida; wildlife mortalities due to pesticides are extremely difficult to observe even when experienced searchers are involved in the monitoring efforts; fenthion is highly toxic to birds used as an adulticide at current usage rates; an independent risk assessment reveals that 42% of an insectivorous passerine species population will suffer mortality when exposed to one application of fenthion during a normal application for the control of mosquitoes; ultra low volume spraying leads to increased risk for birds because smaller particles designed to be airborne for longer periods of time could result in increased inhalation risks with ULV spraying and ULV spraying may result in unacceptable levels of fenthion deposited in nearby streams, estuaries, ponds and marshes because of drift during and after application; fenthion bioaccumulates in the fatty tissues of living organisms; the long-term, chronic effects of fenthion on birds have not been adequately studied; the reproduction study with the red-wing blackbirds (Powell 1984) does not adequately address avian reproduction concerns; fenthion is a poor insecticide choice for the chemical management of resistance; and Florida ecosystems are critical to the maintenance of health populations of vast numbers of resident and migratory birds. With these comments, the American Bird Conservancy urged the EPA to consider a full cancellation of fenthion due to its acute and chronic avian toxicity, its potential to bioaccumulate, a documented history of wildlife kills, and the fact that less hazardous and more effective alternatives exist under present conditions.

Response: The Agency was informed on August 2, 2000 by the US Fish and Wildlife Service about bird kills caused by fenthion sprays for adult mosquito control on Marco Island, Collier County, Florida. This information, along with information on other bird kills from the use of fenthion for adult mosquito control, leads the Agency to believe that mitigation measures are needed to eliminate exposure of shorebirds to fenthion to ensure their protection under the Endangered Species Act and the Migratory Bird Treaty Act. In addition to these concerns, the Agency is also concerned about the risk to workers who handle fenthion and to residents from post application exposure from the mosquito adulticide use. The Agency has developed proposed mitigation measures which are outlined in this document. Because of the importance of this chemical for public health, the Agency intends to hold a comment and stakeholder process to further discuss mitigation measures.

C. Decision on Tolerance Reassessment

Based on a review of the generic data for the active ingredient fenthion, the Agency has sufficient information to reassess tolerances for fenthion. Specific findings are discussed in the following section.

D. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt

to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to fenthion is not within its own "risk cup." In other words, even if fenthion did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for fenthion do not meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are not within acceptable levels; that is, combined risks from all exposures to fenthion do not "fit" within the individual risk cup. Therefore, the fenthion tolerances will be revoked based on a phased voluntary cancellation of all food uses of fenthion.

b. Tolerance Summary

In the individual assessment, tolerances for residues of fenthion in/on livestock commodities [40 CFR §180.214] are presently expressed in terms of the combined residues of fenthion and its cholinesterase-inhibiting metabolites.

The data that were available to evaluate the established tolerances for the livestock commodities for fenthion required extrapolations which result in a very conservative dietary risk assessment. Anticipated residues (ARs) for beef and milk were extrapolated from existing livestock dermal treatment studies since no data were available at the maximum use rate and 21-day pre-slaughter interval. These ARs are higher than current tolerance levels for cattle tissues. While these ARs represent a best estimate using the limited data available, they are an overestimate. In order to refine the risk, residue data are needed for cattle reflecting the maximum application rate and minimum PSI (21 days). All types of treatments (including ear tag treatment) must be represented by adequate residue data. In light of these data requirements, Bayer decided to voluntarily cancel the livestock uses of fenthion. A detailed description of the phased voluntary cancellation can be found in section D. A summary of the fenthion tolerance actions is outlined in Table 7.

Table 7. Tolerance Summary for Fenthion.

Tolerances Listed Under 40 CFR §180.214			
Commodity	**Current Tolerance, ppm**	**Tolerance Reassessment, ppm**	**Comment**
Cattle, fat	0.1	Revoke	Per voluntary cancellation
Cattle, meat	0.1	Revoke	Per voluntary cancellation
Cattle, (mbyp)	0.1	Revoke	Per voluntary cancellation
Hogs, fat	0.1	Revoke	Per voluntary cancellation
Hogs, meat	0.1	Revoke	Per voluntary cancellation
Hogs, (mbyp)	0.1	Revoke	Per voluntary cancellation
Milk	0.01(N)	Revoke	Per voluntary cancellation

The Agency will commence proceedings to revoke the tolerances referred to above at the appropriate time in relation to the phased voluntary cancellation request received from Bayer.

2. Endocrine Disruptor Effects

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

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

3. Labels

No label amendments are necessary at this time. The Agency intends to hold a stakeholder process to identify risk mitigation measures for fenthion.

E. Regulatory Rationale

The following is a summary of the rationale and proposals for managing risks associated with the current use of fenthion.

1. Risk Mitigation

a. Dietary Mitigation

(1) Acute and Chronic Dietary (Food)

Acute dietary risk from food exceeds the Agency's level of concern for the general U.S. population and all population subgroups, including infants and children. A DEEM™ analysis yielded a percent acute PAD value of 800% for the most highly exposed subgroup (children 1-6 years). The risk falls below the Agency's level of concern between the 90th and 95th percentiles.

As discussed earlier, this risk assessment was based on limited data available at the time of the risk assessment. In order to refine this risk assessment, further magnitude of residue studies in livestock would be required. As a result, Bayer has submitted a request to voluntarily cancel all livestock uses of fenthion. EPA contacted the USDA (APHIS) to inquire whether this cancellation would adversely affect stakeholders (i.e., cattlemen, dairy farmers, etc...). USDA contacted various stakeholders and determined that they would not be adversely affected because of the availability of registered alternatives.

Bayer proposed a phased cancellation of their products, which the Agency has accepted. The fenthion livestock products will be cancelled as follows in Table 8:

Table 8. Phased Voluntary Cancellation of Fenthion Livestock Products

Product Name	EPA Registration Number	Cancellation Date	Existing Stocks Provision
Spotton (Fenthion) Cattle Insecticide 20% Ready-To-Use	EPA Reg. No. 11556-37	October 2000 (30 day comment period)	none
Tiguvon Brand of Fenthion Swine Insecticide Pour-On	EPA Reg. No. 11556-34	October 2000 (30 day comment period)	1 year from date of cancellation
Tiguvon (fenthion) Technical Grade 100	EPA Reg. No. 11556-36	12/31/2000 (30 day comment period)	none
Lysoff Pour-On	EPA Reg. No. 11556-48	12/31/2000 (30 day comment period)	1 year from date of cancellation
Cutter Blue Insecticide Cattle Ear Tag	EPA Reg. No. 11556-105	12/31/2000 (30 day comment period)	1 year from date of cancellation

(2) Drinking Water

As explained earlier in this document, the only potential dietary exposure via drinking water is surface water in Florida as a result of the mosquito adulticide use; even then, exposure is expected to be small because the application rate is low and because the key to controlling adult mosquitoes is application such that minute fenthion droplets (generated via fogging or ultralow volume treatments) remain airborne for as long as possible to increase the opportunity for droplets to contact a mosquito. This application technique facilitates drift, reduces deposition, and widens the area of deposition. As a means of estimating the relative magnitude of potential risk associated with fenthion in drinking water compared to food and residential sources, EECs were compared to the PADs. Modeled fenthion exposure estimates due to drinking water alone (i.e., without considering food sources) indicate that small amounts of the aPAD and the cPAD could be utilized by residues in drinking water alone. There is little concern for adults and children from exposure to fenthion in drinking water because: (i) the EECs utilized in these calculations were derived from conservative, screening-level models, and (ii) only minor exposure to surface water is possible due to the application rate and method.

b. Public Comment and Stakeholder Meeting Process

Given the high toxicity of fenthion and potential risks posed to workers, residential bystanders, birds, and aquatic invertebrates, the Agency has developed a number of mitigation measures which it proposes in order to reduce the risks outlined in this document. However, since fenthion has significant benefits and there are few if any viable alternatives, the Agency believes that it is important that a broad stakeholder process be conducted to discuss these measures and/or to develop other workable mitigation measures that adequately protect those at risk. Therefore, the Agency is planning to conduct a public comment and stakeholder process to accomplish this objective.

During the public comment period, commencing with the publishing of a Federal Register Notice, comments and suggestions will be collected and reviewed concerning the measures outlined in this document. These revised mitigation measures will be discussed at a stakeholder meeting that will be held within 9 months from the issuance of this interim RED at a location to be determined. For this meeting to be most efficient and successful, all interested parties and viewpoints will be welcomed and considered. Following the conclusion of this process, the Agency will make a final determination on the mitigation measures it believes must be adopted in order for products containing fenthion to be eligible for reregistration.

c. Proposed Risk Mitigation Measures

The following mitigation measures are proposed for the remaining fenthion products (i.e., the mosquito adulticide and the aquaculture SLN's). These measures are to be discussed as part of the public review and stakeholder meeting process mentioned above.

(1) Occupational Risk Mitigation

(a) Mosquito Adulticide Use

For mosquito control adulticide applications, the Agency has concerns for mixers/loaders and applicators for both aerial and ground applications of liquid formulations for mosquito adulticide applications of fenthion.

Data Requirements: The Agency does not have worker exposure data which is specific to mosquito applications. All analyses were completed using data from PHED which is generally used for agricultural situations. Because mosquito applications vary greatly from agriculture type situations, the Agency is requiring generic mixer/loader/applicator exposure data to be submitted for all mosquito pesticide applications. These data requirements will be included in a generic DCI for all mosquito pesticides. Medical monitoring studies will also be required in the mosquito pesticide DCI.

Proposed Risk Mitigation Measures:

- Handlers must use closed systems only. The current labels give protective clothing statements for both closed systems and non-closed systems. The Agency believes that requiring closed systems for all types of mosquito control applications will result in less exposure to workers.
- Add a prohibition of human flaggers to the label. Bayer indicated in their Phase 5 comments that human flaggers are never used in mosquito control applications, but that they would amend their labels by adding this prohibition.
- Change the use rate on the label to only allow the highest rate for public health use (i.e., when disease has been confirmed in mosquito traps and sentinel chickens). The typical rates of 0.056 lb ai/acre (aerial) and 0.03 lb ai/acre (ground) or lower must be used. These typical rates were based on data from various Florida mosquito control districts.

(b) Aquaculture Use

The Agency has concerns regarding the use of fenthion in aquaculture. In order to mitigate risk to handlers in this occupational scenario, the Agency is proposing the elimination of the backpack sprayer method of application. A handwand sprayer would be used.

(2) Post-Application Residential Risk Mitigation

There are no risk concerns for exposure of adults associated with any treatment scenario. However, for intermediate-term toddler exposures the MOE is 257 at the maximum aerial application rate (target level of concern is 300). Even though this number slightly exceeds the Agency's level of concern, the Agency does not have serious concerns for this scenario because of the conservative nature of the risk assessment and the fact that mosquito control districts in Florida rarely use the

maximum use rate for fenthion. Generally, a lower typical rate is used. The intermediate-term MOE at the lower (typical) application rate is 460.

Data Requirements. In order to further refine this risk assessment, chemical-specific deposition and turf transferrable residue studies need to be submitted. These studies will be required in a generic DCI for all mosquito control pesticides. A DNT study is also required for this chemical.

Proposed Risk Mitigation Measures

- Change the use rate on the label to only allow the highest rate for public health use (i.e., when disease has been confirmed in mosquito traps and sentinel chickens). The typical rates of 0.056 lb ai/acre (aerial) and 0.03 lb ai/acre (ground) or lower must be used. These typical rates were based on data from various Florida mosquito control districts.

(3) Environmental Risk Mitigation

Ecological risks are of concern to the Agency. Fenthion is very highly toxic to birds and highly toxic to estuarine/marine invertebrates. The mosquito adulticide use of fenthion has been implicated in several bird kill incidents, including recent bird kills on Marco Island, Florida. These kills on Marco Island are currently under investigation by the US Fish and Wildlife Service.

Data Requirements. Avian reproduction studies with the northern bobwhite and the mallard are required. Three acute toxicity studies with the mysid shrimp are required: 1 using a formulation, 1 using the sulfoxide degradate, and 1 using the sulfone degradate. Additional environmental fate data are not required. The available data is adequate to assess the risk to fenthion. Additional data would not alter the risk picture.

Proposed Risk Mitigation Measures

- Restrict the use of fenthion to mosquito control districts in Florida that have developed a plan to identify critical/sensitive bird habitats and endangered species in their counties and have addressed ways to avoid exposure to those areas.
- Change the use rate on the label to only allow the highest rate for public health use (i.e., when disease has been confirmed in mosquito traps and sentinel chickens). The typical rates of 0.056 lb ai/acre (aerial) and 0.03 lb ai/acre (ground) or lower must be used. These typical rates were based on data from various Florida mosquito control districts.
- Require buffer zones to protect aquatic organisms, especially invertebrates.
- Require certain label changes to improve applications and lessen risk to non-target organisms.

F. Other Labeling

In order to remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing fenthion. Because the Agency intends to hold a

stakeholder process in the near future to identify risk mitigation measures for fenthion, any necessary label changes will be made after the stakeholder process has taken place. No label amendments are necessary at this time.

1. Endangered Species Statement

The Agency has developed The Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticides uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future *Federal Register* notice. The Agency is not imposing label modifications at this time through the IRED. Rather, any requirements for product use modification will occur in the future under the Endangered Species Protection Program.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling as specified in section V of this document. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, labels should be amended to include the following spray drift related language.

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

"Do not allow this product to drift"

VI. What Registrants Need to Do

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

Avian reproduction studies with the northern bobwhite and the mallard are required. Three acute toxicity studies with the mysid shrimp are required: 1 using a formulation, 1 using the sulfoxide degradate, and 1 using the sulfone degradate.

A mosquito pesticide worker exposure DCI will be issued in the near future for all mosquito pesticides. This DCI will also include post-application bystander data requirements such as deposition studies and turf transferrable residue studies.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. The developmental neurotoxicity study is required for fenthion because it is used as a wide area mosquito adulticide which results in residential exposure.

2. Labeling for Manufacturing Use Products

Because the Agency intends to hold a public stakeholder meeting to determine the best ways to reduce risks associated with the use of fenthion, the registrant does not need to submit applications for amended registration at this time.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling for End-Use Products

Because the Agency intends to hold a public stakeholder meeting to determine the best ways to reduce risks associated with the use of fenthion, the registrant does not need to submit applications for amended registration at this time.

C. Existing Stocks

The registrant may distribute and sell the livestock products according to Table 8 in Section V of this document which was based upon the registrant's proposed phased cancellation of these products which the Agency has accepted.

No existing stocks provisions are necessary for the remaining fenthion products because no label changes are necessary at this time.

D. Labeling Changes Summary Table

No labeling changes are necessary at this time. The Agency will conduct a public stakeholder meeting in the near future to identify the best ways to reduce the risks associated with fenthion exposure.

VI. Related Documents and How to Access Them

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

The docket initially contained preliminary risk assessments and related documents as of [date]. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal “Response to Comments” document and the revised risk assessment to the docket on [date].

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

VII. APPENDICES

Appendix A. Currently Registered Use Patterns for Reregistration

Application Site Application Type Application Equipment	Formulation	Single Application Rate	Use Directions and Limitations
AIRCRAFT APPLICATION Mosquitoes (Adults Only) (Florida Only)	95% Soluble Concentrate [3125-148]	0.66 - 1.3 Fluid Ounces	**Ultra Low Volume Spray**: For cotnrol of mosquito adults, BAYTEX Liquid concentrate may be applied undiluted in any aircraft equipment that has been adapted and calibrated for applying ultra low volumes of spray material. Applied specified dosage (0.05 to 0.1 lb active ingredient) per acre using the liquid concentrate in undiluted form with aircraft equipment capable of applying the proper volume per acre. Use lower rate when applying to open non-canopied areas; use higher rate when applications are made in areas having a vegatation canopy. No more than 5% of the droplets should exceed 80 MMD.
AIRCRAFT APPLICATION Mosquitoes (Adults Only) (Florida Only)	95% Soluble Concentrate [3125-148]	0.4 Fluid Ounces	**Thermal Fog:** For control of mosquito adults apply specified dosage (0.03 lb active ingredient) per acre using the product mixed in 0.2 to 0.8 quarts of oil per acre. Apply as a thermal fog by injecting solution into FAA approved engine exhaust system. Repeat applications as necessary.
INSECT GROUND APPLICATION Mosquitoes (Adults Only) (Florida Only)	95% Soluble Concentrate [3125-148]	0.03 lbs Per Acre	**Ground ULV Concentrate Application:** Applications may be made in residential areas, municipalities, tidal marshes, swamps and woodlands. Do not apply to any agricultural crops. Apply undiluted BAYTEX Liquid Concentrate at the rate of 1.2 fluid ounce/minute at 5 mph; 2.4 fluid ounce/minute at 10 mph and 3.6 fluid ounce/minute at 15 mph; applying a 300-foot swath. These flow rates are equivalent to 0.03 pounds active ingredient per acre. **CAUTION - SPECIAL INSTRUCTIONS:** This application can be made only under the following conditions: (1) Application in calm air conditions is to be avoided. (2) Application is not to be made in the immediate vicinity of pedestrians. (3) Vehicles used to apply must be air conditioned, or equipped with automatic speed control flow device. SEE NOTE.

Application Site Application Type Application Equipment	Formulation	Single Application Rate	Use Directions and Limitations
INSECT GROUND APPLICATION Dragonfly Larvae Only (Arkansas, Florida, Missouri Only)	95% Soluble Concentrate [3125-148)	0.5 Fluid Ounces	**Aquaculture Treatments:** Special Local Needs to control larval dragonflies in commerically operated freshwater ponds prior to stocking ornamental fish such as koi carp, goldfish, comets, shubunkins, fantails and baitfish such as shiners and minnows. Applied 0.5 ounces of BAYTEX Liquid Concentrate per 40,000 gallon pond, resulting in a aquatic concentration of 0.1 ppm ai. The material is applied by handheld equipment and is made by diluting the appropriate amount of BAYTEX with water at the rate of 1 ounce of BAYTEX per gallon water and distribution uniformly over the pond. Single applications are allowed 2 to 4 days prior to stocking. No discharge of ponds can be made within 7 days of treatment. This is a “restricted use” application and must be made by a certified applicator or a person under their direct supervision.

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

GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703)487-4650.

2. Use Pattern (Column 2). 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 (Column 3). 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 (MIRD) 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.

Data Supporting Guideline Requirements for the Reregistration of Fenthion

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	40085801, 40223002, 41026101, 42167901, 42167903
61-2A	Start. Mat. & Mnfg. Process	ALL	40085801, 41026101, 42167901, 42167903
61-2B	Formation of Impurities	ALL	40085801, 41026101, 42167901, 42167903
62-1	Preliminary Analysis	ALL	40223001, 41026101, 42167902
62-2	Certification of limits	ALL	41026101, 40223001, 42167902, 41026103
62-3	Analytical Method	ALL	41026101, 40223001, 42167902, 41026104
63-2	Color	ALL	40085802
63-3	Physical State	ALL	40085802
63-4	Odor	ALL	40085802
63-5	Melting Point	ALL	40085802
63-6	Boiling Point	ALL	40085802
63-7	Density	ALL	40085802
63-8	Solubility	ALL	40085802
63-9	Vapor Pressure	ALL	40085802 (data gap - upgradable)
63-10	Dissociation Constant	ALL	40085802
63-11	Octanol/Water Partition	ALL	40085802 (data gap - upgradable)
63-12	pH	ALL	40085802
63-13	Stability	ALL	40085802
63-17	Storage stability	ALL	41026102, 41026105, 104232, 115899, 115931, 115935, 159021
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,C,E	40186701, 41171701
71-1B	Acute Avian Oral - Quail/Duck TEP	A,C,E	40186701, 41171701
71-2A	Avian Dietary - Quail	A,C,E	40186702
71-2B	Avian Dietary - Duck	A,C,E	40186703

Data Supporting Guideline Requirements for the Reregistration of Fenthion

REQUIREMENT		USE PATTERN	CITATION(S)
71-3	Wild Mammal Toxicity	A,C,E	reserved
71-4A	Avian Reproduction - Quail	A,C,E	data gap
71-4B	Avian Reproduction - Duck	A,C,E	data gap
71-5A	Simulated Field Study	A,C,E	waived
71-5B	Actual Field Study	A,C,E	waived
72-1A	Fish Toxicity Bluegill	A,C,E	40274101
72-1B	Fish Toxicity Bluegill - TEP	A,C,E	40856102
72-1C	Fish Toxicity Rainbow Trout	A,C,E	40214201
72-1D	Fish Toxicity Rainbow Trout- TEP	A,C,E	40856102
72-2A	Invertebrate Toxicity	A,C,E	40246401
72-2B	Invertebrate Toxicity - TEP	A,C,E	reserved
72-3A	Estuarine/Marine Toxicity - Fish	A,C,E	40495501
72-3B	Estuarine/Marine Toxicity - Mollusk	A,C,E	40564101, 40879401
72-3C	Estuarine/Marine Toxicity - Shrimp	A,C,E	data gap
72-3D	Estuarine/Marine Toxicity Fish- TEP	A,C,E	40856106
72-3E	Estuarine/Marine Toxicity Mollusk - TEP	A,C,E	40856105
72-3F	Estuarine/Marine Toxicity Shrimp - TEP	A,C,E	40856110
72-4A	Early Life Stage Fish	A,C,E	40564102
72-4B	Life Cycle Invertebrate	A,C,E	40871401
72-5	Life Cycle Fish	A,C,E	reserved
72-6	Aquatic Organism Accumulation	A,C,E	reserved
72-7A	Simulated Field - Aquatic Organisms	A,C,E	waived
72-7B	Actual Field - Aquatic Organisms	A,C,E	waived
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A,C,E	40186704
81-2	Acute Dermal Toxicity - Rabbit/Rat	A,C,E	40186705
81-3	Acute Inhalation Toxicity - Rat	A,C,E	40186706

Data Supporting Guideline Requirements for the Reregistration of Fenthion

REQUIREMENT		USE PATTERN	CITATION(S)
81-4	Primary Eye Irritation - Rabbit	A,C,E	40186708
81-5	Primary Dermal Irritation - Rabbit	A,C,E	40186709
81-6	Dermal Sensitization - Guinea Pig	A,C,E	40186710
81-7	Acute Delayed Neurotoxicity - Hen	A,C,E	41283401, 41283402
81-8	Neurotoxicity - Rats	A,C,E	44326401
82-1A	90-Day Feeding - Rodent	A,C,E	waived
82-1B	90-Day Feeding - Non-rodent	A,C,E	waived
82-2	21-Day Dermal - Rabbit/Rat	A,C,E	40329501, 40808601
82-4	90-Day Inhalation - Rat	A,C,E	waived
82-7	Subchronic Neurotoxicity - Rats	A,C,E	44339401
82-5A	90-Day Neurotoxicity - Hen	A,C,E	40933601, 43121401
83-1A	Chronic Feeding Toxicity - Rodent	A,C,E	42699902, 42457201, 41743101, 41103701, 40327001
83-1B	Chronic Feeding Toxicity - Non-Rodent	A,C,E	42901402, 4269901, 41632801, 40341701
83-2A	Oncogenicity - Rat	A,C,E	42699902, 42457201, 41743101, 00147478
83-2B	Oncogenicity - Mouse	A,C,E	42901403, 42759701, 41869201, 00147478
83-3A	Developmental Toxicity - Rat	A,C,E	40329401
83-3B	Developmental Toxicity - Rabbit	A,C,E	40462701
83-4	2-Generation Reproduction - Rat	A,C,E	42901401, 41348601
84-2A	Gene Mutation (Ames Test)	A,C,E	41283404
84-2B	Structural Chromosomal Aberration	A,C,E	41283403
85-1	General Metabolism	A,C,E	00115926, 00116396, 00132309, 00154967
ENVIRONMENTAL FATE			
161-1	Hydrolysis	A,C,E	Mobay Report No. 49130
161-2	Photodegradation - Water	A,C,E	40110401
161-3	Photodegradation - Soil	A,C,E	inapplicable
161-4	Photodegradation - Air	A,C,E	reserved

Data Supporting Guideline Requirements for the Reregistration of Fenthion

REQUIREMENT		USE PATTERN	CITATION(S)
162-1	Aerobic Soil Metabolism	A,C,E	inapplicable
162-2	Anaerobic Soil Metabolism	A,C,E	inapplicable
162-3	Anaerobic Aquatic Metabolism	A,C,E	40825801
162-4	Aerobic Aquatic Metabolism	A,C,E	40825802
163-1	Leaching/Adsorption/Desorption	A,C,E	40194201
163-2	Volatility - Lab	A,C,E	waived
163-3	Volatility - Field	A,C,E	reserved
164-1	Terrestrial Field Dissipation	A,C,E	waived
164-2	Aquatic Field Dissipation	A,C,E	reserved
164-3	Forest Field Dissipation	A,C,E	inapplicable
164-5	Long Term Soil Dissipation	A,C,E	waived
165-1	Confined Rotational Crop	A,C,E	inapplicable
165-2	Field Rotational Crop	A,C,E	inapplicable
165-3	Accumulation - Irrigated Crop	A,C,E	inapplicable
165-4	Bioaccumulation in Fish	A,C,E	reserved
165-5	Bioaccumulation - Aquatic NonTarget	A,C,E	reserved
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A,C,E	waived
171-4B	Nature of Residue - Livestock	A,C,E	41404201, 41774201, 41774202, 41362201, 00093415, 00093416, 00093422, 00115887, 00115895, 00115908, 00115932, 00116381, 00116748, 00116386, 41082501, 00062094, 00115216, 00115889
171-4C	Residue Analytical Method - Plants	A,C,E	inapplicable
171-4D	Residue Analytical Method - Animal	A,C,E	41404201, 41774201, 41774202, 41362201, 00093415, 00093416, 00093422, 00115887, 00115895, 00115908, 00115932, 00116381, 00116748, 00116386, 41082501, 00062094, 00115216, 00115889

Data Supporting Guideline Requirements for the Reregistration of Fenthion

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	Storage Stability	A,C,E	00093415, 00093416, 00093422, 00115887, 00115895, 00115908, 00115932, 00116381, 00116748, 00116386, 41082501, 00062094, 00115216, 00115889
171-4F	Magnitude of Residues - Potable H2O	A,C,E	waived
171-4G	Magnitude of Residues in Fish	A,C,E	reserved
171-4H	Magnitude of Residues - Irrigated Crop	A,C,E	inapplicable
171-4I	Magnitude of Residues - Food Handling	A,C,E	inapplicable
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	A,C,E	reserved
171-4K	Crop Field Trials	A,C,E	inapplicable
171-4L	Processed Food	A,C,E	inapplicable

Appendix C. Technical Support Documents

Additional documentation in support of this interim RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

The docket initially contained preliminary risk assessments and related documents as of August 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 16, 1999.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/op

These documents include:

HED Documents:

1. Health Effects Preliminary Assessment
   - Summary
   - Report of the Hazard Identification Assessment Review Committee
2. Revised Health Effects Assessment
   - Overview of Fenthion Revised Risk Assessment
   - Fenthion Summary
   - Revised Assessment, February 18, 1999
   - Revised Assessment, March 5, 1999
   - Occupational and Residential Exposure Assessment
   - Acute and Chronic Dietary Exposure Analysis
   - Replacement of Human Study Used in Risk Assessments
   - Re-evaluation of the Dermal Absorption Factor
   - Quantitative Usage Analysis
   - Response to Comments on the Preliminary Risk Assessments

EFED Documents:

1. Environmental Fate and Effects Preliminary Assessment
   - Environmental Fate and Effects Preliminary Assessment
2. Revised Environmental Fate and Effects Assessment
   - Addendum to the Revised Environmental Fate and Effects Assessment
   - Bird kills from Adult Mosquito Sprays in Collier Co., Florida

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

GUIDE TO APPENDIX D

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

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

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

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

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

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

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

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

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

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

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

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

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00093415 Mobay Chemical Corporation (1966) Fenthion: Analytical, Residue, and Flavor Information on Backline Application to Cattle. Includes method dated Aug 18, 1965. (Compilation; unpublished study, including report nos. 16,509, 16,913, 16,951..., received Jul 22, 1966 under 7F0531; CDL:090637-A; 090636; 090638)

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00115887 Mobay Chemical Corp. (1970) [Fenthion Residues in Milk, Eggs, Poultry Tissues and Alfalfa Hay]. (Compilation; unpublished study received on unknown date under 9F0811; CDL:093129-A)

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Appendix E. Generic Data Call-In

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

Requirements Status and Registrant's Response PAGE 1 OF 1

Appendix F. Product Specific Data Call-In

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

PRODUCT SPECIFIC REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE
PAGE 1 OF 3

PRODUCT SPECIFIC FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS PAGE 1 OF 2

PRODUCT SPECIFIC FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS PAGE 2OF 2

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

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response, " asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5), or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are

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

Ten products were found which contain ***Fenthion*** as the active ingredient. These products have been placed into ***two*** batches and a ***"No Batch"*** category in accordance with the active and inert ingredients and type of formulation.

Batch 1

EPA Reg. No.	Percent active ingredient	Formulation Type
3125-148	95.0	Liquid
3125-197	95.0	Liquid
11556-36	95.0	Liquid

Batch 2

EPA Reg. No.	Percent active ingredient	Formulation Type
5481-83	1.0	Solid
5481-84	1.0	Solid
5481-101	2.0	Solid

No Batch

EPA Reg. No.	Percent active ingredient(s)	Formulation Type
11556-34	3.0	Liquid
11556-37	20.0	Liquid
11556-48	7.6	Liquid
11556-105	Fenthion-20% Piperonyl Butoxide-15%	Solid

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

Insert List–Page 1 of 1

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

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

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

   Date of receipt
   EPA identifying number
   Product Manager assignment

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

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.